

IN THE MATTER OF

ROCKVILLE EYE SURGERY, LLC

d/b/a PALISADES EYE SURGERY

CENTER

DOCKET NO. 14-15-2352

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BEFORE THE

MARYLAND

HEALTH CARE

COMMISSION

STAFF REPORT AND RECOMMENDATION
July 17, 2014

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I. INTRODUCTION

Rockville Eye Surgery, LLC, d/b/a Palisades Eye Surgery Center (“PESC”) is a licensed freestanding ambulatory surgical facility that is Medicare-certified as an ambulatory surgery center. It is a dedicated eye surgery facility. It has one operating room and two non-sterile procedure rooms and is located at 4818 Del Ray Avenue in Bethesda (Montgomery County). It is owned by seven physicians who practice at the facility.

PESC proposes to relocate to other leased space in the building where it is currently located and to establish a three-operating room suite in this larger space. The relocated center will continue to also operate two non-sterile procedure rooms.

A Certificate of Need (“CON”) issued by the Maryland Health Care Commission (“MHCC”) is required to establish or relocate a “health care facility.” Maryland law defines an “ambulatory surgical facility” as a “health care facility” subject to CON regulation. MHCC regulations define an “ambulatory surgical facility” as “an entity or part of an entity with two or more operating rooms that: (a) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and (b) Seeks reimbursement from a third-party payor as an ambulatory surgical facility.” For this reason, even though PESC is an operating surgical center, this project would be categorized as establishing an ambulatory surgical facility, because, for the first time, it proposes to operate two or more operating rooms.

Background

PESC was established in 2004 by five ophthalmologists. Because it was designed with a single sterile operating room, its establishment did not require a CON.

In 2007, three additional partner physicians joined the original group and, in recent years, PESC has added non-partner physicians to its medical staff. By 2013, 18 surgeons were credentialed to perform ophthalmic surgery at PESC. Most are members of one of six ophthalmic specialty groups in the Maryland, D.C. and northern Virginia area. (DI #3, p. 6 & 9) Appendix A lists the principal physicians that comprise the ownership group and the ophthalmic specialty groups with which PESC’s current surgeons are affiliated.

The Project

PESC proposes to renovate, furnish, and equip 9,178 square feet (SF) of space on the first floor of 4831 Cordell Avenue in Bethesda.¹ The relocated facility will have a three-operating room suite with rooms of approximately 250 SF in size and two smaller non-sterile procedure rooms used for four types of ophthalmic laser procedure. The operating rooms will be used to provide cataract surgery, corneal transplants, pterygium removal, glaucoma procedures, and ophthalmic plastic surgery procedures. A two-room pre-operative and post-anesthesia recovery suite will have space for preparation or recovery of 15 patients. A floor plan diagram of the replacement facility is located at Appendix C.

¹ While this space is in the same building currently housing PESC, it has a different address because of a change in the building entrance associated with the facility location.

The estimated cost of this project is \$3,637,265, which includes capital costs, primarily for the space renovation and equipment, of \$3,494,350, and financing cost and other cash requirements of \$90,500. The anticipated sources of funds for the project are a loan of \$3,377,265 and \$260,000 in cash.

II. PROCEDURAL HISTORY

A. Record of the Review

See Appendix B for a record list of this project review.

B. Interested Parties

There are no interested parties in this review.

C. Support

Two letters of support for the project were provided; by Southern Management Corporation, PESC's landlord, and Thomas J. Murray, of Bethesda, a patient who was provided with surgical services at the facility in 2013.

B. Local Government

No comments were provided by the local health department on this project.

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. The

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**.

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) Information Regarding Charges.

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.

PESC states that it provides to the public, upon inquiry, information regarding charges for the range and types of services provided. The applicant submitted a copy of the facility fee schedule (DI #3, Exhibit 2). The applicant also stated that patients are provided with estimates of actual charges. Based on this information, staff finds that PESC complies with this standard.

(2) Charity Care Policy.

