

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

Applicant Name	Natick Surgery Center, LLC
Applicant Address	313 Speen St, Natick MA 01760
Date Received	December 17, 2018
Type of DoN Application	Ambulatory Surgery
Total Value	\$10,056,917
Project Number	18121721-AS
Ten Taxpayer Group (TTG)	None
Community Health Initiative (CHI)	\$502,845.85
Staff Recommendation	Approval
Public Health Council	May 15, 2019

Project Summary and Regulatory Review

Natick Surgery Center, LLC (Natick ASC or the Applicant), a newly formed joint venture, submitted a Determination of Need (DoN) application for a substantial capital expenditure to develop a licensed ambulatory surgery center (ASC) within an existing building, located at 313 Speen Street in Natick. The proposal is to renovate 13,000 gross square feet (GSF) for three ambulatory surgery operating rooms (ORs), with associated perioperative bays, and support space. The capital expenditure for the Proposed Project is \$10,056,917. A payment of \$502,845.85 will be made to the Community Health Initiatives (CHI) Statewide Initiative Fund.

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.

The Department received no public comment on the application.

## **Background**

The Applicant is a newly formed joint venture established for the purpose of developing an Ambulatory Surgery Center (ASC) in Natick. Its members are ASC Holding Company, LLC (HoldCo), Reliant MSO, LLC (Reliant), and Shields ASC, LLC (Shields ASC). The Proposed Project will provide outpatient surgical procedures in the following surgical specialties: Orthopedics, Ear, Nose and Throat (ENT), Gynecology, Urology, and General/Vascular surgery.

HoldCo includes two community-based orthopedic specialty practices<sup>1</sup> comprising seventeen physicians (Participating Physicians). The physicians from both practices are members of New England Quality Care Alliance (NEQCA).<sup>2</sup> Reliant is the management services organization<sup>3</sup> for Reliant Medical Group (RMG), which represents nearly 500 providers.<sup>4</sup> Shields ASC is affiliated with Shields Health Care Group, with advanced imaging services at more than 30 locations in Massachusetts and New England. Shields Health Care Group has two other partnerships with providers for freestanding ASCs.<sup>5</sup>

In compliance with 105 CMR 100.715(B)(2)(a)(3), both RMG and Wellforce are HPC certified Accountable Care Organizations (ACOs).<sup>6</sup> RMG and Fallon jointly operate a MassHealth ACO Partnership Plan. The Proposed Project is not within the Primary Service Area (PSA) of an existing hospital that is designated, as an independent community hospital by the Health Policy Commission,<sup>7</sup> therefore it is not necessary for the Applicant to develop a joint venture with, or obtain a letter of support from the CEO and board chair of a community hospital within its PSA, as would otherwise be required under 105 CMR 100.715(B)(2)(b)(2).

Currently, the Applicant reports that the Participating Physicians have privileges to perform surgeries at six hospitals in the region that are not affiliated with each other.<sup>8</sup> This makes it difficult for the members to manage their patients enrolled in risk contracts, such as ACOs. The Applicant asserts that the establishment of the ASC will help the members' ACOs and the Commonwealth meet population health and cost containment goals. Further, while it reports a modest 2% growth rate for its risk contracts, the Applicant believes the Proposed Project will position it to address the future needs of those patients, since it anticipates that the number of patients in risk contracts will continue to grow in the years to come. In support of that assertion, it cites an analysis showing that the number of covered lives in ACOs

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<sup>1</sup>Orthopedics New England and New England Hand Associates

<sup>2</sup> NEQCA is a member of Wellforce, Inc. (Wellforce)

<sup>3</sup> Includes financial, statistical, administrative and corporate services to RMG

<sup>4</sup> Both Reliant and RMG are members of OptumCare, a division of United Health Group, Inc.

<sup>5</sup> The Department approved Medford Surgery Center, LLC in January 2019, and HealthCare Enterprises, LLC, in August 2015 (opened in May 2018), called The Surgery Center, Shrewsbury in which Reliant is also a partner.

<sup>6</sup> For a list of approved ACOs and more information see: <https://www.mass.gov/service-details/the-hpc-accountable-care-organization-aco-certification-program>. Wellforce Care Plan is a MassHealth Accountable Care Organization (ACO) Partnership Plan comprised of the Wellforce Care Plan ACO and Fallon Health. Fallon 365 Care is a partnership with Reliant Medical Group and Fallon Health offering a managed care option for MassHealth members.

