STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD

In re: The Collaborative Surgery Center	)	GMCB-008-21con

STATEMENT OF DECISION

Introduction

In this Decision and Order, we review the application of the Collaborative Surgery Center (CSC or applicant) for a certificate of need to develop an un-restricted, multi-specialty ambulatory surgery center in Colchester, VT, consisting of four operating suites and associated ancillary rooms and offices. The total estimated cost of the proposed project is approximately $5.3 million.

For the reasons set forth below, we approve the application and issue a CON to CSC, subject to the conditions set forth therein, one of which initially restricts the surgeries and procedures that can be performed at the center to the four core specialties identified by CSC in its application: orthopedics; ear, nose, and throat; urology; and dental. CSC may propose changes to this initial scope at any time. When submitting such a proposal, CSC should be prepared to address, at a minimum, issues of need and quality described in this decision.

Procedural Background

On July 30, 2021, CSC submitted an application for a certificate of need and a request for expedited review. Notice of the application and the request for expedited review was posted on the Green Mountain Care Board's website on August 6, 2021, in accordance with 18 V.S.A. § 9440(c)(5)(A). On August 25, 2021, we denied the request for expedited review and stated that we anticipated needing to gather data to properly analyze the applicant's claim that the proposed project will meet a need for additional outpatient surgical capacity in Chittenden County.

On August 30, 2021, the Vermont Office of the Health Care Advocate (HCA), representing the interests of Vermont health care consumers, intervened in the proceeding. *See* 18 V.S.A. § 9440(c)(9); GMCB Rule 4.000 (Certificate of Need), § 4.406.

Beginning August 19, 2021, the Board requested, through a series of five sets of interrogatories, that the applicant provide additional or clarifying information to assist the Board with its review. Additionally, on September 17, 2021, the Board requested data regarding surgical capacity and utilization from hospitals and other providers of outpatient surgery in the region. Respondents replied to this request through December 8, 2021. On December 29, 2021, Board staff submitted an analysis of the capacity survey results. The applicant submitted comments regarding the analysis on January 7, 2022.

The application was closed on January 10, 2022. A hearing was held via Microsoft Teams on January 26, 2022.

Jurisdiction

The Board has jurisdiction over the certificate of need process pursuant to 18 V.S.A. § 9375(b)(8). The project as proposed by the applicant is subject to certificate of need review under 18 V.S.A. § 9434(a)(6).

Findings of Fact

1. The applicant proposes to develop a multi-specialty ambulatory surgery center (ASC) at 525 Hercules Drive, Colchester, VT. Application (App.), 21; CSC PowerPoint presented at January 26, 2022 Hearing (CSC ppt), 14. The ASC will consist of four operating suites and associated ancillary rooms totaling approximately 9,016 square feet. Chittenden, Franklin, and Grand Isle Counties in Vermont will be the facility's primary geographic service area. Lamoille, Washington, and Addison Counties in Vermont and Clinton, Essex, Franklin, Washington, Hamilton, Warren, and St. Lawrence Counties in New York will be the secondary service area. The remainder of southern and northeastern Vermont will be the tertiary service area. The applicant also anticipates some patients coming from Canada. Response to Questions (Resp.) (Sept. 21, 2021), 8;[1] *See* CSC ppt, 14; Testimony of Elizabeth Hunt and Susan Ridzon, Jan. 26, 2022 Transcript (Tr.) 64:23 – 65:11.

2. The applicant was formed as a limited liability company (LLC) in 2021. Elizabeth Hunt and Susan Ridzon are the two founding and current members with ownership interests, each owning 50 percent of the shares outstanding in the company. Ms. Hunt and Ms. Ridzon, along with a third individual, Amy Cooper, serve as managers of the company. The company plans to offer additional shares to physicians, each of whom will own a minority stake in the LLC. The founding members will maintain control over the management board. App., 23; Resp. (Oct. 29, 2021), 6.

3. CSC will be connected to another ASC, Green Mountain Surgery Center (GMSC), by a corridor. Although the two entities will be closely connected, there will be no overlapping owners between CSC and GMSC. Ms. Hunt is an owner of CSC and the Operations Manager and Business Office Manager for GMSC. Ms. Ridzon, the other owner of CSC, is the current Executive Director of Healthfirst, Inc. Ms. Cooper, a manager of CSC, is also GMSC's CEO. App., 23-24. At a high level, the management at CSC is expected to have Ms. Hunt in charge of CSC operations, while Ms. Ridzon would oversee the charitable foundation and community partnerships and Ms. Cooper would serve as a manager and consultant to CSC. Testimony of Amy Cooper, Tr. 80:22 – 81:2.

4. ASCs were first developed in 1970 and currently number over 5,700 nationally. App., 5. Technological advancement, faster acting and more effective anesthetics, and less invasive techniques have increased the number and kinds of procedures that can be performed in an outpatient setting. *See* App., 5. Chittenden County's only ASCs are Vermont Eye Surgery and Laser Center (VESLC), which performs only eye-related surgeries and procedures, and GMSC,

[1] For clarity and ease of reference, citations to the Application are to the page listed on the application; citations to the Responses are to the pdf page number.

which has two operating rooms and four procedure rooms. University of Vermont Medical Center (UVMMC) has a hospital-based outpatient surgery program. App., 11. In Franklin County, Northwestern Medical Center (NMC) performs orthopedic, ENT, and urology procedures, among others. *See* GMCB, *Outpatient Surgical Capacity and Volumes Report* (Dec. 29, 2021) 5-7.

5. At the time of the application, the property at 525 Hercules Drive was owned by L, R & W, LLC (LR&W). Colchester Real Estate Company, LLC (CREC) held an option from LR&W to purchase the entire building. CREC, in turn, had a Letter of Intent to Lease with CSC. Resp. (Sept. 21, 2021), 25-28. Prior to the hearing, the structure of the real estate transaction changed. The property was purchased from LR&W by DS Capital, LLC (majority owner); DPR Investments, LLC; and L5, Inc. as tenants in common. Resp. (Jan. 27, 2022), 6. The Letter of Intent to Lease was re-executed with the new owners with substantially similar terms and conditions. Resp. (Feb. 1, 2022), 1-3. Under the Letter of Intent to Lease, the landlord will front the initial $2,413,173.59 cost of fitting up the interior of the building; CSC will reimburse the landlord for the upfront costs over the initial 10-year term of the lease. Annual rent is estimated to be $64/sq. ft. for the first lease year and will increase three percent per year for the remainder of the lease term. CSC will have the option to renew the term for an additional 10-year period for a rent to be determined by good faith negotiations. App., 27-28; Resp. (Sept. 21, 2021), 25-28; Resp. (Feb. 1, 2022), 2-3. The lease is an ordinary lease, not a capital lease. Total aggregate lease payments over 10 years are $6,614,933.50. Resp. (Oct. 29, 2021), 5. The option and lease are contingent on CSC receiving a CON that allows it to perform all orthopedic, dental, ENT, and urology procedures allowed by Medicare at ASCs. App., 27; Resp. (Sept. 21, 2021), 27; Resp. (Feb. 1, 2022), 2.

6. The project cost is $5,293,344.60. Resp. (Dec. 2, 2021), 1-2 and revised Table 1. Applicant is financing the project with a $4,100,652 loan and $1,192,693 in equity contributions. *Id*., Table 2. CSC will finance the medical equipment, inventory, fixtures, working capital, and other start-up costs through bank financing and private investment capital from operating physicians. App., 62. Based on recent actual experience with medical equipment loans, whose interest rates ranged from 5.5% to 9.3%, CSC estimates receiving a 10-year fixed interest loan at a 10% interest rate for the medical equipment. App., 62; Resp. (Oct. 29, 2021), 4, Table 2. CSC expects that it will need to use some working capital to cover lease payments and operating expenses during its first year of operation and that it will thereafter generate sufficient revenues to satisfy lease payments and other operating costs. App., 62.