(a) Each hospital and ambulatory surgical facility 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:

(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.

(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.

(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.

PESC provided a written policy for the provision of complete and partial charity care for indigent patients. PESC's written policy states that "Within two business days following a patient's request for charity care services, application for medical assistance or both, PESC will make a determination of probable eligibility." (DI #10, Exhibit 1) PESC posts notices that include contact information for patients interested in payment programs in its registration area and business office. This information is also provided on the PESC website.

The policy includes provisions that comply with subparagraph (a)(iii) regarding eligibility for charity care for persons with family income that are either below 100 percent of the current federal poverty guideline or for persons above 100 percent but below 200 percent of the federal poverty guideline. (DI #10, Exhibit 1).

(b) A hospital with a level of charity care....that falls within the bottom quartile... shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

This section of the standard is only applicable to hospital surgical projects.

(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.

PESC states that it is committed to meeting the applicable percentage level of charity care provision referenced in part (c) of this standard, based on the most recent year reported year for all ASFs, of 1.2%.

PESC states that it has a history of providing charity care, implemented through the review of a patient's financial status and insurance coverage levels prior to scheduling procedures, to determine eligibility under the facility's policy. It reports the provision of charity care valued at \$37,335 in 2013, just under 1% of total expenses.² It reports substantially smaller levels of charity care provision in 2011 (\$16,921 or 0.51% of total expenses) and 2012 (\$13,324 or 0.34% of total expenses). PESC attributed the increase in the level of charity care in 2013 to:

² PESC also notes the charitable work provided by individual facility physicians in foreign countries, and the support provided by PESC to this "mission" work through donation of equipment, instruments, and supplies. However, this standard is clearly addressing access to care for indigent Maryland citizens for obtaining Maryland health care facility services.

(1) employment of a staff anesthesia provider, allowing expanded charity care participation in this medical specialty not possible through the previous contract vendor being used; (2) the addition to PESC's staff of two new physicians in 2013 specializing in glaucoma treatment who alone accounted for nearly half of the value of charity care in that year; and (3) the introduction of new technology and techniques at PESC in 2013 that, because of limited insurance coverage, were provided to non-covered patients at no cost.

PESC has demonstrated, if its reported information on the value of charity care and expenses is accurate³, that its commitment is credible. Its level of charity care was low in 2011 and 2012, 0.34 – 0.51% of total expenses. But 2013 saw an increase to 0.9%, very close to the 1.2% minimum of the standard.

Its plan for increasing its level of charity care is to continue promotion of its “Medical Financial Assistance Program” to its affiliated physician practices and to target adults who reside in Montgomery County and who currently receive Medicaid, are uninsured, or underinsured, for outreach. It quantifies the objective as approximately 40 cataract surgery patients per year by 2018 qualified for full discount of charges. A strategy described for this outreach is to work with several physician practice groups and individual physicians who serve indigent patients to increase scheduling of charity cases at PESC. The facility submitted two written statements. Dr. Fritz Allen, Visionary Ophthalmology, Rockville, stated that his case load and the practice's cases would support the objectives of PESC in providing medical financial assistance. Dr. Robert Chu, of Washington Eye Consultants, Rockville, stated that his current annual charity caseload is 20 patients and will increase 10% per year.

PESC also states that it will collaborate with the local public health agencies and nonprofit organizations to better reach the indigent. It references meetings with Community Health Integrated Partnership, identified as an organization providing primary care and health-related services to the “medically-underserved” in Montgomery and northern Prince George's Counties and suggests that “formal partnerships” could be established.

It stresses a desire to ensure a continuum of care for indigent patients obtaining surgical services at PESC, describing a “network” of specialists who will follow-up with these indigent patients (presumably, on a charitable basis) for needed follow-up, in addition to the patient's surgeon.