<sup>7</sup> For purposes of the list developed by the Health Policy Commission (HPC), independent community hospitals are those community hospitals that do not have a corporate or contracting affiliation with an academic medical center or teaching hospital.

<https://www.mass.gov/files/documents/2019/01/10/20180110%202019%20independent%20CH%20list.pdf>

<sup>8</sup> Including Metro West Medical Center, Milford Regional Medical Center, Emerson Hospital, Newton Wellesley Hospital, New England Baptist Hospital and UMass Memorial Medical Center.

has grown approximately 6% since 2017,<sup>9</sup> and that CMS hopes to increase the percentage of reimbursements for alternative payment models (including ACOs) from 30% to 50%.<sup>10</sup>

## **Analysis**

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

All DoN factors are applicable in reviewing an ambulatory surgery center DoN Application. This Staff Report addresses each of these factors in turn.

## **Factors 1 & 2**

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

## **Patient Panel**

The Proposed Project is for a new entity, which has no existing patient panel. The discussion of Patient Panel in this analysis refers to the anticipated patients, as directed by the regulation.<sup>11</sup> Thus, the Applicant relies on the patient utilization data from its joint venture partners' Participating Physicians, to assess need for the Proposed Project. The Applicant evaluated historic patient data from the participating provider groups, and given their broad geographic reach throughout central and eastern Massachusetts, elected to limit the target population and geographic scope to towns where 75% of their

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<sup>9</sup> Muhlstein, D., et.al. Recent Progress in the Value Journey: Growth of ACOs and Value-Based Payment Models in 2018, <https://www.healthaffairs.org/doi/10.1377/hblog20170203.058589/full/>, analysis of Leavitt Partners' ACO database

<sup>10</sup> From FY 2016-2018, [https://www.healthit.gov/sites/default/files/facas/Joint\\_DSR\\_slides\\_2015-10-06.pdf](https://www.healthit.gov/sites/default/files/facas/Joint_DSR_slides_2015-10-06.pdf)

<sup>11</sup> 105 CMR 100.100 Patient Panel. 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. Patient Panel also means:

- (1) If the Applicant or Holder has no patient panel itself, the Patient Panel includes the Patient Panel of the health care facilities affiliated with the Applicant; or
- (2) If the Proposed Project is for a new facility and there is no existing patient panel, Patient Panel means the anticipated patients; or
- (3) For a Transfer of Ownership, Patient Panel also includes the Patient Panel of the Entity to be acquired.

patients reside.<sup>12</sup> Staff agrees that, since this is a new entity, this is an acceptable way to identify a potential patient panel, assess need, and develop projections.

The Applicant described its patient panel using only information from RMG and NEQCA for patients under managed care contracts because it did not have information from fee-for-service patients, who come from a wider range of IT billing systems.

*RMG's Patients enrolled in managed care contracts*<sup>13</sup> -In FY 2018, there were 92,400 patients with risk contracts within RMG's physician practices, of which approximately 28% (25,937) reside within the service area for the Proposed Project. Approximately 54% of the RMG patients were female; 36% between ages 0-17; 51% were between ages 18-64; and 12% were age 65 and over (65+). The Applicant reports that between 2016 and 2018, the overall number of patients within the RMG proposed PSA increased 30.4%. The Applicant notes that the pediatric patients ages 0-17 grew at the fastest rate, by 89%, from 2016-2018 as compared with growth in the 18-64 age cohort, which was 15%, and the 65+ cohort experienced a 4% decline. Approximately 38% of the patients are enrolled in FCHP Medicaid, and 12% in Tufts Medicare plans.<sup>14</sup>

*NEQCA's Patients enrolled in managed care contracts*<sup>15</sup> -In FY 2018, there were 270,695 patients with risk contracts within the NEQCA physician practices of which 8% (20,664) live within the Proposed Project's service area. One-half, 51%, of patients were male; 22% were 0-17; 64%, were ages 18-64; and 14% were 65+.

#### Patient Panel for Proposed Project

The Applicant used a combination of historical surgical volume from its Participating Physicians by specialty and methodology proprietary to the Advisory Board to build the baseline projected surgical volume for the proposed ASC. The Applicant has determined that, based upon the baseline, projected growth, and a combined surgical turnaround time of eighty minutes, the three ORs will achieve an 83% utilization rate by Year 4, which comports with ASC industry benchmarks.<sup>16</sup>

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<sup>12</sup> The Applicant defined the PSA for the Proposed Project as those 34 towns where approximately 75% of the patients currently served by RMG, ONE and NEHA, reside.