7. The HVAC, electrical, and plumbing systems, together with the building envelope design are planned to meet all required energy efficiency codes and Efficiency Vermont standards. App., 49. The architect for the project, Wiemann Lamphere Architects, has similar expertise as Efficiency Vermont and has five professionals who are LEED-certified to work with owners and contractors on sustainable design. App., 50. The facility will also comply with the applicable requirements from the 2018 edition of the FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities. App., Exhibit 6.

8. The Board does not have oversight of ASCs' budgets as it does for hospitals and Accountable Care Organizations. *See* 18 V.S.A. §§ 9451-9457 (Hospital Budget Review); 18 V.S.A. § 9382 (Oversight of Accountable Care Organizations).

9. In Vermont, ASCs are licensed by the Vermont Department of Health. 18 V.S.A. §§ 2141-2159. ASCs must maintain certification from the Centers for Medicare and Medicaid Services (CMS) and must accept Medicare and Medicaid patients for ambulatory surgical center facility services. 18 V.S.A. § 2153(a)(5). To be certified by CMS, an ASC must comply with the Medicare Conditions for Coverage at 42 C.F.R. Part 416, which set forth quality and patient safety standards. CMS may deem an ASC to comply with the Conditions for Coverage if the ASC is accredited by a national ASC accrediting body, of which there are several. *See* 42 C.F.R. 416.26. CSC plans to seek accreditation from the Accreditation Association for Ambulatory Health Care, the Joint Commission, or both. App., 22.

10. CSC asserts that it will enhance effective coordination and integration of health care services as a "low-cost, high-value site of care" for the state's ACOs and that it can offer ACOs lower costs and shorter wait times when there are longer than necessary wait times for relevant services at local hospitals. App., 74. No current arrangements are in process, but CSC has had conversations with the ACO OneCare Vermont. CSC does not know when or if the ACO will develop a methodology to deliver fixed payments to ASCs in lieu of fee-for-service, however, CSC intends to participate in any programs applicable to ASCs. Resp. (Sept. 21, 2021), 8.

11. The applicant seeks a CON to offer all procedures approved now and in the future by CMS to be performed at ASCs. Resp. (Sept. 21, 2021), 7. However, the applicant plans to focus initially on four areas ("four core specialties"): orthopedics; ear, nose, and throat (ENT); urology; and dental. Cover Letter (July 30, 2021); App., 3; Resp. (Sept. 21, 2021), 7-8.

12. The applicant plans to employ a staff of 25 full-time equivalents (FTEs), including 15 registered nurses or medical assistants, four surgical technologists, and three administrative and clerical staff. The management will include a full-time administrator, a clinical nurse manager, and a business manager. The Board of Managers will appoint a physician Medical Director and will directly supervise the administrator. App., 29.

13. CSC intends to host only procedures that are not expected to pose a significant safety risk to a patient when performed in an ASC, and for which the patient would not typically be expected to require active medical monitoring and care at midnight following the procedure. App., 22-23 (referencing 42 C.F.R. 416.166 (Medicare's ASC covered surgical procedures)), 29. CSC notes that this list of procedures has grown over the past 40 years, rising from 200 in 1982 to 3,500 as of July 30, 2021. App., 23.

14. The applicant does not believe it will harm volume at other hospitals and that, even in the event some hospital volume is diverted to CSC, physician volume is expected to remain unchanged. App., 42.

15. In response to questions from Board members, a CSC representative testified at the hearing that while there will be some overlapping of services between the CSC and GMSC, it is "planned for" and "there is no hesitation or hard feeling that there will be any sort of pull from either way." Testimony of Elizabeth Hunt, Tr. 69:16 – 21. With respect to VESLC, the CSC representative testified that, with the closure of UVMMC's Fanny Allen outpatient ORs, "there is the possibility of that – of those services being able to be performed at the Collaborative

Surgery Center . . . But we don't foresee that being a large spectrum of care. As we mentioned, our four core does not include the cataracts, so that is not something we would be focusing on, but as we said throughout the application, if there is a community need, if there is a significant backlog, if there is a cataract surgeon who is seeking to be able to provide these services, then we would, of course, accommodate and at least speak to them about how we could accommodate these procedures for them." Testimony of Elizabeth Hunt, Tr. 70:1-18.

16. CSC acknowledges that because of its size and lean staffing, it cannot pursue an extensive array of specialties and maintain quality at the very start. Testimony of Elizabeth Hunt, Tr. 45:17 – 46:1 ("That's not to say that we are going to welcome 500 surgeons into the … doors and allow 500 different procedures to be done. We understand that within a four OR capacity fiscally, calendar-year wise, everything, that's just not reasonable"). CSC is seeking the unrestricted CON so that it has flexibility to adjust its specialties based on its perception of need in the future. *Id.*, 46:2 – 25. ("So our quality measure and need of understanding that you want to have nurses who are specialized to certain specialties and then having an unrestricted license, they are kind of separate issues because it allows us to recruit and meet the need of the community by bringing in surgeons of whatever specialty feels necessary at that point in time").

17. At the hearing, Board members asked whether CSC would use evidence-based research to develop minimum surgical volumes such as those published by the Leapfrog Group to ensure quality surgical care. A CSC representative testified that it would incorporate such standards into its credentialing process: "[The GMSC's Medical Advisory Committee] set[s] up minimum standards that anyone who becomes credentialed has to have done this many surgeries. And if they are close to that number, they actually have a process that's developed to observe, have observations by more experienced surgeons before they can start doing surgeries on their own, if they are anywhere close to the minimum number. So there are actually policies that exist currently [at GMSC] in response to these standards and guided by them. And I think at CSC the intent would be to develop a similar process there." Testimony of Amy Cooper, Tr. 52:19 – 53:6. No process was described, however, for ensuring a minimum number of procedures at the facility. *See id.*

18. CSC will also have a process for reviewing patient feedback that will be similar to GMSC. Testimony of Elizabeth Hunt, Tr. 56: 17 – 20. CSC representatives described how feedback from patient surveys is obtained, incorporated into staff meetings and quality assurance and performance improvement committee meetings, and shared with the Medical Advisory Committee and the medical director and administrator. Testimony of Amy Cooper, Tr. 54:20 – 55:7; Testimony of Elizabeth Hunt, Tr. 55:12 – 56:20.

19. CSC produced projections to support four ORs but did not perform any specific market analysis. *See* Resp. (Sept. 21, 2021), 2-4. Applicant's projections show a capacity rate for four ORs at Year Four of 56.7% (low procedure-time assumption), 64.8% (medium procedure-time assumption), and 81% (high procedure-time assumption); where the Year Four projections for three ORs would be 75.6%, 86.4% and 108%, respectively. Resp. (Dec. 2, 2021), 4, 8. Applicant further provides anecdotes from local physician practices and patients and a compilation of recent media reports regarding wait times. App., 11, Resp. (Sept. 21, 2021), 4-7; *see* Testimony of Amy Cooper, Tr. 59:18 – 61:7.

20. While the applicant did not perform its own analysis, it did reference a 2019 GMCB presentation that included an analysis of wait times. Resp. (Sept. 21, 2021), 7. That presentation found long wait times in certain specialties, including neurology, urology, and ENT. GMCB, *FY2020 Hospital Budgets Non-Financial Reporting* (June 12, 2019), 26.[2]

21. GMCB staff collected data to help evaluate CSC's claim of need for additional outpatient surgical capacity in northwestern Vermont. GMCB staff sent surveys to the five hospitals and two ASCs that currently provide outpatient surgeries within the primary service area of the proposed project. While the data the Board obtained through the survey had limitations, it did suggest that there is, or soon will be, a need to add outpatient surgical capacity in this area of the state. For example, the survey showed that UVM Medical Center expects its outpatient OR utilization, which is already above its benchmark rate of 75%, will surpass 100% in 2021 and reach 122% in 2024. The responses also revealed that regional OR utilization may reach 84.2% by 2024 in the status quo scenario. Under the new entrant scenario (including CSC), OR occupancy rate would be 80.4% in 2024, reflecting a reduction of the occupancy rate by 3.8 percentage points. GMCB, *Outpatient Surgical Capacity and Volumes Report* (Dec. 29, 2021) 2-4.

