STATE OF MARYLAND

Robert E. Moffit, Ph.D.
CHAIRMAN

Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

MEMORANDUM

TO: Commissioners

FROM: Kevin R. McDonald
Chief, Certificate of Need

DATE: June 15, 2017

SUBJECT: Columbia Surgical Institute
Docket No. 17-13-2391

Enclosed is the staff report and recommendation for a Certificate of Need application filed by Columbia Surgical Institute, LLC ("CSI").

CSI is an ophthalmic outpatient surgical center located in Elkridge (Howard County) that was established in 2012. It has one operating room and three non-sterile procedure rooms. As such, it is not a "health care facility" subject to Certificate of Need requirements. Such facilities are referenced as "physician outpatient surgical centers" in the State Health Plan.

CSI proposes to convert one of the existing non-sterile procedure rooms to a second sterile operating room to accommodate growth in its case volume and the need for additional operating room capacity by a growing surgical staff. Expansion to a two-operating room center will establish CSI as an "ambulatory surgical facility," a category of health care facility subject to Certificate of Need requirements.

The total project cost is estimated to be $216,925 and the project is anticipated to take three months to complete.

Staff recommends APPROVAL of the project based on its conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for General Surgical Services, and the other applicable CON review criteria at COMAR 10.24.01.08.

IN THE MATTER OF	*	**BEFORE THE**
	*	
COLUMBIA SURGICAL INSTITUTE, LLC	*	**MARYLAND HEALTH**
	*	
	*	**CARE COMMISSION**
Docket No. 17-13-2391	*	
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Staff Report and Recommendation

June 15, 2017

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I. INTRODUCTION

A. The Applicant and the Project

Columbia Surgical Institute, LLC ("CSI" or "the Institute") is a physician outpatient surgery center ("POSC") dedicated to ophthalmic surgery, located at 6020 Meadowridge Center Drive, Suite H, in Elkridge (Howard County). It has one operating room ("OR") and three non-sterile procedure rooms[1]. The center was established in 2012, without a Certificate of Need ("CON"), as a POSC, the term used in the State Health Plan to describe an outpatient surgical facility with no more than one operating room[2]. POSCs may be established in Maryland without CON review and approval.

CSI provides cataract, glaucoma, corneal, retinal and oculoplastic surgical procedures. CSI is currently the only retinal surgical provider in Howard County. The impetus for this project is the growing demand for retinal procedures and the increase in the facility's credentialed providers and the growth in demand for their services. The Institute's service area covers parts of Anne Arundel County, Baltimore City, Baltimore County, Frederick County, Howard County, Montgomery County and Prince George's County.

The proposed project will convert one of the existing procedure rooms to create a second OR. The estimated cost of this project is $216,925 and the applicant plans to finance this project through a loan. This project is expected to take three months to complete.

CSI is owned by Scott LaBorwit, M.D. (73%) and Allan Rutzen, M.D., F.A.C.S. (27%) and the business is structured as a limited liability company.

B. Summary of Recommendation

Staff recommends approval of this project based on its conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for Facilities and Services: General Surgical Services. The need for the project has been demonstrated, and converting a procedure room to an operating room is a cost effective approach to expand OR capacity.

[1] One of the non-sterile procedure rooms is dedicated to procedures using a yttrium aluminum garnet ("YAG") Laser.

[2] Individuals or organizations seeking to establish an ambulatory surgery center or facility with only one operating room or no operating rooms (i.e., just non-sterile procedure rooms) are required to receive a Determination of Coverage from the Maryland Health Care Commission confirming that a Certificate of Need is not required. Such facilities are called physician outpatient surgery centers or POSCs in the State Health Plan to differentiate them from "ambulatory surgical facilities," which have two or more operating rooms and are, thus, facilities regulated under the CON program.
(http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_amsurg/documents/con_notification_requirements_ambsurg_coverage_20130821.pdf)

II. PROCEDURAL HISTORY

A. Record of the Review

Please see Appendix 1, Record of the Review.

B. Interested Parties

There are no interested parties in this review.

C. Local Government Review and Comment

No comments were received regarding this project.

D. Community Support

Three letters of support were received for this project; two from surgeons credentialed at CSI, and one from James Robey, a patient and Former Maryland Senator and Howard County Executive.

III. STAFF REVIEW AND ANALYSIS

The Commission considers CON applications using six criteria found at COMAR 10.24.01.08G(3). The first of these considerations is the relevant State Health Plan standards and policies.

A. The State Health Plan

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards, policies, and criteria.

The relevant State Health Plan for Facilities and Services ("SHP") chapter for this project review is COMAR 10.24.11, covering General Surgical Services ("Surgical Services Chapter").

COMAR 10.24.11.05 STANDARDS

A. GENERAL STANDARDS. The following general standards encompass Commission expectations for the delivery of surgical services by all health care facilities in Maryland, as defined in Health General §19-114(d). Each applicant that seeks a Certificate of Need for a project or an exemption from Certificate of Need review for a project covered by this Chapter shall address and document its compliance with each of the following general standards as part of its application

(1) <u>Information Regarding Charges</u>
Information regarding charges for surgical services shall be available to the public. A hospital or an ambulatory surgical facility shall provide to the public, upon inquiry or as required by

applicable regulations or law, information concerning charges for the full range of surgical services provided.

The applicant stated that CSI provides information regarding charges for the range and types of services it provides, upon request. A copy of the CSI's Facility Fee Schedule was submitted with its CON application. (DI#2, Exh. E). CSI complies with this standard.