<sup>13</sup> Meaning patients enrolled in risk contracts including ACOs, PPOs, HMOs, and POS plans. Because of disparate data systems of the various providers practicing at different sites, fee for service patients' data could not be aggregated.

<sup>14</sup> The remaining 50% of patients have commercial insurance coverage.

<sup>15</sup> Meaning patients enrolled in risk contracts including ACOs, PPOs, HMOs, and POS plans. Because of disparate data systems of the various providers who are practicing at different sites, fee for service patients' data could not be aggregated.

<sup>16</sup> <https://www.beckersasc.com/asc-turnarounds-ideas-to-improve-performance/13-essential-asc-benchmarks-a-how-to-stay-ahead-of-the-curve.html>; <https://www.beckersasc.com/asc-turnarounds-ideas-to-improve-performance/defining-full-utilization-of-an-ambulatory-surgery-center-gaa-with-jim-scarsella-of-anesthesia-staffing-consultants.html>

<b>Baseline ASC Appropriate<sup>17</sup> Surgeries by Specialty</b>			
<b>Specialty</b>	<b>Total</b>	<b>Managed/Risk Contracts</b>	<b>FFS</b>
Orthopedics	1,898	243	1,655
ENT	107	50	57
Gen. Vascular	62	47	15
Hand	1,007	11	996
GYN	148	85	63
Urology	58	34	24
<b>Total</b>	<b>3,280</b>	<b>470</b>	<b>2,810</b>

Staff notes that the baseline proportion of patients under managed/risk contracts are small (14%). The Applicant has indicated that the Proposed Project is meant to address increasing need for surgeries paid under managed or risk contracts, and staff recommends that the Applicant make focused and intentional efforts toward increasing the proportion of patients under managed or risk contracts.

**Need**

The Applicant bases need for the project on advances in treatments that will likely expand the types of procedures performed on an ambulatory basis, growth in the managed care pediatric population, the projected growth in the aging population, and the need to effectively manage their ACO and other risk contract patients.

Advances in the administration of anesthesia and analgesics, along with the development and expansion of many minimally invasive or non-invasive procedures across many specialties,<sup>18, 19</sup> has resulted in growth in the number and type of lower acuity procedures appropriate for ambulatory surgery and approved by CMS for reimbursement. This, the Applicant asserts, has increased the demand for availability of surgeries in a Freestanding ASC as an alternative to the hospital out-patient departments (HOPDs) where its member patients’ surgeries are currently occurring.<sup>20</sup>

The Applicant notes that they have seen, and anticipate a continuing significant growth in the number of pediatric patients in managed care plans. The Applicant suggests that this growth in pediatric patients will increase the demand for ENT surgeries such as the placement of ear tubes, tonsillectomies and adenoidectomies.<sup>21, 22</sup> A 2015 study showed that tonsillectomies affect approximately 1% of the population under age 16, and account for 16% of all ambulatory surgery within this age cohort.

<sup>17</sup> ASC eligible patient cases are those that have lower patient acuity (ASA<3) and procedures that have been approved for outpatient surgeries.

<sup>18</sup> At the same time, the Centers for Medicare and Medicaid Services (CMS) approved Medicare reimbursement for ambulatory surgery performed both at Hospital Outpatient Departments (HOPDs) and ambulatory surgery centers (ASCs).

<sup>19</sup> Margaret J. Hall et al., *Ambulatory Surgery Data From Hospitals and Ambulatory Surgery Centers: United States, 2010*, 102 NATL HEALTH STATISTICS REPORTS 1 (2017), at <https://www.cdc.gov/nchs/data/nhsr/nhsr102.pdf>

<sup>20</sup> More recently, freestanding ASCs receive a percentage of what HOPDs reimbursement is.

<sup>21</sup> DeFrances CJ, Cullen KA, Kozak LJ. National Hospital Discharge Survey: 2005 annual summary with detailed diagnosis and procedure data. *Vital Health Stat* 13. 2007(165):1–209;

<sup>22</sup> The Applicant suggests that due to the increased awareness of the negative impact of untreated sleep apnea on childhood development, learning and behavior, the number of tonsillectomies, which is an excepted treatment, is