22. The applicant asserts that CSC can offer routine outpatient procedures more efficiently and at a lower cost than hospital outpatient departments. *See* App., 20, 77. Under the Medicare program, CSC will be reimbursed a facility fee at a lower rate than in-state hospitals. *See* App., 31, 68. Under the Vermont Medicaid program, CSC will also be reimbursed for a facility fee at a lower rate than the facility fee for in-state hospitals for most services. Testimony of Amy Cooper, Tr. 78:14 – 79:3 (stating that the Medicaid rate for ASCs is lower than the Medicaid rate paid to in-state Vermont hospitals); *see also* Vermont Medicaid State Plan, Attachment 4.19-B, page 2a (1a) (establishing a peer group base rate for ASCs that is lower than the peer group base rate for in-state hospitals and establishing special payment provisions for outpatient dental services). CSC plans to generate most of its revenues in the commercial market. App., 35, Table 6. CSC estimates that GMSC saved commercial payers $5.3 million in fiscal year 2020. App., 10. Physician fees are billed separately from the facility fee and the physician fee for a procedure or surgery is the same whether performed at an outpatient hospital surgery center or at an ASC. App., 32-33.

23. CSC asserts that "[a]ffordable surgical capacity is particularly needed for orthopedic, ENT, urology, and dental procedures" and that "CSC will help to address this by including these surgical specialties as core procedures." App., 3. CSC provided some information suggesting there is a need for more surgical capacity for specialists practicing in these areas. *See* Resp. (Sept. 21, 2021), 5-7; Testimony of Elizabeth Hunt, Tr. 69:3-15 (describing wait times of up to 10-12 months for pediatric dentistry, resulting in children going to the Emergency Room); 93:17-94:2 (stating that GMSC could serve pediatric dentistry patients five days per week if it had the capacity and "that's not going away any time soon"); App., 37 ("Vermonters with conditions requiring common procedures such as rotator cuff repairs, anterior cruciate ligament (ACL)

[2] The report can be found at: http://gmcboard.vermont.gov/sites/gmcb/files/FY%202020%20Hospital%20Budgets%20Non-Financial%20Report.pdf

reconstruction, and treatment for kidney stones and bladder control often must wait weeks or months for such treatment"); App., 12 (describing projected increases in total hip and total knee replacements in the United States between 2015 and 2040); Resp. (Sept. 21, 2021), 4 (describing difficulty scheduling surgery for orthopedic cases); *see* Testimony of Amy Cooper, Tr. 18:15 – 19:19.

24. CSC further states that it must be permitted to perform at a minimum, orthopedics, ENT, urology, and dental procedures: "[A]s is the case for any healthcare facility planning to be sustainable for the long-term, the investors who will finance the renovation and fit-up of the facility, front the start-up costs, and purchase the medical equipment must have assurance that high-margin and high-growth services will be part of CSC's offering, as well as the more niche or less profitable services. Simply put, to make the project financially feasible and meet our goal to provide a broad range of the most needed services, CSC must have assurance that, at minimum, it will be permitted to perform orthopedic, ENT, urology, and dental procedures." App., 22. Accordingly, CSC's lease is contingent upon it receiving a CON that allows it to perform all orthopedic, dental, ENT and urology procedures allowed by Medicare to be performed at an ASC. App., 27; Resp. (Feb. 1, 2022), 2; *see infra*, Findings, ¶ 5.

25. Physicians performing surgeries at the ASC will not be employed by the applicant and will not lease the operating rooms. Physicians will bill for their fees unless the physician and facility enter into an arrangement for global pricing. CSC will bill one facility fee charge that is inclusive of room time, medications, and recovery. App., 32-33 and n. 67.

26. GMSC has recruited six surgeons and eight staff members from outside the state. Resp. (Sept. 21, 2021), 15 (stating that six surgeons, two administrative staff, and six nurses at GMSC have come from out of state). CSC is "hopeful that [it] will be able to attract needed specialists in ENT, urology, pediatric dentistry, and orthopedics quickly and urgently as these specialties are currently extremely difficult to access for patients in the greater Burlington area." *Id.*

27. The applicant assumes an annual rate of case growth between five percent and eight percent. This base-case growth rate captures the shift of surgical cases from the inpatient to outpatient setting. The applicant assumes an initial case volume of 1,840 in Year 1; 1,943 in Year 2; 2,103 in Year 3; and 2,269 in Year 4. The applicant acknowledges that the project will increase utilization of health care. It suggests, however, that the increase should factor in an acknowledgement that current outpatient surgical resources in Chittenden County are insufficient and that that "an increase in frequency is a natural result of expanded access to health care." App., 34-35.

28. In addressing how the project would impact the ability of existing facilities to provide medically necessary services to all in need, regardless of ability to pay, location, or residence, CSC asserts that while it may draw patients from the hospital, "we anticipate that the cross section of patients who visit the ASC to look very similar to those of the hospital. That is, the ASC anticipates a patient mix that includes Medicare, Medicaid, commercial payer, self-pay, and charity care patients, all in similar proportions to those of the hospital." App., 75. Specifically, CSC estimates a payer mix of 30% Medicare, 12% Medicaid, 53% Commercial, and 5% Self-Pay. App., 35. CSC reached these figures by consulting results from a 2016 survey by the

American Medical Association (AMA) and combining it with their knowledge of the current payer mix at GMSC. The AMA survey showed a national payer mix for surgical subspecialities of 38% Medicare, 12% Medicaid, 39% Commercial and 10% Other. Resp., (Sept. 21, 2021), 13. Additionally, CSC asserts that "[t]he ASC will not select patients based on insurance status." App., 75. On a systemwide basis, hospital payer mix is comparable to CSC's projected payer mix. *See*, *e.g.*, GMCB, *Fiscal Year 2019 Vermont Hospital Budgets Year-End Actuals Reporting* (Feb. 26, 2020), 10.

29. CSC asserts that UVMMC, "the hospital located closest to the proposed site for the ASC and the hospital where most of the specialists planning to utilize the Collaborative Surgery Center currently perform outpatient procedures, will be most directly affected by the proposed ASC." App., 63. Given the size of UVMMC, CSC asserts that the impact of the project on UVMMC will not be material, pointing, among other things to the size of UVMMC's budget, its margins, and studies concluding that an increase of one ASC per 100,000 people was associated with a 4.3% reduction in outpatient surgical volumes for nearby hospitals. App., 63-64.

30. A Patient Financial Assistance (PFA) policy will be adopted by the applicant. The terms of the policy reflect that it will provide free care for eligible uninsured Vermonters with incomes below 200 percent of Federal Poverty Level (FPL) and discounted care for eligible uninsured Vermonters with incomes between 200 and 400 percent of FPL. Free and discounted care will be provided at a level that is on par with Vermont nonprofit hospitals. CSC will accept all forms of insurance, including private pay, Medicare, and Medicaid. App., 58, Exhibit 4.

31. CSC will offer transparent pricing and will publicly post its prices and provide "real-time" price estimates updated based on patients' most recent insurance claims and benefit status. App., 20, 72; Testimony of Elizabeth Hunt, Tr. 25:10 – 26:11.

32. The applicant plans to donate 50% of its distributable profits to its Collaborative Community Foundation (CCF), whose mission will be to provide grants to support primary care, mental health, child counseling, or other needed community services. App., 72-73; CSC ppt, 13. CCF will be a private foundation that will issue grants to other charitable organizations. It will be a separate entity from CSC and will have a board of trustees distinct from CSC's governing board. App., 25. The applicant expects to achieve distributable profits between Year 3 and Year 4 of operation. Grants will be available to health care organizations throughout the state of Vermont. Resp. (Sept. 21, 2021), 8-9.