PESC is not an existing ASF, as outlined in the introduction to this report. This term was used specifically in Part (c)(iii) of the State Health Plan standard, because of its retrospective trigger. PESC has operated as a Physicians Outpatient Surgical Center, as defined in the SHP. It was not established through CON approval and has operated a single operating room. As such, Part (c)(iii) of this standard is not applicable. PESC wants to be an ASF. That is the objective of this CON application. Therefore, PESC will be expected to perform under this standard if this project is approved, in order to obtain any future CON approvals and to meet the terms and conditions of the approved CON.

³ PESC reported a value of charity in 2011 in its CON application is not consistent with the 2011 MHCC Annual Survey report filing by PESC. It reported no charity care value in that year.

(d) A health maintenance organization...if applying for a Certificate of Need for a surgical facility project...shall demonstrate...the historic level of charity care was appropriate to the needs of the population in the proposed service area.

This standard is only applicable to projects sponsored by HMOs.

Staff Analysis

MHCC staff finds that the required commitment has been made by the applicant, and that its track record provides credible support for its ability to fulfill the commitment, given that its charity care level was within 0.3% in 2013 of reaching the statewide average proportion of total expenses used as a benchmark in this standard.

The plan put forward is predictable in its stated approaches but lacks detail or depth. However, as noted, continuing the same approaches used in the past, which may be a major part of the plan's implementation by the applicant, should be viewed in light of how close to the required level of charity care PESC reports achieving last year. PESC's facility plan should allow a larger number of physicians and, by association, physician groups to work at PESC, and this increased number of physicians that PESC can solicit for charitable surgery services appears to be a primary strategy for reaching the compliance level of this standard. For this reason, staff does not believe the lack of detail or depth should be used to reach a finding of non-compliance with this standard.

Staff recommends that the following condition be adopted by MHCC as part of any approval of this project.

Prior to first use approval, Rockville Eye Surgery, LLC d/b/a Palisades Eye Surgery Center will provide an updated and more detailed plan to MHCC for: (1) targeting indigent adults who reside in Montgomery County and qualify for charitable service under the facility's policy; (2) collaborating with Montgomery County public health agencies and nonprofit organizations to better reach indigent adults who reside in Montgomery County and qualify for charitable service under the facility's policy; and (3) promoting scheduling of charity care cases at PESC by all affiliated physicians and physician practices using PESC facilities.

(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.

(b) A hospital shall document that it is accredited by the Joint Commission.

(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, 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

PESC documented that it is licensed in good standing by the Department of Health and Mental Hygiene and fully accredited by The American Association for Accreditation of Ambulatory Surgery Facilities. PESC is certified to participate in the Medicare program, complying with the conditions of participation in that program. (DI #3, pp. 18 & 19, Exhibits 5 & 6) This is a reasonable demonstration of compliance with Parts a) and (d) of this standard, which are the Parts applicable to this project.

(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.

(c) Each ASF shall have procedures for emergency transfer to a hospital that meet or exceed the minimum requirements in COMAR 10.05.05.09.

PESC provided a copy of a signed and compliant transfer agreement with Suburban Hospital (DI #3, Exhibit 7). The emergency transfer of patients by ambulance service is provided by the Emergency Medical System by calling 911. (DI #3, p. 19 PESC meets this standard.

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.

PESC identified its primary service area as zip code areas in Montgomery and Prince George's Counties, Washington, D.C., and Virginia and based this identification on its recent patient origin. (DI #3, p. 19, Exhibit 8) The Applicant has complied with this standard.

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

An applicant proposing to establish or replace a hospital or ambulatory surgical facility shall demonstrate the need for the number of operating rooms proposed for the facility. This need demonstration shall utilize the operating room capacity assumptions and other guidance included in Regulation .06 of this Chapter. This needs assessment shall demonstrate that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the initiation of surgical services at the proposed facility.

Part (a) of this standard is only applicable to establishment or replacement of hospital facilities and Part (c) is only applicable to expansion of existing ASFs. Therefore, this report will only address the applicable Part (b).