The Applicant also states that the anticipated growth in the 55 plus age cohort supports the need for this Proposed Project. Citing the Donahue Institute's projections,<sup>23</sup> this cohort will comprise 35% of the population by 2035, and it will grow 14% between 2020 and 2035. The aggregate population of towns in the Applicant's proposed PSA is projected to grow 20.5% by 2025 for this age group.<sup>24</sup> This age group has experienced the largest increase in number of surgical procedures since 1990 due to a higher incidence of age related conditions some of which benefit from such lower acuity procedures as joint replacements.<sup>25</sup> More than half of all adults and three-quarters of those ages 65 and older suffer from a musculoskeletal disease, including arthritis, back pain and trauma.<sup>26</sup> The Applicant asserts that because of both the projected population growth for this age cohort in the PSA where the Proposed Project will be located, and the continued medical advances in managing the health conditions of this age group, there will be growth in procedure volumes and the need for ASC facilities. Additionally, it cites a projection that approximately half of the population over the age of 65 will likely require surgery at least once in their lifetime;<sup>27</sup> and that these patients will benefit from access to local, easier to navigate, lower cost ASC services.

### **Public Health Value**

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

The Applicant asserts that the ASC will contribute to the function of the RMG ACO as it strives to achieve the ACO goals of improving care delivery, cost containment and population health through greater collaboration among the providers and improved coordination of care. The means for achieving these goals is to improve access by shifting the appropriate resources to the community setting and then providing the tools for the provider team to communicate and collaborate to improve health outcomes. In so doing, to meet its ACO goals, it maintains that all of its patients (managed care and FFS) within the participating physician networks will benefit from these initiatives.

The Applicant maintains that since ASCs offer a lower cost alternative to HOPDs for the provision of outpatient surgery, they play an important role in ACOs' success. ACOs receive payments based on quality and patient outcomes, called value based purchasing.<sup>28</sup> This Proposed ASC will allow its member ACOs to manage the cost and quality of care provided to its patient population that is currently obtaining surgeries at sites that are outside of the ACO. The Applicant asserts that the ASC will contribute to the function of the RMG ACO by shifting appropriate ACO surgical patients to the ASC. This assertion aligns with the Department's expectations – but the percentage of ACO patients is quite small.

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increasing worldwide. <https://www.dovepress.com/ambulatory-anesthetic-care-in-pediatric-tonsillectomy-challenges-and-r-peer-reviewed-fulltext-article-AA>

<sup>23</sup> The Massachusetts Secretary of the Commonwealth contracted with the University of Massachusetts Donahue Institute to produce population projections by age and sex for all 351 municipalities.

<sup>24</sup> using the Advisory Board's *Demographic Profiler*

<sup>25</sup> <https://www.hcup-us.ahrq.gov/reports/projections/2012-03.pdf>;

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4551172/pdf/jbjsam.n01141.pdf>

<sup>26</sup> Debra Wood, RN, The Latest Trends in Orthopedic Surgery , Apr 29, 2018 <https://www.staffcare.com/the-latest-trends-in-orthopedic-surgery/>

<sup>27</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3597305/> Relin Yang, MD, MPH, Matthew Wolfson, and Michael C. Lewis, MD, Unique Aspects of the Elderly Surgical Population An Anesthesiologist's Perspective

<sup>28</sup> ACA will bring more patients to ASCs--- but will profits follow? *OR Manager*, Vol. 30 No.2, February 2014, p. 29 <https://www.ormanager.com/wp-content/uploads/2014/01/ORM-February-2014.pdf>

As such, a condition of approval will require that the Applicant demonstrate intentional efforts to increase the percentage of patients under managed or risk contracts to meet the stated goal of serving ACO patients.

The ASC model is centered on uniformity of procedures performed within a scheduled block of time. Generally, one surgeon works with the same clinical team for the entire block of time performing multiple, very similar types of procedures. The team develops a specialized skill-set and works in a facility designed and equipped to meet the specific needs of ambulatory surgical patients, which, the Applicant says, generates efficiencies and cost-savings due to reduced procedure times as compared to a similar procedure performed in a HOPD.<sup>29, 30</sup> As a result of these efficiencies, more procedures can be performed within the same period of time with fewer disruptions for more acute in-and out-patient cases, than can be scheduled in a HOPD.

The Applicant states that the Proposed Project enables it to provide its fee for service (FFS), ACO and other managed care patients timely access to care. Currently, its Participating Physicians report anecdotally that patients experience a wait time of 1-2 weeks for hand surgery, and 3-4 weeks for other outpatient orthopedic procedures, and that decreased wait times enable patients to return to work, and physical activities more quickly thereby improving quality of life.