33. The applicant expects that it will generate savings for Medicare because Medicare reimburses the facility fee at ASCs at a lower rate than it does hospital outpatient surgery centers for the same procedures. The average Medicare savings is 48% for facility fee costs. Because some private insurers set their outpatient surgery rates based on a percentage of the current Medicare rates, the applicant anticipates a similar, if not greater, rate of savings for private insurers and self-pay patients. App., 33. Applicant reports that GMSC saved Medicare $1 million in fiscal year 2020 and saved commercial payers $5.3 million in the same time period. App., 10. Blue Cross and Blue Shield of Vermont does not contract based on the Medicare fee schedule; it sets rates on an individual basis in a way that makes sure that an ASC is not being reimbursed at a higher rate than the outpatient services offered in the hospital setting. Testimony of Elizabeth Hunt, Tr. 70:19 -71:4, 98:20 – 99:9.

34. The Board has received 11 written public comments on this application. The majority of public comments submitted have expressed support for the project, including letters from insurers Blue Cross and Blue Shield of Vermont (Sept. 1, 2021) and MVP (Oct. 29, 2021); advocacy organization AARP-VT (Oct. 8, 2021), and businesses such as Chroma Technology (Nov. 29, 2021), Main Street Landing (Oct. 10, 2021) and Burton Snowboards (Oct. 6, 2021). See also CSC ppt, 15. One comment (Jan. 11, 2022) took no position on the application, but questioned CSC's characterization of a cardiac procedure's benefits, which Ms. Ridzon acknowledged at the hearing was erroneous. *See* App., 53; Testimony of Susan Ridzon, Tr. 64:18-20. Another comment (Jan. 24, 2022) opposed granting a CON to a for-profit facility and the absence of a State Health Care plan. In addition to the written comments, at the close of the public hearing, one commenter spoke in favor of the project because of the wait times some patients are experiencing. Tr. 118:3 – 119:18.

35. CSC will require all physicians utilizing CSC's facilities to sign a document agreeing to serve Medicaid patients if the Board imposes a CON condition to that effect. Resp. (Sept. 21, 2021), 11.

36. The Vermont Blueprint for Health designs community-led strategies for improving health and well-being in the state. CSC states that it will help the Blueprint by bringing cost-effective, patient-centered care options to the community and that it is well-suited to advance payment reform with its bundled facility fee that can be known in advance. As part of the applicant's credentialing process, physicians who operate at CSC will sign a "Collaborative Care Agreement," whose principles are "(i) timely access to care, (ii) communication, (iii) adherence to widely accepted evidence-based principles of care, and (iv) support of the primary care practice (PCP) as the Medical Home for most patients." CSC states that the agreement's protocols enhance the effectiveness of the patient-centered medical home and contribute to greater continuity of care. Pursuant to the agreement, specialists will provide the patient's PCP with guidelines and instructions for follow-up care, including parameters for additional consultation. App., 73.

37. CSC will use a cloud based EMR platform that is specific to ASCs and that provides a single system for scheduling documentation, dictation, coding, billing, patient portal interaction, and outside physician office scheduling, among other functions. The upfront cost is $13,500 and the subscription rate is $55,000/year. CSC will coordinate with the patient's primary care office to gather applicable clinical information. GMSC currently uses this cloud based EMR and can report data to VDH. CSC will participate in all mandated reporting at state, federal, and regulatory levels electronically through the EMR and can interface with VITL, if requested. Resp. (Oct. 29, 2021), 2-3. It is a priority of CSC to integrate its system with VITL and VHIE. Resp. (Dec. 2, 2021), 5-6.

38. CSC states that it will support access to appropriate mental health care. CSC staff will directly address mental health for patients receiving care at the center as needed; nurses will communicate with patients, referring primary care physicians, and social workers to understand individual patients' unique needs. Resp. (Sept. 21, 2021), 13.

39. CSC will perform implicit bias training with its staff; GMSC performs implicit bias training with its staff currently with diversity training focused on topics such as language barriers and pronoun use, which are factors that impact a patient's level of care and comfort. This practice will be brought to CSC. Testimony of Elizabeth Hunt, Tr. 42:14 – 43:1.

40. CSC's location is close to other medical providers, UVMMC, and pharmacies. CSC will be located off Interstate 89 and will have ample free parking with dedicated handicapped spaces. The location is a 10-minute drive from the center of Burlington and a 5-minute drive from Winooski. The CCTA Milton Commuter bus stops approximately 0.7 mile away. Patients who are eligible for Special Services Transportation Agency may use it to access CSC. CSC is 3.5 miles from UVMMC via Route 2 or 4.5 miles via the interstate. App., 56, 75-76; Resp. (Dec. 2, 2021), 4.

41. CSC will use its best efforts to secure and maintain Medicare certification using Avanza Strategies, which assists ASCs in securing and maintaining certification as a participating Medicare provider. CSC intends to maintain continuous compliance with certification requirements. App., 59.

42. CSC will seek to enter into a transfer agreement with UVMMC to admit patients to the hospital in a safe and timely manner when warranted by their medical conditions. It will similarly use best efforts to secure and maintain a transport agreement with an emergency medical service provider for its emergency transport requirements. CSC will ensure that all staff are well qualified and that the clinical personnel have privileges, or are eligible for privileges, at a local hospital. CSC's medical staff bylaws will require that all CSC clinicians hold a M.D. or D.O. degree from a recognized medical or osteopathic school, maintain a valid Vermont medical or osteopathic license, and strictly abide by the principles of medical ethics. App., 59-60.

43. CSC will institute a quality review system, cooperate with all public and private review organizations, and institute best practices protocol. App., 59-60, Exhibits 5 and 8. CSC will have to participate in the Ambulatory Surgical Center Quality Reporting (ASCQR) program, a quality reporting program implemented by the Centers for Medicare and Medicaid Services (CMS). VDH Ambulatory Surgical Center Licensing Rule, § 5.4.2. There are currently seven measures that ASCs must report under this program. App., 43. Data collected through the ASCQR program is publicly reported so that consumers can compare the quality of care provided at ASCs. CMS, ASC Quality Reporting, http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting. CSC will also post its reports on quality measures on its website. App., 44.

44. CSC will also have to participate in the Patient Safety Surveillance and Improvement System (PSSIS), which is administered by the Vermont Program for Quality in Health Care through a contract with the Vermont Department of Health. *See* 18 V.S.A. § 2153(a)(4). The PSSIS collects information on National Quality Forum serious reportable events (e.g., surgery performed on the wrong patient or the wrong site, and foreign object left in patient) and the occurrence of intentional unsafe acts. *See* VDH, Patient Safety Surveillance and Improvement, https://www.healthvermont.gov/health-professionals-systems/hospitals-health-systems/patient-safety. Data submitted is confidential by law. 18 V.S.A. § 1917(a).

45. CMS, in partnership with the Agency for Healthcare Research and Quality, has developed a standardized patient survey program for ASCs and hospital outpatient departments – the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS). Some of the data CSC cites in its application comes from these surveys. *See* App., 19, Figure 4; *see also* App., 18. The OAS CAHPS survey asks patients about their experience preparing for the surgery or procedure as well as the check-in process, cleanliness of the facility, communications with the facility staff, discharge from the facility, and preparation for recovering at home. The survey also asks patients whether they received information about what to do if they had possible side-effects during their recovery. The survey is administered by CMS-approved vendors on behalf of ASCs and hospitals. ASCs can add questions to the survey. The survey program is voluntary. *See* CMS, Outpatient and Ambulatory Surgery Consumer Assessment (OAS CAHPS); Ambulatory Surgery Center Association, OAS CAHPS Survey® FAQs.

46. The HCA presented its position on four topics during this proceeding. First, it advocated for Board oversight of CCF. Second, it recommended that the Board require CSC's PFA be at least as generous as UVMMC's, be updated every two years, be adopted by CSC's participating physicians, and be provided to potential patients as a plain-language summary; it also asked the Board to prohibit CSC from using debt collection agencies or other aggressive methods. Third, the HCA recommended that the Board require CSC to conduct implicit bias training. Fourth, the HCA supported a Board requirement for CSC to include patient and community representation on its quality committee and Board of Managers. HCA Comments (Jan. 28, 2022), 1-2; Testimony of Sam Peisch, Tr. 36:8 – 37:5; 39:15-23; 40:12 – 42:8.