(b) An applicant proposing the establishment of a new ambulatory surgical facility shall submit a needs assessment that includes the following:

(i) Historic trends in the use of surgical facilities for outpatient surgical procedures by the proposed facility's likely service area population;

(ii) The operating room time required for surgical cases projected at the proposed facility by surgical specialty or, if approved by Commission staff, another set of categories; and

(iii) Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.

To meet this standard the applicant must demonstrate that its existing operating rooms were utilized at optimal ASF capacity in the most recent 12-month period. Optimal capacity for ASF ORs is defined in the General Surgical Services chapter of the State Health Plan as 80% of "full capacity use" (i.e., operating a minimum of 8 hours a day, 255 days a year, or 2,040 hours

annually). So, optimal capacity is considered to be 1,632 hours, or 97,920 minutes, per year. PESC reported its historical utilization as shown in Table 1 below.

**Table 1: Palisades Eye Surgery Center
Reported Utilization of Single Operating Room, CY 2011 – 2013**

Year	Number of Cases	Surgical procedure time (minutes)	Turnover Time (minutes)	Total Hours	Utilization as Percentage of Optimal Capacity
2011	3,074	85,151	46,110	2,188	134%
2012	3,341	114,120	50,115	2,737	168%
2013	3,573	89,325	53,595	2,382	146%

Source: DI #1st completeness, Exhibit 4

PESC has been operating above optimal capacity for the past few years and is now operating above full capacity as defined in the plan. The applicant reports that it is currently unable to offer operating room time to accommodate all surgeons credentialed at PESC. In order to accommodate additional need in 2014, PESC will extend hours from 7AM to 8PM. The application states that in 2013, 407 operating room cases were performed at other facilities by surgeons who would have preferred to operate at PESC.⁴ (DI #3, p. 21 & DI #10, p. 6)

PESC projected future volume and use of additional operating rooms as shown in the following table.

**Table 2: Historical and Projected Utilization,
Palisades Eye Surgery Center's Operating Rooms (ORs), 2011 through 2017**

	Utilization Two Most Recent Years		Current Year Projected	Projected Years				
	2011	2012	2013	2014	2015*	2016	2017	2018
Number of ORs	1	1	1	1	3	3	3	3
Total Cases	3,074	3,341	3,573	3,961	5,221	5,994	6,663	7,420
Total Surgical (minutes)	85,151	114,120	89,325	99,035	130,516	149,851	166,577	185,509
Turn-over time (15 mins/case)	46,110	50,115	53,595	59,415	78,315	89,910	99,945	111,300
Total OR mins	131,261	164,235	142,920	158,450	208,831	239,761	266,522	296,809
Total OR hours	2,188	2,737	2,382	2,641	3,481	3,996	4,442	4,947
Optimal Capacity (hrs)	1,632	1,632	1,632	1,632	4,896	4,896	4,896	4,896
Full Capacity (hrs)	2,040	2,040	2,040	2,040	6,120	6,120	6,120	6,120
Utilization as % of optimal capacity	134%	168%	146%	162%	71%	82%	91%	101%
Utilization as % of full capacity	107%	134%	117%	129%	57%	65%	73%	81%

Source: DI #10, p. 6 and Exhibit 4

*Additional operating rooms available

The projected volume increases are expected, foremost, because most of the partners' volumes have grown and, for the most part, are projected to continue to grow and additional associates have been – and continue to be – added (see Table 3 for a detailed list of each surgeon's projections). The applicant cites the aging population as a major force driving demand for eye surgery, citing a 2003 article⁵ published in the *Annals of Surgery* that found surgical

⁴ These cases were performed at Friendship Ambulatory Surgery Center, and Suburban, Shady Grove, George Washington, and Providence Hospitals.