(2) Charity Care Policy

(a) Each hospital and ASF shall have a written policy for the provision of charity care that ensures access to services regardless of an individual's ability to pay and shall provide ambulatory surgical services on a charitable basis to qualified indigent persons consistent with this policy. The policy shall have the following provisions:

CSI submitted a copy of its Financial Assistance policy and described the Institute's current charity care provisions. (DI#2, pp. 20-24 and Exh. F). It states that services will be provided to patients regardless of their ability to pay within the financial capability of the center.

(i) Determination of Eligibility for Charity Care. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the facility shall make a determination of probable eligibility.

The Financial Assistance Policy includes a provision that determination of probable eligibility for financial assistance will be made within two business days after the initial application for financial assistance is received.

(ii) Notice of Charity Care Policy. Public notice and information regarding the facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population and in a format understandable by the service area population. Notices regarding the surgical facility's charity care policy shall be posted in the registration area and business office of the facility. Prior to a patient's arrival for surgery, facilities should address any financial concerns of patients, and individual notice regarding the facility's charity care policy shall be provided.

CSI stated that public notice of its financial assistance policy will be distributed via personal contact, correspondence, and the applicant's website (http://www.columbia-surgical.com) and will also be displayed at the facility's reception desk. CSI states that it has established relationships with Howard County Community Partnership Services, the Howard County Housing Commission, Howard County Social Services, Anne Arundel County case managers, Anne Arundel County social workers, the Anne Arundel Public Health Nursing Program personnel and faith-based organizations, who will distribute the information on the policy to potential indigent patients.

(iii) Criteria for Eligibility. Hospitals shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. ASFs, at a minimum, must include the following eligibility criteria in charity care policies. Persons with family income below 100 percent of the current federal poverty guideline who

have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services free of charge. At a minimum, persons with family income above 100 percent of the federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands. A health maintenance organization, acting as both the insurer and provider of health care services for members, shall have a financial assistance policy for its members that is consistent with the minimum eligibility criteria for charity care required of ASFs described in these regulations.

CSI's Financial Assistance Program policy includes the following income eligibility guidelines:

- persons with a family income below 100% of the current federal poverty level are eligible for services free of charge;
- persons with incomes above 100% but below 200% of the current federal poverty level are eligible for services discounted on a sliding scale; and
- persons above 200% of the poverty level are considered for financial assistance on a case by case basis (DI# 2, pp.22-23 and Exhibit F).

(c) A proposal to establish or expand an ASF for which third party reimbursement is available, shall commit to provide charitable surgical services to indigent patients that are equivalent to at least the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses. The applicant shall demonstrate that:

(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment; and

(ii) It has a specific plan for achieving the level of charitable care provision to which it is committed.

(iii) If an existing ASF has not met the expected level of charity care for the two most recent years reported to MHCC, the applicant shall demonstrate that the historic level of charity care was appropriate to the needs of the service area population.

CSI has made a commitment to "not only meeting but…exceeding the minimum requirement." CSI's operating budget projects provision of charity care valued at $30,600 from 2017 through 2020, which would range from 1.11% to 0.81% of total operating expenses.

Although as a POSC it had no required commitment to charity care, it does have a reported track record for providing free and reduced cost surgical and non-surgical services. CSI reported provision of charity care valued at $21,225 in CY 2015 and $38,035 in CY 2016 (DI# 2, p.22). This amounted to 1.26% and 2% of the facility's operating income in 2015 and 2016 respectively, both surpassing the reported 0.52% statewide average for ASC's in 2015.

CSI described a proactive approach to identifying individuals in need of assistance, describing an outreach program that includes building relationships with community agencies and organizations (e.g., Howard County Community Partnership Services, the Housing Commission and

Social Services) in Howard and Anne Arundel Counties, as well as contact with case managers, public health nurses, and social workers. (DI# 2, pp.44-45).

CSI has demonstrated compliance with the Charity Care standard.

Standards .05A(3) Quality of Care, .05A(4) Transfer Agreements, and .05B(4) Design Requirements.

Among the remaining applicable standards are several that prescribe policies, facility features, and staffing and/or service requirements that an applicant must meet, or agree to meet prior to first use. Staff has reviewed the CON application and confirmed that the applicant provided information and affirmations that demonstrate full compliance with the following standards:

.05A(3) Quality of Care,
.05A(4) Transfer and Referral Agreements, and
.05B(4) Design Requirements,

Staff has concluded that the proposed project meets the requirements of these standards. The applicant is licensed, in good standing, with the Maryland Department of Health; is in compliance with the conditions of participation of the Medicare/Medicaid program; and is accredited by the Accreditation Association for Accreditation of Ambulatory Surgical Facilities. CSI has a written transfer agreement with Howard County Hospital, and the applicant states that the facility is designed in compliance with Section 3.7 of the 2014 Facilities Guideline Institute's Guidelines for Design and Construction of Healthcare Facilities. The text of these standards and the locations within the application where compliance is documented are attached as Appendix 2.

B. PROJECT REVIEW STANDARDS. The standards in this section govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate consistency with all applicable review standards.

(1) Service Area

An applicant proposing to establish a new hospital providing surgical services or a new ambulatory surgical facility shall identify its projected service area. An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall document its existing service area, based on the origin of patients served.

CSI defined its existing service area as the zip code areas from which the first 85% of its discharges originated. That service area includes zip code areas in Anne Arundel, Baltimore, Frederick, Howard, Montgomery and Prince George's Counties, and Baltimore City. (DI#2, p.26). Howard and Anne Arundel Counties account for approximately two thirds of the case volume from this primary service area.

The applicant meets this standard.