Standard of Review

Vermont's CON process is governed by 18 V.S.A. §§ 9431-9446 and Green Mountain Care Board Rule 4.000. An applicant bears the burden of demonstrating that it has met each of the criteria set forth in 18 V.S.A. § 9437. Rule 4.000. § 4.302(3).

Introduction

CSC requests a certificate of need to construct an unrestricted, multi-specialty ASC in Colchester, VT consisting of four operating suites and associated ancillary rooms and offices. We approve the application and issue a CON to CSC, subject to the conditions set forth therein. One of these conditions restricts the surgeries and procedures that can be performed at CSC to the four "core" specialties identified by CSC in the application: orthopedics; ENT; urology; and dental. As discussed further below, CSC did not provide us with concrete and reviewable plans to host procedures outside of these four core specialties. While CSC desires flexibility to add and remove services in the future based on its business judgments, without a more robust record demonstrating that CSC's business judgments would align with CON criteria, we are unable to grant that level of flexibility at this time. Moreover, CSC has not demonstrated that it can maintain appropriate volumes across a broad range of surgeries and procedures, and we are concerned that, given its limited staff and facility size, CSC will be stretched too thin if it seeks to broaden its scope beyond the four core specialties it has identified.

Conclusions of Law

I.

Under the first statutory criterion, an applicant must show that the proposed project aligns with statewide health care reform goals and principles because it takes into consideration health care payment and delivery system reform initiatives; addresses current and future community needs in a manner that balances statewide needs; and is consistent with appropriate allocation of health care resources, including appropriate utilization of services, as identified in the Health Resource Allocation Plan (HRAP). 18 V.S.A. § 9437(1).

Statewide Health Care Reform Goals and Principles

The Vermont All-Payer Accountable Care Organization Model (All-Payer Model) is the State's overarching health care payment and delivery system reform initiative. The goals of the All-Payer Model are to control growth in the cost of certain health care services, improve the health of Vermonters, and improve the quality of the care Vermonters receive. The All-Payer Model seeks to achieve these goals by shifting provider payments from a fee-for-service system that rewards the delivery of more services, to a system that rewards providers for promoting health, preventing disease, and delivering high quality care and good health outcomes at a lower cost. Under the All-Payer Model, accountable care organizations (ACOs) are the vehicle for this transformation. *See In re: Vermont All-Payer Accountable Care Organization Model Agreement* (Oct. 27, 2016). ACOs are organizations of health care providers that agree to be accountable for the cost, quality, and overall care of a defined group of people. *See* 18 V.S.A. § 9373(16).

Recently, fixed reimbursement approaches have been identified as particularly important to the success of the All-Payer Model. Truly fixed payments made prospectively to providers, when coupled with incentives to maintain or improve quality, can curb provider incentives to maximize volume and can deliver enough predictability, stability, and flexibility that providers change the way they meet the needs of their patients. *See* Vermont Agency of Human Services, *Implementation Improvement Plan: Vermont All-Payer Accountable Care Organization Model Agreement* (Nov. 19, 2020).

CSC asserts that it will be a low-cost, high-quality option for patients and, as such, can help ACOs meet their quality and cost targets. CSC has had conversations with the ACO OneCare Vermont and intends to participate in any fixed payment programs developed by the ACO that are applicable to ASCs. *See* Findings, ¶ 10.

Given the above, we condition our approval of the CON on CSC participating in one or more risk-bearing ACOs and, after sufficient time has passed to allow for the development of a fixed payment reimbursement approach, on CSC accepting fixed payment reimbursement in lieu of fee-for-service reimbursement for patients attributed to the ACO. We believe such a condition is needed to ensure that the project aligns with the statewide health care reform goals reflected in the All-Payer Model. We also believe such a condition helps make the project more consistent with CON Standard 1.3 (collaborative approach to delivering services has been taken or is not feasible or appropriate) and CON Standard 2.2 (new ambulatory care services must be

consistent with state focus on health promotion, with the highest priority for services to prevent diseases and minimize their effects).

Current and Future Needs

We address the issue of need in our discussion of the third statutory criterion below.

Health Resources Allocation Plan

The Health Resources Allocation Plan (HRAP) identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis.[3] In light of the factual findings and conditions in the CON, we conclude that the project is consistent with the HRAP. We note the following:

- **CON Standard 1.3** (collaborative approach to delivering services has been taken or is not feasible or appropriate) and **CON Standard 2.2** (new ambulatory care services must be consistent with state focus on health promotion, with the highest priority for services that prevent diseases and minimize their effects) are addressed by Conditions 5 and 20 of the CON.
- **CON Standard 1.4** (project will maintain appropriate volume and will not erode volume at other Vermont facilities in such a way that quality could be compromised) and **CON Standard 1.6** (collect and monitor health care quality and outcomes data and align with other related data collection and monitoring efforts) are discussed more fully below and are addressed by Conditions 13 and 14 of the CON.
- **CON Standard 3.16** (applicant proposing to establish an ASC must demonstrate how the project will provide access to all residents of each community within the identified service area without regard to payer type, insurance status, or ability to pay) is discussed more fully below and is addressed by Condition 17 of the CON.
- **CON Standard 1.7** (the project is consistent with evidence-based practice) is addressed by Conditions 6, 8, and 14 of the CON.
- **CON Standard 1.8** (the applicant has a comprehensive evidence-based system for controlling infectious disease) and **CON Standard 3.13** (ASC procedures can be safely performed in an ASC and will not require overnight stay) are addressed by VDH licensing rules, Medicare Conditions of Coverage, and Condition 4 of the CON.
- **CON Standard 3.14** (ASC located within appropriate travel time to hospital with 3+ operating rooms) is met. *See* Findings, ¶ 40.
- **CON Standard 3.15** (ASC will provide services for post-operative complications and patient questions on a 24-hour basis) is addressed by Conditions 7 and 9 of the CON.
- **CON Standard 3.17** (ASC applicant must demonstrate it will secure Medicare certification; develop and maintain a transfer agreement with at least one nearby hospital and an emergency transport agreement; ensure staff are well qualified and clinical

[3] The Vermont legislature in Act 167 (2018) made several changes to the State's CON law. As amended by Act 167, 18 V.S.A. § 9437(1)(C) continues to reference the HRAP, which is in the process of being updated. In the interim, we consider the current HRAP standards. The Health Resource Allocation Plan is posted to the Board's website at https://gmcboard.vermont.gov/sites/gmcb/files/documents/Vermont%20Health%20Resource%20Allocation%20Plan%202009%207.1.09.pdf.

personnel are eligible for or have privileges for similar surgical procedures at a local hospital; institute a quality review system; cooperate with public and private review organizations; and demonstrate the ASC will institute best practices protocol) is addressed by Conditions 4 and 5 of the CON.

II.

The second criterion requires an applicant to demonstrate that the cost of the project is reasonable. The applicant must show that it can sustain any financial burden likely to result from the project; that the project will not result in an undue increase in the cost of care or an undue impact on the affordability of medical care for consumers; that less expensive alternatives do not exist, would be unsatisfactory, or are not feasible or appropriate; and that appropriate energy efficiency measures have been incorporated into the project. 18 V.S.A. § 9437(2).

Based on our review of the record, together with the conditions we place on the CON, we are sufficiently comfortable that CSC can sustain the financial burden likely to result from the project. The cost of fit-up, estimated to be approximately $2.4 million, will be borne up front by the landlord and CSC will pay those expenses over time through its lease. The details of the real estate transaction were revised close to the time of hearing and a full lease had not been executed.[4] Findings, ¶ 5. Because the landlord and CSC have not yet finalized arrangements regarding the possibility of cost overruns beyond those factored into the fit-up budget, we require CSC to submit a copy of the finalized lease once it is executed.