⁵ Etzioni, D.A. et al, *The Aging Population and Its Impact on the Surgery Workforce*, *Ann. Surg.* 2003 August;

“specialties in which older patients constitute a greater share of procedure-based work have larger forecasted increases in workloads.” The paper projected increases in workload through 2020 and found that ophthalmology has the largest forecasted increase (47% between 2000 and 2020 at a national level), largely because of the predominance of older patients as consumers of cataract surgery.(DI #3, pp. 20 & 21)

Total projected volumes for PESC were constructed by summing projections for each practitioner. For existing practitioners at PESC, assumed growth rates are based on the compound average growth rate from 2011 to 2013.⁶ For new practitioners who started providing services at PESC in 2013, growth rates of 5%, 15%, 25%, 15%, and 15% were projected for the out years of 2014-2105. One surgeon is expected to phase in 850 cases in the next five years. Table 3 shows the volumes that current and prospective practitioners expect to bring to PESC once additional capacity is available. (DI #10, pp. 4 & 5). The timeline for implementation of this project is availability of the relocated facility for use within seven months of CON approval.

Table 3: Projected Volume at Palisades Eye Surgery Center by Practitioner, 2011-2018

	2011	2012	2013	2014	2015	2016	2017	2018
Historic and projected volume of practitioners at PESC since 2011								
Chu	311	227	335	348	361	375	389	403
Clinch	603	740	694	745	799	857	919	986
Frank	258	263	323	361	407	456	510	571
Kane	216	252	276	312	353	399	451	509
Kang	467	571	534	571	611	653	698	747
Martinez	562	530	477	477	477	477	477	477
Pluznik	300	345	376	421	471	528	591	661
Allen	80	77	107	124	143	166	191	221
Fischer	136	164	128	124	120	117	113	110
Gupta	30	1	35	38	41	44	48	51
Mayer	89	138	173	241	406	566	790	1,101
Vicente	1							
Zeller	21	22	23	24	285	298	312	327
Historic and project volume of practitioners recently added to the PESC staff								
Green-Simms		1	36	38	70	88	101	116
Nguyen		10	16	17	19	24	28	32
Cremers			12	13	23	29	34	39
Chaudhary			3	3	43	53	61	70
Gess			16	17	21	27	31	35
Yin			9	9	13	16	18	21
Projected volume of practitioners planning to use PESC when more OR capacity is available								
Schor				17	19	24	28	32
Ghafouri				100	600	800	850	850
Total	3,074	3,341	3,573	3,961	5,221	5,994	6,663	7,420

Source: PESC, D.I#11

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⁶ While MHCC has traditionally relied on 5 and 10-year growth rates for projections, the applicant reported that data for years prior to 2011 are not available due to a change in its billing company in 2010, which has since filed for bankruptcy. (DI #10, pp. 7 & 8)

This standard requires that applicants demonstrate the need for additional proposed operating rooms using the benchmarking guidance on OR capacity and the documentation requirements of the SHP. The applicant has presented projections, validated by the individual physicians, that present a credible basis, given the historic experience of PESC, that optimal capacity of three ORs can be achieved by 2018 if the practitioners use PESC as they have projected. PESC used assumptions in line with the guidance in the SHP in developing the need assessment. The assessment forecasts utilization of three ORs at 91% of optimal capacity in 2017 and at optimal capacity in the following year. Based on this, staff recommends a finding that PESC has demonstrated the need for additional operating rooms, consistent with this standard.

(3) Need – Minimum Utilization for Expansion of an Existing Facility.

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 the 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) Prove 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 capacity; and

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

This standard is not applicable to this project. The applicant is not an existing hospital or ASF.

(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.

(b) An ASF shall meet the requirements in Section 3.7 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.

PESC supplied a letter from the architectural firm Hardaway Associates attesting that the proposed design meets the 2010 FGI Guidelines for Design and Construction of Health Care Facilities. (DI #3, Exhibit 10)

The relocated PESC design complies with this standard.

(5) Support Services.

Each applicant shall agree to provide, as needed, either directly or through contractual agreements, laboratory, radiology, and pathology services.

PESC utilizes LabCorp and LabQuest for tissue and specimen analysis and maintains CLEA certification and performs screens for glucose on site. It states that it does not have a surgical facility that requires direct or contractual provision of radiology services.

PESC complies with this standard.