The Applicant states that surgery in ASCs is associated with decreased morbidity, hospital admission rates, and mortality, and that patients in ASCs experience shorter surgery and recovery times overall. Rates of revisit to the hospital one week post-surgery are lower for ASC patients. Infection rates for procedures performed in ASCs are half that for the same procedures performed in the hospital setting. Patients experience reduced pain levels and less nausea when receiving surgery in an ASC.<sup>31</sup> To assess the impact of the proposed ASC the Applicant has proposed three reporting metrics related to clinical quality and patient satisfaction that are included in Attachment 1.<sup>32</sup>

The Applicant asserts that in its ongoing commitment to health equity, it will employ culturally competent staff, and develop culturally appropriate support services to ensure high quality experience and outcomes for patients. As part of that plan, it will develop a translation program using multiple tools that include offering Language Line and InDemand interpreting services, which enable audio and/or video interpretation.

Given the suburban location, Staff inquired about transportation to and from the site. The Applicant responded that because post-surgery patients are recovering from anesthesia, they require a transport

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<sup>29</sup> AMBULATORY SURGERY CENTERS: A POSITIVE TREND IN HEALTH CARE (Ambulatory Surgery Center Ass'n), available at

<http://www.ascassociation.org/advancingsurgicalcare/aboutascscs/industryoverview/apositivetrendinhealthcare>

<sup>30</sup> EL. Munnich & ST. Parente, Procedures Take Less Time At Ambulatory Surgery Centers, Keeping Costs Down And Ability To Meet Demand Up, at <https://www.healthaffairs.org/doi/10.1377/hlthaff.2013.1281>

<sup>31</sup> Crawford DC, Li CS, Sprague S, Bhandari M., Clinical and Cost Implications of Inpatient Versus Outpatient Orthopedic Surgeries: A Systematic Review of the Published Literature, <https://www.ncbi.nlm.nih.gov/pubmed/26793295>; Hall MJ, Schwartzman A, Zhang J, Liu X., Ambulatory Surgery Data From Hospitals and Ambulatory Surgery Centers: United States, 2010, <https://www.ncbi.nlm.nih.gov/pubmed/28256998>

<sup>32</sup> CMS has a number of quality reporting requirements for ASCs focusing on measures that have a high impact on, and support HHS and CMS priorities for improved health care outcomes, quality, safety, efficiency and satisfaction for patients. Available at: <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/asc-quality-reporting/index.html>; <https://www.ascfocus.org/ascfocus/content/articles-content/articles/2018/digital-debut/asc-quality-reporting-program-requirements-for-2019>

from a family member or home care provider. As such, for safety reasons, public transportation is not an option either.

The Applicant indicated it will offer additional tools to improve the patient experience. These include an online pre-registration system that is available in over 70 languages and will allow patients to register from home. Also, in development is a price transparency tool that will enable anyone who wishes to use it, to access the cost of a procedure after entering his or her insurance.<sup>33</sup> This tool will allow patients to determine affordability of their recommended surgery. Additionally, the Applicant will provide financial counselors to assist patients in understanding their health insurance benefits.

Through care management services, patients gain access to linkages to resources designed to assist with issues related to social determinants of health (SDOH). The Applicant states that its administrative, nurse management and care management teams will establish a proactive dialogue with primary care practices and social work resources within their patient referral community, and that unique patient needs associated with SDOH will be addressed early in their engagement with the ASC so that a discharge plan is in place prior to discharge. Patients will meet with a case manager who will screen patients for social determinant of health needs and, when needed, make connections for follow-up care to ensure a “seamless” recovery plan. The Applicant adds that it “is prepared to follow-up multiple times to ensure that recovery of at-risk patients is going smoothly.”

Staff is concerned that an ASC that is not a part of a larger provider system and that draws patients from multiple provider systems could lead to care fragmentation. The Applicant has indicated that it “will take advantage of the HL7 standard and SFTP for data exchange to assure that there is interoperability between the surgery center and the referring community.” In addition, the Applicant has stated that “the care team will establish a robust dialogue and communication plan with the patient’s specialist, PCPs and social workers as needed.” In order to demonstrate these capabilities, staff recommends post-approval reporting associated with completion of PT/OT and all cause visits to the emergency department or admission to hospital within 7 days after surgery.