(2) Need – Minimum Utilization for Establishment of a New or Replacement Facility

This standard is not applicable as this proposed project seeks to expand an existing facility.

(3) Need - Minimum Utilization for the Expansion of Existing Facilities

An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall:

(a) Demonstrate the need for each proposed additional operating room, utilizing the operating room capacity assumptions and other guidance included at Regulation .06 of this Chapter;

(b) Demonstrate that its existing operating rooms were utilized at optimal capacity in the most recent 12-month period for which data has been reported to the Health Services Cost Review Commission or to the Maryland Health Care Commission; and

(c) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity. The needs assessment shall include the following:

(i) Historic trends in the use of surgical facilities at the existing facility;

(ii) Operating room time required for surgical cases historically provided at the facility by surgical specialty or operating room category; and

(iii) Projected cases to be performed in each proposed additional operating room.

To meet this standard, the applicant must demonstrate that the existing OR was utilized optimally over the past 12 months and that the expanded two-OR capacity is likely to be used at optimal capacity[3] or higher levels of use within three years of the completion of the project. CSI provided historical and projected data on surgical volume to demonstrate its ability to meet this standard, which is examined below.

Volume trends and projections

CSI's case volume grew from 503 cases in 2013 to 1,663 cases in 2016. CSI attributes its growth to:

- **Growth in the Number of Providers.** The number of surgeons credentialed at CSI has more than tripled over the past four years. In 2013, CSI established its practice with four providers. Since that time, the number of providers increased to seven in

[3] "Optimal capacity" is defined in the General Surgical Services Chapter of the State Health Plan as 80% of "full capacity use." "Full capacity" (for a general purpose outpatient OR) is defined as operating for a minimum of 255 days per year, eight hours per day, which results in an available full capacity of 2,040 hours per year. Thus optimal capacity is 1,632 hours per year.

2015 and to 13 in 2017. Appendix 3 details the projected case volume by provider between 2016 and 2021. (DI#2, p.30).

- **Addition of Retinal Surgical Services.** In 2016, CSI started offering retinal surgical services, making it the only facility (ASF or hospital) to offer retinal surgical services in Howard County. (DI#2, p.6). In its first year, CSI completed 30 retinal cases with one specialist. With the addition of a second retinal specialist at the end of 2016, CSI projects that the number of retinal cases will continue to grow to 511 cases by 2020.

Table III-1 below presents CSI's recent and projected surgical volume and room utilization statistics.

Table III-1: Historic and Projected Utilization at CSI, CY 2014-2019

Year	OR Cases	Operating Room and OR Cleaning/Preparation Time (Hours)			Historic and Projected OR Time as % of		ORs	ORs Needed
		Surgical Time	Turnover Time	Total Time	…Full Capacity	… Optimal Capacity		
2014	1,251	542	542	1,084	53%	66%	1	**0.66**
2015	1,430	620	620	1,240	61%	76%	1	**0.76**
2016 projected (annualized based on first 10 months)	1,663	776	721	1,497	73%	92%	1	**0.92**
2017 projected	2,430	1,256	932	2,188	54%	67%	2	**1.34**
2018 projected	2,919	1,508	1,119	2,627	64%	80%	2	**1.61**
2019 projected	3,175	1,637	1,217	2,854	70%	95%	2	**1.75**

Source: DI# 2, p.42 DI# 9, p.9.

CSI projected operating at 92% of optimal capacity in 2016 based on its use during 10 months of that year. It projects an ability to nearly double it case load between 2016 and 2019, based on growth in the number of active practitioners at the center. There is not a clearly established trend in case volume that supports this rate of growth. However, it is noteworthy that, if the caseload that CSI has managed to reach by its fourth year of operation, 1,663 cases, can be duplicated, on a nominal basis, in its second four-year period of operation, 2016-2020, it would need a total of approximately 2,619 hours of OR time in 2019 (assuming a smooth line of case volume growth), compared to the 2,854 OR hours it projects. This would be equivalent to approximately 80% of optimal capacity for two operating rooms, compared to the applicant's projected 95% of optimal capacity use. By 2020, which is arguably the third year following implementation of the proposed project if it is completed in 2017, using these same case growth assumptions, CSI would need OR hours equivalent to 92% of optimal capacity. Thus, the range of projected use, based on the applicant's assumptions or the more conservative assumptions based on historic experience, are relatively narrow.

Staff recommends that the applicant be found to have demonstrated substantive compliance with this standard.

(5) Support Services.
Each applicant shall agree to provide, either directly or through contractual agreements, laboratory, radiology, and pathology services.

The applicant maintains a laboratory but outsources testing that exceeds its in-house capabilities and authorizations to Quest and LabCorp.

(6) Patient Safety
The design of surgical facilities or changes to existing surgical facilities shall include features that enhance and improve patient safety. An applicant shall:

(a) Document the manner in which the planning of the project took patient safety into account; and

(b) Provide an analysis of patient safety features included in the design of proposed new, replacement, or renovated surgical facilities;

The applicant stated that the room design will maintain the recommended clearances and space requirements as outlined in the FGI Guidelines, and will include finishings that maximize the facility's ability to sanitize the space. The heating, ventilation, and air conditioning system will be updated to control the flow of air in the new OR, converting the existing procedure room into a sterile environment. Finally, an emergency power generator will be installed that is equipped to operate essential electrical equipment within 30 seconds of power failure.

Staff concludes that the applicant has demonstrated that the planning of the proposed renovation took patient safety into account, and recommends that the Commission find that the applicant has met the requirements of this standard.

(7) Construction Costs
The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

Subpart (a) does not apply because this is not a hospital project.