(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.

PESC has relied on scheduled design process reviews and interaction between the architect and staff to shape the facility design. It reviewed several ways in which its proposed project will maintain or enhance the ability of PESC to reduce the risk of adverse events for patients or staff. It notes that the project will be replacing a facility through renovation of shell space, so the opportunity to design and construct the facility with “scaleability” and adaptability is a key advantage. With respect to specific issues related to patient safety, these are, in summary:

- PESC argues that the increased OR capacity will allow the additional surgical caseload potential for the facility from additional surgical staff to be accommodated with shorter days, avoiding late afternoon/early evening cases in which fatigue can present a higher risk of error;
- The project’s ORs will be larger than the existing PESC OR, in line with current design standards;
- OR design and layout will be standardized;
- The design complies with the 2010 FGI Guidelines for Design and Construction of Healthcare Facilities. These guidelines are based on considerations of minimizing infection risks and assuring sterility and appropriate air filtration and ventilation for operating rooms;

- PESC has engaged users of the existing facility in the design and equipment planning process, with staff input influencing choices related to patient flow and the flow of instruments and supplies, and lighting;
- The pre-op/PACU bays are laid out for direct visibility and close proximity of all bays to the nursing station and the bay layout is standardized; and
- An electronic medical information system will be used for physician order entry and electronic charting;

PESC further notes that noise reduction, mobile and wireless charting systems to improve staff/patient interaction, design for circulation to minimize crossing of patient, staff, visitor, and material flows, and placing documentation stations and support areas close to recovery bays are also design features that will enhance patient safety. The project complies with 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 MVS. For comparison, an MVS 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 also includes a variety of adjustment factors, including adjustments of the base costs to the costs for the latest month, the locality of the construction project, as well as factors for the number of building stories, the height per story, the shape of the building (such as the

relationship of floor area to perimeter), and departmental use of space. The MVS Guide identifies costs that should not be included in the MVS calculations. These exclusions include costs for buying or assembling land, making improvements to the land, costs related to land planning, discounts or bonuses paid for through financing, yard improvements, costs for off-site work, furnishings and fixtures, marketing costs, and funds set aside for general contingency reserves.⁷

While the standard calls for a comparison to the benchmark cost of good quality Class A construction, the applicant states that the cost of renovations will be comparable to a good quality A-B in an analysis entitled “Marshall Valuation Service Valuation Benchmark.” The MVS cost index is based on the relevant construction characteristics of the proposed project, which takes into account the base cost per square foot for construction by type and quality of construction for a wide variety of building uses.

The following table presents the MVS benchmark costs per square foot developed by Staff for the new construction of both a good quality class A and a good quality class C outpatient surgical center of similar building characteristics located in Baltimore, Maryland.

**Table 4: Palisades Eye Surgery Center
Marshall Valuation Service Benchmark Calculation**

Class	Class A-B
Type	Good
Square Footage	9,178
Perimeter	547
Wall Height	14.3
Stories	1
Average Area Per Floor	9,178
Net Base Cost	\$358.66
Add-ons	None
Adjusted Base Cost	\$358.66
Gross MVS Base Cost	\$358.66
Perimeter Multiplier	1.001
Height Multiplier	1.054
Multi-story Multiplier	1
Refined Square Foot Cost	\$378.43
Current Cost Modifier (Dec 2013)	1.02
Local Multiplier (Baltimore, Oct 2013)	1.07
Final Square Foot Benchmark	\$413.02

Source: CON Application, DI #3,

PESC calculates the construction cost of the project, adjusted using the MVS Guidelines, is \$254. This is a renovation project starting with a shell, so this cost estimate falling well below the new construction benchmark is not unexpected. The project's construction cost compare favorably with the benchmark called for in the standard.

(8) Financial Feasibility.

A surgical facility project shall be financially feasible. Financial projections 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 projections.

(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;

(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;

(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

(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.

(b) A project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project may be approved upon demonstration that overall facility financial performance will be positive and that the services will benefit the facility's primary service area population.