### **Competitiveness and Cost Containment**

The shift of lower-acuity surgery from HOPDs to the ASC will, the Applicant argues, produce cost savings that can be passed on to consumers and payers in the form of lower deductibles and copayments. Medicare pays \$1,024 for a knee arthroscopy with meniscus repair in an ASC, compared to \$2,116 in an HOPD. Medicare beneficiaries without supplemental insurance have a co-pay of \$256 in ASCs and \$529 in HOPDs.<sup>34</sup>

The Applicant asserts that on average the Medicare program and its beneficiaries share in more than \$2.6 billion in savings annually as a result of surgeries performed in an ASC, where reimbursement rates approximate 48% of the amount paid to HOPDs.<sup>35</sup> In addition, the Applicant cites a study that asserts that if half of the eligible procedures were shifted to ASCs, Medicare would save an additional \$2.5

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<sup>33</sup> A similar tool is in use at Shields Health Care Imaging Services.

<sup>34</sup> <https://www.beckersasc.com/asc-coding-billing-and-collections/cms-posts-payments-for-ascs-vs-hopds-medicare-pays-ascs-359-less-for-colonoscopy-1-092-less-for-knee-arthroscopy.html>, November 28, 2018

<sup>35</sup> *Medicare Cost Savings Tied to Ambulatory Surgery Centers* (Rep.). (2013, September 10). Retrieved July, 2018, from University of California Berkeley website:

<https://www.ascassociation.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=7b33b916-f3f1-42e5-a646-35cc2f38fe4d&forceDialog=0>

billion annually.<sup>36</sup> Consequently, the Applicant asserts that approval and implementation of this project will have a direct impact in lowering total medical expenses (TME).

Working with the Center for Health Information and Analysis (CHIA), staff performed an analysis of average payments<sup>37</sup> for proximate hospitals and ASCs for two orthopedic procedures that are approved for ambulatory surgery payments. The lowest mean reimbursement in 2017 for facilities within a 0-20 mile radius of the Proposed Project is indexed to 1.00.

CPT Code 29827 Arthroscopy Shoulder		CPT Code 29888 Arthroscopically Knee	
Facility Type <sup>38</sup>	Index	Facility Type	Index
ASC	1.00	ASC	1.00
ASC	1.29	ASC	1.15
ASC	1.66	ASC	1.19
CH	2.29	CH	1.73
CH	2.48	CH	1.77
CH	2.54	AMC	2.33
AMC	2.75	AMC	2.51
CH	2.91	CH	2.69
CH	3.14	CH	3.03
AMC	7.39	CH	3.20

## Community Engagement

Prior to submitting a DoN application, the DoN Regulation requires applicants to provide evidence of sound community engagement and consultation throughout the development of the Proposed Project. The *Community Engagement Standards for Community Health Planning Guideline* describes community engagement processes on a continuum from “Inform” and “Consult” through “Community driven-led.”<sup>39</sup> For the purposes of factor 1, engagement defines “community” as the Patient Panel, and requires that the minimum level of engagement for this step is “Consult.”<sup>40</sup>

During the planning phase of the Proposed Project, each of the participating physician groups held community forums that included presentations about plans, discussed what they described as the collaborative nature of the Natick ASC organizational structure, and the benefits to patients of the shift to outpatient surgery.<sup>41</sup> Based upon a review of the materials, it appears that there was opportunity for

<sup>36</sup> See Commercial Insurance Cost Savings in Ambulatory Surgery Centers, at <https://www.ascassociation.org/advancingsurgicalcare/reducinghealthcarecosts/costsavings/healthcarebluebookstudy>

<sup>37</sup> Data from the All Payer Claims Database (APCD) includes commercial insurance, MassHealth and dual-eligible Medicare.

<sup>38</sup> CH is Community Hospital; AMC is Academic Medical Center

<sup>39</sup> <https://www.mass.gov/files/documents/2017/01/vr/guidelines-community-engagement.pdf>

<sup>40</sup> Id at Page 13

<sup>41</sup> Including lower costs, providing more choices, increasing access, community based care.

questions, discussion, and feedback with a commitment to keep the participants informed. Additionally, no ten-taxpayer groups formed in response to this project.

In the context of factors 1 and 2, the Applicant can be found to have met the community engagement standards in the planning phase of the Proposed Project.

### **Factor 3**

The Applicant has certified that it is in compliance and in good standing with federal, state, and local laws and regulations, including, but not limited to M.G.L. c. 30, §§ 61 through 62H and the applicable regulations thereunder, and in compliance with all previously issued notices of Determination of Need and the terms and conditions attached therein.