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of an ambulatory surgical facility construction or renovation project shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality,

and other listed factors.
(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost by 15% or more, then the applicant's project shall not be approved unless the applicant demonstrates the reasonableness of the construction costs. Additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility may be provided to support an applicant's analysis of the reasonableness of the construction costs.

This standard requires a comparison of the project's estimated construction cost with an index cost derived from the Marshall Valuation Service ("MVS") guide. To make this comparison, a benchmark cost is typically developed for new construction based on the relevant construction characteristics of the proposed project. The MVS cost data includes the base cost per square foot for new construction by type and quality of construction for a wide variety of building uses including outpatient surgical centers. The MVS guide adjusts for a variety of factors, including cost data: for the latest month; the location of the construction project; the number of building stories; the height per story; the shape of the building (the relationship of floor area to perimeter); and departmental use of space.

The MVS Guide also identifies costs that should not be included in the MVS calculations. These exclusions include costs: for buying or assembling land, for improvements to the land, related to land planning, for discounts or bonuses paid for financing, for yard improvements, for off-site work, for furnishings and fixtures, for marketing costs, and for general contingency reserves[4].

In this project CSI is proposing the renovation of 315 square feet ("SF") of existing building space. A special procedure room of approximately 249 SF will be renovated and expanded into a new 251 SF operating room. Among the renovations will be modifications to the HVAC, plumbing system, and doorways to the biohazard closet, surgery room and adjacent surgery suite. Outside the actual room renovations, 64 SF of space will be renovated to upgrade the door, flooring, and signage in the corridor.

Both CSI and MHCC staff found that the estimated cost per square foot for this very small scale project to be substantially lower than the index cost we calculated using the MVS guidelines (shown in more detail in Appendix 4). Staff calculated a benchmark MVS index cost of $454.63 per SF because the project develops expensive operating room space in space currently used as a special procedure room.

Meanwhile the estimated cost of the project is only $216,925 -- and most of that is for equipment (which is not included the MVS per square foot costs). The estimated cost for the components accounted for in the MVS guide (the building cost, architectural and engineering fees, permits, and a portion of the financing fees) is $39,121 -- or $124.19 per SF. This cost/SF is approximately 70% lower than the benchmark. The applicant used a different method of calculating the benchmark, and calculated a smaller spread of 64% between that MVS benchmark cost and the estimated project cost.

[4] Marshall Valuation Service guidelines, Section1, p.3 (January 2016).

The fact that the estimated cost of this project is substantially less than the benchmark is not surprising given that this is a renovation project. Renovation projects vary greatly and the MVS benchmarks typically calculated in the CON review process using the calculator section of MVS do not specifically reflect these variations. The MVS base costs found in the calculator sections are for new construction of the specific building use and type and quality of construction. The derivation of a more representative MVS benchmark for a renovation project like that envisioned by this application would use the segregated cost method, which would require very detailed information on the material and labor necessary to complete the project. Therefore, this project complies with this standard.

(8) Financial Feasibility

A surgical facility project shall be financially feasible. Financial projects filed as part of an application that includes the establishment or expansion of surgical facilities and services shall be accompanied by a statement containing each assumption used to develop the projects.

(a) An applicant shall document that:

(i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the likely service area population of the facility;

CSI states that it based its projected utilization on its historic trends and population growth.

(ii) Revenue estimates are consistent with utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant facility or, if a new facility, the recent experience of similar facilities;

Revenue estimates are based on the utilization projections and current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity provisions as experienced by CSI.

(iii) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant facility, or, if a new facility, the recent experience of similar facilities; and

Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and anticipated future staffing needs to meet growth at CSI.

(iv) The facility will generate excess revenues over total expenses (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years of initiating operations.

CSI reported net income of $120,670 in 2014 and $478,333 in 2015. As shown in Table III-2 below, CSI projects that net income will grow at an increasing rate over the first three years following implementation of the project. (DI# 18).

Table III-2: CSI Uninflated Financial Projections, CYs 2016-2020

	2016	2017	2018	2019	2020
Cases	1,663	2,286	2,759	3,001	3,261
Revenue	$2,276,294	$3,323,970	$3,848,482	$4,190,091	$4,561,792
Expenses	$1,905,098	$2,682,856	$3,118,763	$3,376,785	$3,670,310
Net Income	***$371,196***	***$641,114***	***$729,719***	***$813,306***	***$888,873***

Source: DI#18

(9) Preference in Comparative Review

This is not a comparative review, so this standard does not apply.

B. Need

COMAR 10.24.01.08G(3)(b) requires that the Commission consider the applicable need analysis in the State Health Plan. If no State Health Plan need analysis is applicable, the Commission shall consider whether the applicant has demonstrated unmet needs of the population to be served, and established that the proposed project meets those needs.

This criterion directs the Commission to consider the "applicable need analysis in the State Health Plan," which, in this instance, is found in the Surgical Services Chapter at COMAR 10.24.11.05B(3), Need – Minimum Utilization for Expansion of an Existing Facility. As previously outlined and supported by the data provided in Table III-1, the proposed project is substantively consistent with the Chapter's need standard for OR additions.

In addition, the applicant expanded on describing the need for the project, and identified four factors driving the need for the project -- operational challenges, a service area gap in retina providers, advanced technology, and growing demand from the aging population. These are discussed below.

Operational Challenges. CSI currently operates Monday through Friday from 7:00 am to 3:00 pm. Surgeries are only performed Monday through Thursday so that Fridays are available to provide post-operative appointments within 36 hours of surgery. Immediate (within the first 36 hours) post-operative examinations are required in this 36 hour "window" for all ocular surgeries to identify complications associated with possible post-operative infections and to give the surgeons an opportunity to assure the position of the implant(s). This limits surgical scheduling to four days a week. (DI# 2, p.37).