The financial projections developed for this project are logically based on the transition of the existing PESC to the new and larger space, assumed to occur in 2015. They can be viewed at Appendix D of this report.

The facility reports profitability in the last two years. It reports generating income from operations in 2011 and 2012 equivalent to 22.6% of net operating revenues. It has relied on the unit cost experience of PESC, which has operated since 2004, in developing expense projections for the replacement facility. The utilization assumptions driving the revenue projections have been reviewed previously in this report in a review of the applicant's project need assessment. This applicant has supplied written documentation from eye surgeons confirming their agreement with the assumptions employed by PESC to model their future use of the larger ASF. The revenue projections based on this forecast of use allow PESC to project a profitable

transition in 2015 to the new space, with revenue growth from volume increases easily covering the higher fixed expense base created by the relocation and replacement of the original PESC.

PESC has done a good job of meeting the requirements outlined in Part (a) of this standard in developing and presenting its financial projections and underlying assumptions and, with respect to Part (b), can credibly project income from operations on an ongoing basis. A letter of interest from PNC Bank, Rockville Eye Surgery, LLC's bank, was provided. The financial performance of the existing facility strongly supports the availability of the cash equity identified as a project source of funds and PNC has also documented the adequacy of cash balances maintained by PESC for this purpose. The project is consistent with this standard.

(9) Preference in Comparative Reviews.

In the case of a comparative review of CON applications to establish an ambulatory surgical facility or provide surgical services, preference will be given to a project that commits to serve a larger proportion of charity care and Medicaid patients. Applicants' commitment to provide charity care will be evaluated based on their past record of providing such care and their proposed outreach strategies for meeting their projected levels of charity care.

This standard is not applicable to this project review.

B. Need

The Commission shall 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.

PESC describes its primary service area as the zip code areas providing the highest proportions of its patients accumulated in rank order to 60% of the patient total. It cites a Claritas estimate that these primary service area zip code areas, located in two Maryland jurisdictions, D.C., and northern Virginia, contain a population of 1.13 million and are projected to experience population growth of 6.8 percent over the next five years. The elderly population of the PSA is projected to grow over three times faster.

The State Health Plan includes a "minimum utilization" standard (see subparagraph .05B(2)above) that is definitive with respect to the need criterion applicable to a proposal such as this one. It does not include a population-based projection method for assessing need for surgical facilities or operating rooms. Staff's review of this standard, covered earlier in this report, recommended a finding of compliance. As noted in our review, this existing facility is operating well above optimal capacity of its single operating room, has added physician staff that have limited access to OR time, and has additional physicians who have identified their interest in bringing cases to PESC but are awaiting replacement with a larger center.

This SHP standard fulfills the intent of this criterion in this type of project review. Therefore, staff recommends the Commission consider staff's review of this standard as covering all necessary aspects of this general "Need" criterion.

C. Availability of More Cost-Effective Alternatives

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

PESC notes that the other means of achieving the service capacity objectives of the proposed project would be acquisition of existing ORs; by purchasing a small facility to consolidate with PESC or a larger ASF to renovate and use as a replacement of PESC. The obvious drawback of these alternatives is their likely higher costs, given that both would still require some substantive renovation and equipment expenditures in addition to the acquisition costs.

PESC's business objective of developing an eye surgery center in Bethesda with significant scale of operation, thereby allowing participation by a much larger network of eye surgeons, could not likely be achieved at a lower level of cost that would outweigh the effectiveness advantages of the proposed project. The proposed option allows replacement and expansion without requiring any change in a successful and established business location. It provides maximum flexibility for the existing physicians and staff to design the workplace.