### **Factor 4**

Under factor 4, the Applicant must demonstrate that it has sufficient funds available for capital and operating costs necessary to support the Proposed Project without negative effects or consequences to the existing patient panel. Documentation sufficient to make such finding must be supported by an analysis conducted by an independent CPA. The Applicant submitted an analysis performed by Bernard L. Donohue, III, CPA, (Donohue) dated December 13, 2018 (CPA Report).

In order to render an opinion, Donohue reviewed 5-Year Projected Financial Statements (FY 2019-2023) and assumptions prepared by Shields, relevant government and private websites including center for Medicare Ambulatory Surgical Center Payment System, Shields Health Care Group and Becker's ASC websites,<sup>42</sup> and VMG Health Intellimarker Multi-Specialty ASC Study 2017. To aid in rendering an opinion on the Proposed Project's financial feasibility over five years, Donohue analyzed key financial metrics<sup>43</sup> for liquidity, operations, and solvency.

Donohue found that the revenue and operating expense projections were reasonable based on the projections provided by the Applicant. After a startup negative profit margin in year one, the projections show a net pre-tax profit margin ranging from 16.1% to 21.8% for years 2 through 5 of the project.

To determine the reasonableness of revenues, Donohue analyzed the Applicant's assumptions for utilization levels, payer mix, and reimbursement rates (including a 1% annual inflation rate) of the respective public and private payers for the multiple specialty ambulatory procedures to be performed at the site. Donohue then compared them to an outside 2017 survey of ambulatory surgery centers and found the Applicant's projections were within the ranges of the survey.

Donohue also analyzed operating expenses of the Proposed Project for reasonableness and feasibility and compared them to the 2017 survey, finding that projections for medical surgical supplies, salaries and benefits were consistent.

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<sup>42</sup> <https://www.cms.gov/Center/Provider-Type/Ambulatory-Surgical-Centers-ASC-Center.html>; <https://Shields.com>, and <https://beckersasc.com> respectively.

<sup>43</sup> Metrics are standard financial ratios which are used to assess financial strength of an entity. Financial ratios allow for comparisons between companies, between different time-periods for one company, and between a single company and its industry average.

Donohue also reviewed the lease agreement and equipment financing to determine whether future cash flows would be sufficient to support these and continued operations and determined that they were reasonable and feasible.

Donohue found that based on his review of the relevant documents, including financial projections for the Proposed Project and analysis of financial metrics, “the project and continued operating surplus are reasonable and based upon feasible financial assumptions ... and not likely to have a negative impact on the patient panel, or result in liquidation of the assets of the Natick ASC.”

### **Factor 5**

Factor 5 requires the Applicant to “describe the process of analysis and the conclusion that the Proposed Project, on balance, is superior to alternative and substitute methods for meeting the existing Patient Panel needs and addressing, at a minimum, the quality, efficiency, and capital and operating costs of the Proposed Project relative to potential alternatives or substitutes.”

The Applicant only compares the Proposed Project to the alternative of not constructing the freestanding ASC and maintaining the status quo which, the Applicant reports, is the surgeons continuing to perform their surgeries at six hospital-based sites.

The Applicant asserts that while operating expenses for Year 1, the first full year of operation are projected to be \$4,311,565, that implementation of the ASC will generate projected downstream savings of \$8M in TME including approximately \$1.3M to Medicare, and that it will deliver improved patient outcomes.<sup>44</sup>

The Applicant suggests that the selected location of the Proposed Project was based on accessibility and convenience for patients in the designated service area, including access to free parking, and close proximity to amenities and major thoroughfares; and asserts, further, that some of the Participating Physicians’ offices are already located at the site of the Proposed ASC, ensuring patients have ready access to outpatient appointments for pre- and follow-up care. Additionally, the Applicant asserts, navigating a HOPD is challenging for many patients, including pediatric and those over age 65.

### **Factor 6**

Since the Applicant is not required to and does not regularly conduct a community health needs assessment or community health improvement as required under the affordable care act or to comply with community benefit requirements, it is not obligated to undertake a community engagement process or submit a community engagement plan under factor 6. Instead, the Applicant’s CHI funding shall be directed to the CHI Statewide Initiative in the amount of \$502,845.85. The Applicant has committed to do so upon project approval.