CSC will finance the medical equipment, inventory, fixtures, working capital, and other start-up costs through bank financing and private investment capital from operating physicians. CSC indicates that it can obtain financing with reasonable terms and conditions. While CSC expects that it will need to use some working capital to cover lease payments and operating expenses during its first year of operation, it also expects to generate sufficient revenues thereafter to satisfy lease payments and other operating costs. Findings, ¶ 6.

We also conclude that less expensive alternatives are not available, would be unsatisfactory, or are not feasible or appropriate, and that appropriate energy efficiency measures have been incorporated into the project. CSC submitted utilization projections suggesting that it can support four ORs. Findings, ¶¶ 19, 27. Additionally, the project involves fit-up of existing space rather than new construction and the planning appears to have been done by experienced professionals to best utilize the space that is available. Finally, the HVAC, electrical, and plumbing systems, together with the building envelope design are planned to meet all required energy efficiency codes and Efficiency Vermont standards. *See* Findings, ¶¶ 5-7.

Next, we analyze whether the applicant has demonstrated that the project will not result in an undue increase in the cost of care or an undue impact on the affordability of medical care for consumers. In our analysis, we must consider and weigh relevant factors, including the

[4] There are multiple close relationships among the principals to the real estate transaction. The owners of the property are two limited liability companies and a corporation who own it as tenants in common. All three ownership entities have other connections to the project, with one LLC owned by the spouse of the CSC consultant who testified at the hearing; one LLC owned by the president of the architecture firm performing the fit-up; and the corporation owned by the principal of the law firm representing the applicant in this proceeding. *See* Findings, ¶ 5.

financial implications of the project on hospitals and other clinical settings, including the impact on their services, expenditures, and charges, and whether these impacts, if any, are outweighed by the benefit of the project to the public. 18 V.S.A. § 9437(2)(B).

The clinical settings likely to be impacted by the project are nearby hospitals and ASCs. With respect to hospitals, CSC asserts that UVMMC will be most directly affected by the proposed ASC. Given its size, CSC asserts that any impact the project will have on UVMMC will be immaterial. We agree that the impact of the project on UVMMC and other local hospitals is likely to be small and is unlikely to have any material impact on hospital services, expenditures, or charges, particularly if CSC's payer mix is similar to that of local hospitals. *See* Findings, ¶¶ 14, 28-29.

CSC's application failed to address the impacts the project would have on the other two ASCs in the area, GMSC and VESLC. Given the common leadership and overlapping interests between CSC and GMSC, and based on the testimony offered at the hearing, we are sufficiently comfortable that the project will not have a material impact on GMSC's services, expenditures, or charges. Findings, ¶¶ 3, 15. We cannot reach the same conclusion with respect to VESLC. It is not possible to analyze the likely impact of the project on VESLC without more concrete plans and data, which CSC did not provide. *See* Findings, ¶ 15. However, with the conditions we place on the CON, the project should have no impact on VESLC at this time.

As for the benefit of the project to the public, the applicant asserts that it can offer routine outpatient procedures more efficiently and at a lower cost than hospital outpatient surgery departments. Under current payment methodologies, CSC will be reimbursed at a lower rate than in-state hospitals for all services provided to Medicare patients and will also be reimbursed at a lower rate than in-state hospital outpatient surgery facilities for most services provided to Vermont Medicaid patients. Findings, ¶ 22.

The need for lower costs, however, is particularly acute in the commercial market,[5] which is where CSC plans to generate most of its revenues. *See* Findings, ¶ 28. CSC estimates that GMSC saved commercial payers $5.3 million in fiscal year 2020. Findings, ¶ 33. GMSC was required to ensure that its commercial reimbursements are lower than any hospital in Vermont. *In re: ACTD LLC, d/b/a The Green Mountain Surgery Center*, GMCB-010-15con, Statement of Decision (June 4, 2019), 22-23. To ensure CSC similarly reduces costs for the commercially insured population, we impose the same condition in CSC's CON.

With the conditions we impose, CSC will be a lower price option compared to hospital outpatient departments. However, from a broader perspective, a reimbursement rate ("price") is not the same thing as "cost." Cost in this context is a function of both price and

[5] While we acknowledge that affordability is particularly needed in the commercial health insurance markets, we take issue with CSC's attempts to single out Vermont in this respect. CSC compares the 2021 premium cost of a benchmark silver plan for a 40-year-old individual making $30,000 a year in Vermont, Maine, Massachusetts, New Hampshire, and Rhode Island. App., 68. However, this is not an apples-to-apples comparison. *See* Vermont Agency of Human Services, *Report on Health Insurance Affordability and Merged Markets 2019 Report to the Legislature*, Appendix 1, 3 (explaining that Vermont's community rating and higher average age of enrollees contribute to its 40-year-old rate being notably higher than most states and the national average, but that premiums for a 60-year-old are much more competitive and "Vermont's average rate is likely less or around the national average, all else equal").

utilization. Even if CSC can accommodate surgeries and procedures at a lower price, if the project increases utilization, it may result in higher total expenditures or total cost of care. At the same time, increased utilization may be warranted or desirable if there is a lack of access to needed care. *See* Findings, ¶ 27. In addition to unnecessary suffering, delays in accessing care can cause patients' conditions to worsen, ultimately leading to higher costs. As explained elsewhere in this decision, there is evidence of a need for additional outpatient surgical capacity to meet demand in the four core specialties CSC identified, suggesting that higher utilization may be warranted. Several of the conditions in the CON, such as the use of shared decision-making and meaningful participation in health care reform, are intended to ensure that utilization at CSC, which will operate outside of the regulatory system applicable to hospitals, is appropriate, and that the project does not end up increasing systemwide costs beyond what is necessary to meet this need.

Based on the above discussion, and in light of the conditions imposed in this CON, we conclude that the applicant has satisfied the second criterion.

III.

The third criterion requires that the applicant demonstrate that there is an "identifiable, existing, or reasonably anticipated need for the proposed project which is appropriate for the applicant to provide." 18 V.S.A. § 9437(3). While the record lacks the kind of data we would prefer on the issue of need, we conclude that CSC has demonstrated that additional outpatient surgical capacity is needed in CSC's service area to meet demand in the four "core specialties" of orthopedics, ENT, urology, and dental. *See* Findings, ¶ 23. We do not find, however, that CSC demonstrated a similar need with respect to all procedures authorized by Medicare for payment in an ASC.[6]

CSC claims that the project will alleviate long wait times for specialty care, citing news articles, GMCB reports, and other information regarding specialty wait times. Findings, ¶ 19. Of course, we acknowledge that specialty wait times are a problem and that Vermonters are having to wait too long to see many types of specialists. And the data that our staff gathered in connection with this application, while limited, suggested that there is or soon will be a need for additional outpatient surgical capacity in northwestern Vermont. Findings, ¶ 21. However, the applicant did not convincingly connect the general issues of wait times and overall need for surgical capacity to a specific demonstration of need outside of the four core specialties. *See* Findings, ¶ 23. While we certainly understand CSC's desire for flexibility to add and remove services in the future based on its business judgments, without a more robust record demonstrating that CSC's business judgments would align with CON criteria, we are unable to grant that level of flexibility at this time. *See* Findings, ¶ 16.