Gap in Retina Providers. CSI states that it is currently the only provider of retinal surgery in Howard County. However, functioning with just one OR hinders CSI's ability to provide retinal care. The applicant described the delicate set-up and break-down maneuvers required to prepare the OR for retinal surgery, and then remove that same equipment (and install other equipment) prior to other surgeries. A second room could be dedicated to retinal surgery without disrupting CSI's ability to perform other eye surgery.

Technological Advances. CSI is one of only nine providers in the applicant's service area with LexSX technology, a laser technology used for and in conjunction with cataract

surgery, that the applicant states "makes the perfect opening in the eye lens without the need for surgical blades." (DI#2, p.40). Use of this technology, however, increases OR time by 10 minutes per case. Since cataract surgeries make up an average of 87% of CSI's OR cases, use of this new technology cuts into the available amount of OR time available for other cases.

Growing demand for Ophthalmology Services by an Aging Population. In 2014, *An Aging Nation* by the U.S. Census indicated that Americans are living longer. People of advanced age have an increased risk of eye conditions including: cataracts, glaucoma, macular degeneration, and retinopathy. CSI has tracked the population growth of people ages 65 and older in its service area and noted that an increase in that age group will trigger an increase in demand for ophthalmological surgical services.

Proportion (%) of Population Aged 65 and Over

Maryland Counties Served	2010	2015	Percent Change
Anne Arundel	11.8	13.7	16.1
Baltimore City	11.7	12.5	6.8
Baltimore County	14.6	16.1	10.3
Carroll County	13.0	15.8	21.5
Frederick County	11.1	13.3	19.8
Harford County	14.6	15.9	8.9
Howard County	10.1	12.7	25.7
Montgomery County	12.3	14.1	14.6
Prince George's County	9.4	11.7	24.5
Queen Anne's County	14.9	17.8	19.5

Source: DI#2, p.41

Staff has concluded that the applicant has provided documentation that its volume projections are not unreasonable, and that two operating rooms are likely to be used at or very close to optimal capacity levels within three years of expansion of the center. Staff recommends that the Commission find that the applicant has adequately demonstrated a need for the project.

C. Availability of More Cost-Effective Alternatives

COMAR 10.24.01.08G(3)(c) requires the Commission to compare the cost-effectiveness of providing the proposed service through the proposed project with the cost-effectiveness of providing the service at alternative existing facilities, or alternative facilities which have submitted a competitive application as part of a comparative review.

The applicant identified two alternatives for meeting the proposed projects objectives: (1) expand hours of operation or (2) refer retina patients to other ASF's or hospitals outside of Howard County for treatment.

Extending Hours of Operation. This option would require the facility to extend its hours of operation into the evening hours and Fridays, and add hours on Saturday. The applicant looked at extending the hours of operation by four hours a week, eight hours a week and adding six hours on Saturday. Extended evening hours would require the facility to hire additional staff at premium pay rates; the applicant calculated the financial impact to be

incremental staff salary costs of $1,100 a week for four hours of overtime, $2,200 a week for eight hours of overtime and $427 to support six hours of post-operative appointments on Saturdays. (DI#9, pp.17-18).

In addition, CSI stated that evening hours could put the patients who receive treatment in the evening at increased risk for falls by adding the variable of darkness to a mix that already includes compromised visual acuity and moderate sedation.

The applicant rejected this option due to the overtime staffing expense and potential risks to patients.

Referring Retina Patients to Other Providers. CSI also considered referring all of their retina patients to other providers. Since CSI is the only retina surgical facility in Howard County, patients would have to be referred to one of the surrounding hospitals (Anne Arundel Medical Center, Greater Baltimore Medical Center, Sinai Hospital, Suburban Hospital, or University of Maryland Medical Center Midtown) or to an ASF in Montgomery County. CSI stated that the disadvantages to patients of making such referrals would be twofold: further travel and cost. CSI stated that the closest alternate facility would be 30 miles away, and that its charge for repairing a retinal detachment is $1,660, compared with charges ranging from $3000 - $6,922 at these alternative facilities. (DI#2, p.38). The applicant rejected this option based on the additional cost and travel time that would be imposed on patients.

Staff concludes that the applicant has made a reasonable demonstration that the decision to renovate and convert an existing procedure room into a second OR is the most cost effective alternative for meeting the applicant's goals. The capital cost is modest and the project provides CSI with additional OR space to meet the demands associated with additional practitioners and anticipated growth in the volume and range of cases performed at CSI.

Staff recommends that the Commission find the project to be a more cost effective approach than the practical alternatives available.

D. Viability of the Proposal

COMAR 10.24.01.08G(3)(d) requires the Commission to consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frame set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

Availability of Resources to Implement the Proposed Project

The project budget is $216,915, and would be financed with a loan. In lieu of audited financials, the applicant provided a letter from Chris Marasco of Howard Bank, attesting to the availability of CSI's line of credit for this project. (DI #2, Attachment L).

The applicant also submitted three letters of support: two from ophthalmologists credentialed at CSI and one from James Robey, a patient at CSI and retired Senator and former Howard County Executive.

The applicant has demonstrated that it has the financial resources and community support needed to undertake this project. (DI #4, Exhibit 18)

Availability of Resources to Sustain the Proposed Project

As shown in Table III-3 below, CSI projects continued profitable operations through 2020. As discussed earlier in the Financial Feasibility standard, MHCC staff concluded that these projections were supported by reasonable and well-documented assumptions.