### **Findings and Recommendations**

The Applicant has provided evidence in support of factor 1, and we have included conditions to ensure that the Proposed Project meet the Applicant’s stated goals for the patient panel. The Proposed Project is likely to improve efficiency, and address the Commonwealth’s Cost Growth and delivery system

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interests. Conditions have been added to strengthen public health value by ensuring access to all patients regardless of payer, ensuring integration with primary care and other providers to achieve optimal post-surgical outcomes, and providing access to prices and language assistance that enable patients the opportunity to make informed decisions. Conditions have also been added to ensure that annual reports about clinical and quality of life outcomes are stratified by payer, managed/risk contracts vs. fee-for-service, and by measures of health equity.

The Applicant has submitted evidence of compliance with factor 3.

In the context of factor 4, based upon the CPA analysis, the Proposed Project is financially feasible; renovation within an existing facility that is co-located with the Participating Physicians' practices is, on balance, the superior alternative for meeting the Patient Panel needs from the perspective of quality, efficiency, and capital and operating costs as required by factor 5; and the Applicant will make its CHI contribution to the Statewide Initiative as required under factor 6.

Based upon a review of the materials submitted, Staff finds that, with the addition of certain conditions described in this Staff Report, the Applicant has met each DoN factor and recommends that the Department approve this Determination of Need application for three ambulatory surgery operating rooms, and associated support space, subject to all applicable standard and other conditions (105 CMR 100.310, 105 CMR 100.360(A) and (C)).

**Additional Conditions:**

1. The Holder shall demonstrate improved public health value by ensuring access for patients regardless of payer and linguistic ability:
  - a. In addition to the ASC's obligation to participate in MassHealth, pursuant to 105 CMR 100.310(11), Holder must ensure that all physicians and health professionals who practice at the facility are enrolled as participating providers of MassHealth to ensure patients have equitable access to all clinicians at the facility regardless of payer.
  - b. The Holder's website shall provide a clear offer for patients to access services in the language the patient can understand, speak, or write for effective interaction with administrative and medical personnel at the new ASC.
2. The Holder shall provide, in its first report to the Department, a description or reproduction of its price transparency tool and demonstrate how its tool has helped individuals make informed decisions.
3. With its annual report required by 105 CMR 100.310(12), the Holder must provide the following information to ensure health equity, evidence of care coordination, and the highest possible quality of care.
  - a. The Holder shall track and report the numbers of patients by primary care provider zip code.
  - b. The Holder shall track and provide evidence of timely communications with patients' primary care providers before and after surgery, specifically how information was communicated, and the timeframes within which such communications took place before or after interactions with patients under the primary care provider's care.

- c. The Holder shall track and report the following, stratified by age group, sex, race and ethnicity, zip code, and payer mix including fee-for-service versus managed contracts:
  - a) use of interpreter services
  - b) the length of time from the date of final specialty consultation to the date of surgery
  - c) the number of patients referred to PT/OT, and the number who completed their PT/OT
  - d) clinical and quality of life outcomes for each type of surgery and as a minimum for:
    - i. infection,
    - ii. surgical revision,
    - iii. nerve injury,
    - iv. all cause visit to emergency department or admission to hospital within 7 days after surgery.

The Holder shall provide reports with as much specificity as possible while ensuring that reporting is compliant with HIPAA confidentiality requirements.

- 4. The Holder shall demonstrate continued annual growth in the proportion of patients under managed/risk contracts receiving care at the ASC compared to those under fee-for-service plans (payer plan type) and stratified by payer mix, at a minimum by Medicaid, Medicare, and Commercial. In reporting its payer plan type, the Holder must show the proportion of patients served under each plan type relative to a benchmark that reflects the plan type proportions for the new ASC's patient panel. If the Holder cannot demonstrate continued annual growth, or the Holder continues to serve a disproportionate number of fee-for-service patients relative to the benchmark, then the Holder must submit with its annual report an explanation for why growth of patients under managed/risk contracts could not be achieved in the prior year, as well as a plan for improving growth of this group in the coming year.

## Attachment 1

The Applicant developed the following metrics to measure patient satisfaction and quality.

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

**Measure:** The Outpatient & Ambulatory Surgery Community Assessment of Healthcare Providers and Systems (OAS-CAHPS) survey will be provided to all eligible patients.

The OAS-CAHPS survey focuses on six (6) key areas:

- 1) Before a patient's procedure
- 2) About the ASC facility and staff
- 3) Communications about the patient's surgical procedure
- 4) Patient recovery
- 5) Overall experience
- 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.

**2. 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 meet or exceed the national benchmark of 0.10% surgical site infection rates, ultimately reaching a target of 0%.

**Monitoring:** Reviewed quarterly by clinical staff.

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

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

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

**Monitoring:** Reviewed quarterly by clinical staff.