In light of the above, as well as concerns described in Section IV below, we include a condition in today's CON requiring that the applicant petition the Board for approval before expanding beyond the initial core specialties. *See* Condition 2. This decision is not a denial of

[6] In this decision, we analyze the issue of "need" as one of access and capacity. We have addressed cost elsewhere in this decision because the project's impact on cost of care is a separate criterion. *See, infra,* Conclusions of Law, § II; see also 18 V.S.A. § 9437(2).

any part of CSC's application *See* 18 V.S.A. § 9440(d)(4) (approval may be in whole, in part, or subject to conditions); *see also* GMCB Rule 4.000, § 4.500(5) (for applications involving multiple services, if one or more of the services does not meet the necessary criteria, then the Board shall issue a CON for only those services that do meet the necessary criteria). In CON proceedings, when an application is denied, the applicant may not reapply for permission to provide an identical or substantially similar new project for a year from the date of the order. GMCB Rule 4.000, § 4.500(6). We set no such time constraint here. We invite CSC to request the ability to host procedures and surgeries in additional specialties as soon as it can demonstrate a need beyond its general preference for flexibility and can demonstrate how the proposed expansion meets other CON criteria that may apply. *See* 18 V.S.A. § 9444(b)(1) (material changes are subject to CON review); GMCB Rule 4.000, § 4.600 (Project Changes). In particular, and as discussed in Section IV below, when requesting the ability to add specialties beyond the starting "four core," CSC will need to demonstrate that it can develop its staff in such a way that it will be able to offer a high-quality outpatient surgical experience across its entire array of specialties and procedures.

Based on the above, and in light of the conditions we place on the CON today, we conclude that the project meets the third criterion.

IV.

To satisfy the fourth criterion, the applicant must demonstrate that the project improves the quality of health care or provides greater access for Vermonters, or both. 18 V.S.A. § 9437(4).

Quality

Even with the restrictions we impose today, CSC will be authorized to perform a broad scope of surgeries and procedures, namely all procedures and surgeries approved by Medicare for payment in ASCs now and into the future in four core specialties of orthopedics, ENT, urology, and dental. As such, we are concerned about how low volumes might affect CSC's ability to deliver quality care. This concern is clearly reflected in CON Standard 1.4 of the HRAP, which states that for an application that proposes services for which a higher volume is positively correlated to better quality, the applicant must show it will be able to maintain appropriate volume for the service and that the addition of the service at the facility will not erode volume at another Vermont facility in such a way that quality could be compromised.

A significant amount of research has been done on the relationship between surgical quality and surgical volume (the "volume-outcome relationship"). As a result of this research, minimum volume standards have been developed for certain surgeries. For example, based on research by Dartmouth-Hitchcock Medical Center, Michigan Medicine, and Johns Hopkins Medicine, as well as guidance from a national expert panel, the Leapfrog Group has identified eleven high-risk procedures for which there is a strong volume-outcome relationship, including total knee and total hip replacement surgeries (both of which are cited in CSC's application), and has developed minimum hospital volume standards and minimum surgeon volume standards for these surgeries. *See* The Leapfrog Group, Factsheet: Adult and Pediatric Complex Surgery,

https://ratings.leapfroggroup.org/sites/default/files/inline-files/2021%20Surgical%20Volume-Appropriateness%20Fact%20Sheet_2.pdf.

When asked, representatives indicated that CSC will incorporate volume standards into its credentialing process. Findings, ¶ 17. While it will be important for CSC to develop such standards for physicians, facility-level standards are critical as well; just like surgeons, surgical support staff at the facility must have sufficient experience in the types of surgeries that will be performed to ensure quality is maintained. In addition to limiting CSC to the four core specialties as a way to ensure that its staff will have sufficient experience, we also condition our approval of the project on CSC reviewing both physician and facility surgical volumes as part of its quality assurance and performance improvement program and incorporating both physician and facility minimum volume thresholds where they are applicable and have been established, such as with hip and knee replacements.

A well-functioning quality improvement program also requires robust data collection. *See, e.g.,* 42 CFR 416.43 (requiring that ASCs develop, implement, and maintain an ongoing, data-driven quality assessment and performance improvement program). This is reflected in CON Standard 1.6 of the HRAP, which requires an applicant to explain how it will collect and monitor data relating to health care quality and outcomes and which states that, to the extent practicable, such data collection and monitoring must align with related data collection and monitoring efforts, whether within the applicant's organization, other organizations, or the government.

There are two quality/safety reporting programs that CSC is required to participate in, the Ambulatory Surgical Center Quality Reporting (ASCQR) program and the Patient Safety Surveillance and Improvement System (PSSIS). The ASCQR program is a quality reporting program implemented by CMS. Data collected through the ASCQR program is publicly reported so that consumers can compare the quality of care provided at ASCs. CSC states that it will also post its reports on quality measures on its website, a commitment that we incorporate into the CON as a condition. Findings, ¶ 43. The PSSIS, meanwhile, is a safety reporting system that collects information on serious reportable events (e.g., surgery performed on the wrong patient or wrong site, and foreign object left in patient) and the occurrence of intentional unsafe acts. It is administered by the Vermont Program for Quality in Health Care through a contract with the Vermont Department of Health. Findings, ¶ 44.

In addition to these mandatory programs, there is a voluntary patient survey program, OAS CAHPS, which is administered by CMS-approved vendors on behalf of both ASCs and hospital outpatient departments. The OAS CAHPS survey asks patients about their experience preparing for the surgery or procedure as well as the check-in process, cleanliness of the facility, communications with the facility staff, discharge from the facility, and preparation for recovering at home. The survey also asks patients whether they received information about what to do if they had possible side-effects during their recovery. Findings, ¶ 45.

CSC representatives testified about the importance of patient feedback for the proper functioning of the facility's quality assurance and performance improvement program. *See* Findings, ¶ 18. Participation in the OAS CAHPS program will help CSC identify opportunities that could lead to improvements in patient care and will do so in a way that aligns with the data

collection efforts of other ASCs and the federal government, thereby enabling comparisons between CSC and other ASCs nationally. See Findings, ¶ 45. Accordingly, we condition our approval of the project on CSC participating in this program and either reporting the results on its website or providing a link to the results. In light of the significant importance of patient perspectives to quality improvement, we also require CSC to include patient and community representation on its Quality Assurance and Performance Improvement Committee.

Access

As stated above, while the record lacks the kind of hard data we would like, we conclude that CSC has demonstrated that additional outpatient surgical capacity is needed in CSC's service area to meet demand in the four "core specialties" of orthopedics, ENT, urology, and dental. The project will help meet this need, thereby increasing access. CSC also hopes to be able to recruit specialists in ENT, urology, pediatric dentistry, and orthopedics from outside the state, which would also help increase access in these areas. *See* Findings, ¶ 26.

For the reasons discussed above, and with the conditions imposed today, we find this fourth criterion satisfied.

V.

The fifth criterion requires an applicant to show that the project "will not have an undue adverse impact on any other existing services provided by the applicant." 18 V.S.A. § 9437(5). Because the applicant offers no services at this time, to the extent this criterion is applicable, we conclude that it is satisfied.

VI.

What was previously the sixth criterion is now an overarching consideration, namely that the project serves the public good. *See* Act 167 (2018), § 6 (repealing 18 V.S.A. § 9437(6) and moving the "public good" language to the lead-in sentence). Our administrative rule identifies factors that we may consider in determining whether a project will serve the public good. GMCB Rule 4.000, § 4.402(3). Several of these factors are relevant to this project and we therefore address them here.

Needs of the Medically Underserved and Goals of Universal Access

The first factor we consider is whether the project will help meet the needs of medically underserved groups and the goals of universal access to health services.[7] Rule 4.000, § 4.402(3)(a). This application presents three issues related to this factor: 1) access for patients

[7] CSC mentions its proposed charitable organization, the Collaborative Community Foundation (CCF), in support of this and other criteria. While we commend CSC for its interest in charitable works, we evaluate CSC's application as an ASC on its own merits and do not take CCF into account in our review of the CON criteria. CCF is still only conceptual in nature; any funding for CCF is many years off; and the manner in which profits are calculated may be a concern. Moreover, at the state level, the Secretary of State and the Attorney General are the appropriate entities to oversee charitable organizations. *See, e.g.*, 11B V.S.A. § 1.01 *et seq*.; 9 V.S.A., § 2471 *et. seq.*

with Medicaid or who are unable to pay, 2) transparent pricing, and 3) implicit bias training. The first of these issues also relates to CON Standard 3.16, which provides that an applicant proposing to establish an ASC must demonstrate how the applicant will provide access to all residents of each community within the identified service area without regard to an individual's payer type, insurance status, or ability to pay for necessary services.