Table III-3: CSI Projected Revenues and Expenses, CY 2018-2020

Revenue	**CY 2016**	**CY 2017**	**CY 2018**	**CY 2019**	**CY 2020**
Outpatient Services	$2,292,276	$3,326,743	$3,848,618	$4,188,886	$4,599,192
Gross Patient Services Revenues	2,292,276	3,326,743	3,848,618	4,188,886	4,599,192
Charity Care		13,951	16,218	17,559	19,086
Net Patient Services Revenue	2,292,276	3,340,694	3,864,836	4,206,445	4,578,278
Other Operating Revenues: Refunds on Deductibles	-15,984	-16,725	-16,354	-16,354	-16,477
Net Operating Revenues	**$2,276,294**	**$3,323,970**	**$3,848,482**	**$4,190,091**	**$4,561,801**
Expenses					
Salaries, Wages, and Professional Fees	$537,437	$685,363	$760,767	$828,586	$902,330
Contractual Services	$304,828	$370,751	$444,961	$484,628	$527,367
Interest on Current Debt	20,134	23,157	23,086	22,126	22,790
Interest on Project Debt		7,329	5,827	4,263	2,636
Current Depreciation	19,600	50,825	42,833	37,753	43,804
Project Depreciation		23,142	23,142	23,142	23,142
Project Amortization		44,200	44,200	44,200	44,200
Supplies	947,355	1,385,439	1,662,752	1,810,980	1,972,157
Other Expenses Donations, entertainment, repairs, and maintenance	75,743	92,650	111,195	121,108	131,886
Total Operating Expenses	**$1,905,098**	**$2,682,856**	**$3,118,763**	**$3,376,785**	**$3,670,310**
Income					
Income from Operations	371,196	641,114	729,719	813,306	888,873
Net Income (Loss)	**$371,196**	**$641,114**	**$729,719**	**$813,306**	**$888,873**

Source: DI #18

Staff concludes that the proposed project is viable.

E. Compliance with Conditions of Previous Certificates of Need

COMAR 10.24.01.08G(3)(e) requires the Commission to consider the applicant's performance with respect to all conditions applied to previous Certificates of Need granted to the applicant.

This criterion is not applicable as the applicant has not pursued a CON prior to this application.

F. Impact on Existing Providers

COMAR 10.24.01.08G(3)(f) requires the Commission to consider information and analysis with respect to the impact of the proposed project on existing health care providers in the service area, including the impact on geographic and demographic access to services, on occupancy when there is a risk that this will increase costs to the health care delivery system, and on costs and charges of other providers.

Impact on other providers

The applicant referenced an industrywide "shift from hospital-based ophthalmology surgery to an ASF {setting}" that is well underway, and stated that it was unlikely that proposed project will have an adverse impact on existing health care providers in the service area. (DI#2, p.55). Based on an analysis of each CSI surgeons' practices, CSI stated that the expansion proposed will not adversely impact other existing providers in any significant way. First of all, most of the surgeons at CSI are at the early stages of their careers, and building their practices. For these practitioners, there would be very little, if any, shift from other facilities. Among the more established surgeons, one will shift approximately 60 cases from Baltimore Eye Surgical Center (about 2% of that facility's volume), two currently only operate at CSI, one will continue to perform complex and emergency retina cases at Suburban Hospital, and one will be shifting some hospital cases and some from existing ASFs in "order to access retina technology." CSI projects very little impact on the volumes or payor mix of other providers.

Impact on access to health care services for the service area population

CSI states that access to health care services will improve in the service area because of "expanded availability of specialized providers, including retina specialists," and because the expanded capacity will allow CSI to "provide a surgical home for several surgeons building or expanding their practices." CSI also stated that implementation of the project would significantly boost access for patients needing retinal surgery.

Staff concludes that there will be very little impact on existing providers, that access to ophthalmological surgical care would improve, and that the cost of this care may be lowered because of this project, and thus recommends that the Commission find that the application complies with this criterion.

IV. SUMMARY AND STAFF RECOMMENDATION

Based on its review of the proposed project's compliance with the Certificate of Need review criteria in COMAR 10.24.01.08G(3)(a)-(f) and the applicable standards in COMAR 10.24.11, the General Surgical Services Chapter of the State Health Plan, Commission staff recommends that the Commission approve the project. It complies with the applicable State Health Plan standards, is needed, is a cost-effective approach to meeting the project objectives, is viable, and will have a positive impact on the Center's ability to provide outpatient surgery without adversely affecting costs and charges or other providers of surgical care.

Accordingly, Staff recommends that the Commission **APPROVE** the application of the Columbia Surgical Institute, LLC's for a Certificate of Need authorizing the addition of a second operating room through the renovation of currently leased space, converting an existing non-sterile procedure room to a sterile operating room.

IN THE MATTER OF	*	**BEFORE THE**
	*	
COLUMBIA SURGICAL INSTITUTE, LLC	*	**MARYLAND HEALTH**
	*	
	*	**CARE COMMISSION**
Docket No. 17-13-2391	*	
	*	

*** ***

FINAL ORDER

Based on the analysis and findings contained in the Staff Report and Recommendation, it is this 15th day of June, 2017, by a majority of the Maryland Health Care Commission, **ORDERED:**

That the application for a Certificate of Need to renovate a procedure room and convert it to a second operating room at the Columbia Surgical Institute, LLC, an existing physician outpatient surgery center, in leased space at 6020 Meadowridge Center Drive, Suite H, Elkridge, Maryland, at a cost of $216,925 is **APPROVED.**

Maryland Health Care Commission

APPENDIX 1

RECORD OF THE REVIEW

Record of the Review

Item #	Description	Date
1	Commission staff acknowledge receipt of Letter of Intent.	12/9/16
2	The applicant filed their Certificate of Need application.	2/3/17
3	Commission staff requested that the *Maryland Register* publish notice of receipt of application.	2/3/17
4	Commission staff acknowledged receipt of application for completeness review.	2/6/17
5	Commission staff requested that the *Baltimore Sun* publish notice of receipt of application.	2/6/17
6	Notice of receipt of application was published in the *Baltimore Sun*.	2/15/17
7	Following completeness review, Commission staff requested additional information.	2/22/17
8	Commission staff received request for extension to file completeness information until 3/22/17 from applicant's counsel.	3/7/17
9	Commission staff received responses to additional information request.	3/21/17
10	Commission staff received responses to additional information request.	4/11/17
11	Commission staff notified the applicant of formal start of review of application effective 9/16/16.	4/14/17
12	Commission staff requested that the Baltimore Sun publish notice of formal start of review.	4/14/17
13	Commission staff requested that the Howard County Times publish notice of formal start of review.	4/14/17
14	Commission staff requested that the *Maryland Register* publish notice of formal start of review.	4/14/17
15	Request made for comments from the Local Health Planning Department on the CON application.	4/14/17
16	Commission staff requested that the Baltimore Sun publish notice of formal start of review.	4/19/17
17	Commission staff received additional information from the applicant regarding turnaround time via email exchange.	6/2/17
18	Commission staff requested and received additional information from the applicant via email exchange.	6/5/17

APPENDIX 2

Excerpted CON Standards for General Surgical Services From State Health Plan Chapter 10.24.11

Excerpted CON standards for General Surgical Services
From State Health Plan Chapter 10.24.11

Each of these standards prescribes policies, services, staffing, or facility features necessary for CON approval that MHCC staff have determined the applicant has met. Bolding added for emphasis. Also included are references to where in the application or completeness correspondence the documentation can be found.

STANDARD	**APPLICATION REFERENCE (Docket Item #)**
A.(3) Quality of Care. A facility providing surgical services shall provide high quality care. … (a) An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health and Mental Hygiene. (c) An existing ambulatory surgical facility shall document that it is: (i) In compliance with the conditions of participation of the Medicare and Medicaid programs; and (ii) Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation agency recognized by the Centers for Medicare and Medicaid as acceptable for obtaining Medicare certification. (d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will: (i) Meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, and anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment. (ii) Obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility.	DI#2, p.24 DI#2, Appendix G
A.(4) Transfer Agreements. (a) Each ASF and hospital **shall have written transfer and referral agreements** with hospitals capable of managing cases that exceed the capabilities of the ASF or hospital. (b) Written transfer agreements between hospitals shall comply with the Department of Health and Mental Hygiene regulations implementing the requirements of Health-General Article §19-308.2.	DI #2, p. 25
B.(4) Design Requirements. Floor plans submitted by an applicant **must be consistent with the current FGI Guidelines.** (a) A hospital shall meet the requirements in Section 2.2 of the FGI Guidelines. (c) Design features of a hospital or ASF that are at variance with the current FGI Guidelines shall be justified. The Commission may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.	DI #2, p. 31 Appendix K

APPENDIX 3

Projected OR Cases by Provider

Projected OR Cases by Provider

Provider	Specialty	2016	2017	2018	2019	2020	2021
LaBorwit		830	872	915	961	1009	1059
Lima		65	130	137	143	150	158
Rutzen		329	362	398	438	482	530
Lui		234	281	309	340	374	411
Schor		18					
Bernfeld		40					
Wray		37	60	66	73	80	84
Hanna		57	114	137	150	166	174
Heffez		30	36	60	84	108	132
Ali		21	144	288	317	348	366
Chan		2	144	158	174	192	201
Goel			156	192	211	232	244
Syed			60	120	132	145	152
Swamy			24	42	46	51	53
Salvo			48	96	106	116	122
Total Cases		1,663	2,431	2,918	3,175	3,453	3,686

Source: DI#2, p.27 & p.31

APPENDIX 4

Marshall Valuation Service Review

Marshall Valuation Service Review

The Marshall Valuation System – what it is, how it works

In order to compare the cost of a proposed construction project to that of similar projects as part of a cost-effectiveness analysis, a benchmark cost is typically developed using the Marshall Valuation Service ("MVS"). MVS cost data includes the base cost per square foot for new construction by type and quality of construction for a wide variety of building uses.

The base cost reported in the MVS guide are based on the actual final costs to the owner and include all material and labor costs, contractor overhead and profit, average architect and engineering fees, nominal building permit costs, and processing fees or service charges and normal interest on building funds during construction. It also includes: normal site preparation costs including grading and excavation for foundations and backfill for the structure; and utilities from the lot line to the structure figured for typical setbacks.

The MVS costs do not include costs of buying or assembling land, piling or hillside foundations (these can be priced separately), furnishings and fixtures not found in a general contract, general contingency set aside for some unknown future event such as anticipated labor and material cost increases. Also not included in the base MVS costs are site improvements such as signs, landscaping, paving, walls, and site lighting. Offsite costs such as roads, utilities, and jurisdictional hook-up fees are also excluded from the base costs.[5]

MVS allows staff to develop a benchmark cost using the relevant construction characteristics of the proposed project and the calculator section of the MVS guide. In developing the MVS benchmark costs for a particular project the base costs are adjusted for a variety of factors (e.g.,an add-on for sprinkler systems, the presence or absence of elevators, number of building stories, the height per story, and the shape of the building. The base cost is also adjusted to the latest month and the locality of the construction project.)