Eliminating barriers to accessing health care based on insurance status or ability to pay is fundamental to the goals of meeting the needs of medically underserved groups and promoting universal access to health services. With the conditions imposed today, CSC will provide a lower-cost-facility alternative, which should increase access for the uninsured and those facing high deductibles and copays.

CSC states that it will accept all forms of insurance, including private pay, Medicare, and Medicaid, and that "[t]he ASC will not select patients based on insurance status." Findings, ¶¶ 28, 30; *see also* 18 V.S.A. § 2153(a)(5) (requiring that ASCs accept Medicare and Medicaid patients for ASC services). This is a hollow statement, however, if the physicians performing surgeries and procedures at CSC do not accept Medicaid patients. CSC has stated that it will require all physicians utilizing the facility to serve Medicaid patients if the Board imposes a CON condition to that effect. Findings, ¶ 35. As such, we include a condition in the CON requiring CSC to develop and implement a policy, which it must post to its consumer website, requiring that physicians practicing at the facility certify that they accept Medicaid and will not consider a patient's source of payment or ability to pay when determining whether to perform the patient's surgery at CSC.

We are pleased to see that CSC projects a payer mix that is similar to the average payer mix at Vermont hospitals, with 12% of its revenues coming from Medicaid. Findings, ¶ 28. While we appreciate that projections are estimates, because of the incentives that exist for physician-owners of an ASC to treat more profitable commercially insured patients at the ASC, we believe it is important to monitor this number. We therefore impose a condition in the CON requiring CSC to monitor and report on its payer mix and, if it is not in line with projections, to provide the Board with a justification for the deviations and proposed remedies.

CSC has represented that it will adopt a PFA policy as generous as area hospitals. *See* Findings, ¶ 30. To ensure that consumers with limited means have similar opportunities to access care regardless of the location they choose, and to ensure that consumers are aware of the policy, we include a condition in the CON that requires the applicant to maintain a PFA policy at least as generous as UVMMC's and to post a plain language version of the policy on its website.

CSC has also committed to offer transparent pricing, with "real-time" estimates updated based on patients' most recent insurance claims and benefit status. *See* Findings, ¶ 31. However, CSC charges only a facility fee. Patients will also receive bills from one or more specialists for services provided at the ASC. *See* Findings, ¶ 22. As such, the CON includes a condition requiring CSC to provide patients with written price estimates on request and written disclosures in advance of surgery that outline the total price of their procedure or surgery, including the facility fee and the physicians' fees. CSC also represented that it will post its prices on its website and we impose a condition that requires CSC to do so. *See* Findings, ¶ 31.

Finally, recognizing GMSC's experience with implicit bias training and the importance of such training to providers' ability meet the needs of medically underserved groups, we require CSC to conduct implicit bias training on an annual basis. *See* Findings, ¶ 39.

Blueprint for Health

The second factor we consider under this overarching criterion is whether the project will help facilitate implementation of the Blueprint for Health. GMCB Rule 4.000, § 4.402(3)(b). CSC has indicated that it will help the Blueprint by bringing cost-effective, patient-centered care options to the community. As part of the credentialing process, CSC says it will have physicians sign a Collaborative Care Agreement in which they agree to support the primary care practice as the medical home for most patients. Findings, ¶ 36. The CON includes a condition to ensure that CSC follows through on this commitment.

Project Impact, Effective Integration, Consistency with Reform

The final factors are whether the applicant has demonstrated that it has analyzed the impact of the project on the Vermont health care system and whether the project furthers effective integration and coordination of health care services and is consistent with current reform initiatives; and whether and to what extent the project will adversely impact the ability of existing facilities to provide medically necessary services to all in need. GMCB Rule 4.000, § 4.402(3)(c), (d), and (f). These issues have been discussed elsewhere and with the conditions included in the CON, we find that they have been met.

VII.

The seventh criterion requires that the applicant adequately consider the availability of affordable, accessible patient transportation services to the facility. 18 V.S.A. § 9437(7). We find this condition has been satisfied. The ASC is close to the interstate, has ample free parking with dedicated handicapped spaces. Public transportation is also available. Findings, ¶ 40.

VIII.

The eighth criterion, pertaining to information technology projects, has been satisfied, to the extent it may be applicable. 18 V.S.A. § 9437(8). CSC will use the same cloud based EMR platform as GMSC. The EMR platform is a single system that performs multiple functions and can be used for all mandated reporting at state, federal, and regulatory levels. Findings, ¶ 37.

IX.

The ninth and final criterion requires the applicant to demonstrate that the project supports equal access to appropriate mental health care that meets standards of quality, access, and affordability equivalent to other components of health care as part of an integrated, holistic system of care, as appropriate. 18 V.S.A. § 9437(9). We find this criterion satisfied, to the extent applicable. CSC will address mental health as necessary for patients receiving care at the center and CSC staff will communicate with patients, referring primary care physicians and social workers to best address patient needs. Findings, ¶ 38.

Conclusion

The Board issues a Certificate of Need to the applicant based on our conclusion that it has met its burden of proof. The conditions we impose today will help ensure that the project will increase access to care, lower health care costs, and maintain or improve the quality of health care in Vermont.

SO ORDERED.

Dated: March 16, 2022 at Montpelier, Vermont

s/ Robin Lunge)
s/ Tom Pelham)
s/ Thom Walsh)

GREEN MOUNTAIN CARE BOARD OF VERMONT

Board Member Holmes, with whom Chair Mullin joins, dissenting in part and concurring in part.

While I join the Board in much of its analysis, I respectfully dissent from its decision to initially limit CSC to orthopedic, ENT, urology, and dental procedures and surgeries. *See* CON, Condition 2.

For me, the project addresses two needs, neither of which justifies limiting the types of procedures and surgeries that can be done at the ASC. First, the project addresses a general need for more outpatient surgical capacity, as demonstrated by the survey responses gathered by the Board. *See* Findings, ¶ 21. Second, the project addresses a need for a lower cost and more convenient setting of care. Given the existing reimbursement methodologies employed by Medicare and Medicaid and the condition in the CON relating to commercial reimbursements, which I fully support, CSC will be lower cost than hospital outpatient surgery departments. *See* Findings, ¶ 22; CON, Condition 16. CSC will also offer a more relaxed and less imposing setting, which some patients prefer. Limiting the types of surgeries and procedures that can be done at the ASC is not necessary to ensure the project meets these needs. In fact, I worry that this limitation will allow CSC to focus on high-margin surgeries and procedures, such as orthopedics, and will discourage it from pursuing surgeries and procedures that are needed but may be low-margin (e.g., dermatology). Finally, based on GMSC's success in this regard, I believe the project has the potential to help bring more specialist physicians and other medical professionals into the state, which could help address long wait times that exist in certain specialties. *See* Findings, ¶ 26.

Like my colleagues, I have concerns about CSC's ability to host a broad range of procedures and surgeries and maintain quality—that it will be stretched too thin. However, the CON contains conditions that address this concern. With these conditions, which I support, I am comfortable allowing CSC to expand beyond the four specialties it identified without first obtaining Board approval.

For the reasons stated above, I would grant a CON that does not limit CSC to orthopedic, ENT, urology, and dental procedures and surgeries, but that is otherwise identical to the CON issued today by the Board.

Dated: March 16, 2022 at Montpelier, Vermont.

s/ Kevin Mullin, Chair)
s/ Jessica Holmes)

GREEN MOUNTAIN CARE BOARD OF VERMONT

Filed: March 16, 2022

Attest: s/ Jean Stetter
Green Mountain Care Board
Administrative Services Director

NOTICE TO READERS: This document is subject to revision of technical errors. Readers are requested to notify the Board (by email, telephone, or in writing) of any apparent errors, so that any necessary corrections may be made. (Email address: abigail.connolly@vermont.gov)