Developing an MVS Benchmark for This Project

Columbia Surgical Institute calculated the benchmark to be $347.70 per square foot using an online service of CoreLogic® provider of Marshall & Swift cost estimating for commercial property. "The calculation considered updated multipliers (auto-calculated by the program) based on site terrain, building levels, and geographic locality. Other relevant components were factored such as type of occupancy (ASF) and systems (HVAC and sprinklers). Analysis of the project construction."[6]

Using the information submitted in the CON application and information obtained from the MVS guide, MHCC staff calculated an MVS benchmark of $454.63 per square foot. (Note: this project primarily involves the conversion and expansion of a special procedure room to an operating room, the most expensive space within an outpatient surgery center). Therefore, Commission staff applied a weighted average differential cost factor for a hospital operating rooms

[5] Marshall Valuation Service Guidelines, Section 1, p. 3 (January 2016).
[6] Columbia Surgical Institute CON Application, page 34

(1.89)[7] and internal corridor space (0.6) to the MVS base cost for Class A-B, good quality outpatient surgical centers. Staff applied further adjustments for the shape of the OR and corridor space, the ceiling height, and the closest location multiplier (Anne Arundel Co.), all updated to May 2017 to derive an initial benchmark square foot cost of $710.37 per SF. To account for the fact that the project involves renovations of existing space and not construction of new space, staff subtracted the cost of constructing shell space from this benchmark.[8]

The following table identifies selected building characteristics, the MVS base cost and the adjustments made by MHCC staff:

Maryland Health Care Commission Staff's Calculation of Marshall Valuation Service Benchmark

Building Characteristics		
Construction Class/Quality	Class A-B/Good Quality Outpatient Surgery Center	
Number of Stories	1	
Square Feet	315	
Average Perimeter	63	
Weighted Average Wall Height	10	
Average Area Per Floor	315	
Marshall Valuation Service Benchmark Calculations		
	Calculations of Benchmark for New Outpatient Surgical Space	**Calculations of Benchmark for Outpatient Surgical Center Shell Space**
Base Cost per SF (11/2015)	**$365.78**	**$365.78**
Adjustment for Dept. Cost Differences	1.58848	0.5
Adjusted Base Cost per SF	**$581.03**	**$184.53**
Multipliers		
Perimeter Multiplier	1.385	1.385
Story Height Multiplier	.943	.943
Multi-Story Multiplier*	1.000	1.000
Refined Cost per SF	$669.65	$241.08
Sprinkler Add-on per SF	N/A	N/A
Adjusted Refined Square Foot Cost	$669.65	$241.08
Update/Location Multipliers		
Current Cost Modifier (99.3)May 2017	1.02	1.02
Local Multiplier (99.8) Anne Arundel Co.	1.04	1.04
MVS Building Cost Per Square Foot	**$710.37**	**$ 255.74**
Final MVS Benchmark for Project	**$454.63**	

Source: Columbia Surgical Institute CON Application (pages 34-35), Marshall Valuation Service®, published by Core Logic and Commission Staff Calculations
*Multi-story multiplier is .5% (.005) per floor for each floor more than three stories above ground.

[7] MVS does not include departmental differential cost factors for outpatient surgical centers
[8] Staff calculated the cost of the shell space by applying the hospital differential cost factor for unassigned space (0.5) to the adjusted base cost for an outpatient surgical center and subtracted the results ($255.74 per SF) from the initial benchmark to arrive at an adjusted benchmark for this project of $454.63 per square foot.

Comparing Estimated Project to the MVS Benchmark

CSI compared its estimated project cost to the MVS benchmark it calculated for the project, as described above and determined that the estimated project costs are well below the benchmark. MHCC staff also compared the same estimated project costs (adding an allocation of financing fees to the benchmark as described above), and arrived at an estimated construction cost of $124.19 per square foot – just 27% of the MVS benchmark of $454.63/SF.

The following table compares the estimated project cost to the respective MVS benchmarks calculated by the applicant and by staff.

Comparison of Columbia Surgical Institute's Renovation Budget to Marshall Valuation Service Benchmark Developed by

Project Budget Item	CSI Estimate	MHCC Staff Estimate	Explanation of any Variance
Building	$32,825	$32,825	
Fixed Equipment	3,000	3,000	
Site Preparation	0	0	
Architectural Fees	3,000	3,000	
Permits	100	100	
Renovation Subtotal	$38,925	$38,925	
Allocated Capitalized Construction Int. & Financing Costs	**$0**	**$196**	CSI did not allocate the $1,000 in financing fees. MHCC staff allocation this fee based on the portion of project that is included in MVS. This percentage is only 19.6% because most of the project costs are for equipment, which is not included in MVS.
Adjusted Total for MVS Comparison	$38,925	$39,121	
Total Additional Square Footage	315	315	
Adjusted Project Cost Per SF	**$123.71**	**$124.19**	
CSI and MHCC calculated MVS Benchmark Cost Per SF.	**$347.70**	**$454.63**	CSI used an online service of CoreLogic® provider of Marshall & Swift cost estimating for commercial property. MHCC staff calculated the benchmark for construction of a new OR in shell space.
Total Over (Under) MVS Benchmark	**($223.99)**	**($330.44)**	

Data Sources: Columbia Surgical Institute CON Application, pages 34-34; CSI's March 21, 2017 response to Commission staff completeness questions (pages 5-7); Commission Staff calculations