Maryland's regulatory posture of easy entry for new small surgical center development has created a large number of small surgical facilities and, in the aggregate, substantial OR capacity, which is often not located and operated for high capacity use, because of its fragmentation into many different physician practices and small corporate/physician joint venture settings. Staff does not believe this pattern of development and the capacity it yields should serve in CON regulation to block attempts to develop larger scale ambulatory surgical operations that can make more sense from a cost and quality perspective. Scale of operation and "focused factory" specialization in outpatient surgery is not encouraged by Maryland's regulatory policies but can be given an opportunity to get established in major markets, such as the Bethesda and D.C. area, with judicious regulation. Larger surgical facilities with the scale to support a full range of surgical equipment and high case volumes, which might improve the proficiency of physicians and staff, can be a means to provide more cost-effective outpatient surgery.

This applicant has presented an application that is worthy of such an opportunity, based on its demonstration of compliance with applicable criteria and standards. The proposed facility should be capable of producing eye surgery at a level of effectiveness equal to or better than the existing PESC, because of the upgrade in facilities and the continuity of leadership for the facility, the principal physicians that have a track record of success in PESC's first nine years of operation. The greater scale of operation envisioned will clearly make lower unit cost of production possible and these production efficiency gains can be realized even with the increased rent and debt cost associated with the replacement project, if the physicians bring the replacement facility the case volume they have certified as accurately representing their potential and intentions.

D. Viability

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

The estimated cost of the relocation and replacement of PESC is \$3,637,265.

Table 5
PESC Project Budget Estimate

A. Use of Funds	
Capital Costs	
Renovations	
Building	\$2,050,000
Architect/Engineering Fees	205,000
Permits	75,000
SUBTOTAL	2,330,000
Other Capital Costs	
Equipment	964,600
Contingencies	174,750
Moving	25,000
SUBTOTAL	1,164,350
Total Current Capital Costs	\$3,494,350
Inflation Allowance	52,415
TOTAL PROPOSED CAPITAL COSTS	\$3,546,765
Financing Cost and Other Cash Requirements	
Loan Placement Fees	\$20,500
Legal Fees/CON Consulting.	70,000
SUBTOTAL	90,500
TOTAL USES OF FUNDS	\$3,637,265
B. Sources of Funds For Project	
Cash	\$260,000
Loan	3,277,265
TOTAL SOURCES OF FUNDS	\$3,637,265

Source: DI #9, CMR 27

As will be noted in the review of the applicable financial feasibility standard of the SHP, COMAR 10.24.11.05B(5), earlier in this report, the applicant has demonstrated the availability of the funds needed for this project, which involves renting and renovating space in the same building where PESC has successfully operated since 2004. It has the cash and its bank has indicated an interest in providing debt financing. As an existing and profitable POSC that is proposing to elevate itself to ASF status with a larger facility and medical staff, it has also demonstrated that it can sustain its operation long-term if it realizes a substantial portion of the additional physician caseloads that doctors have affirmed. The assumptions used in its financial projections are reasonable.

The proposed project, if utilization projections are realized, will require a 62% increase in staff FTEs. Contract labor expenses for PESC are not large. PESC states that it has success in recruiting staff using its website, referrals from existing employees, on-line recruitment services, and nurse magazine and newspaper advertising. PESC experienced a vacancy rate of only 1.5% in 2013 but a relatively high turnover rate of 45%, which it attributes to staff pregnancies and one termination.

**Table 6: Palisades Eye Surgery Center
Regular Employee Information**

Position	2013 Current No. FTEs	Base Salary	Change in FTEs	2018 Projected No. FTEs
Administration	2.0	\$246,440	1.0	3.0
Admin Support	3.3	137,280	0.0	3.3
RN	4.0	291,200	4.0	8.0
Medical Assistant	4.0	158,080	3.0	7.0
Scrub Tech	2.0	124,800	1.5	3.5
Total	15.3	\$957,800	9.5	24.8
Benefits *		246,130		
Total Cost		\$1,203,930		

Source: DI#11

The positive findings with respect to the SHP standard for “Financial Feasibility” and the documentation of funds availability fulfill the intent of this criterion in this type of project review. Therefore, staff recommends the Commission consider staff’s review of this standard as covering all necessary aspects of this general “Viability” criterion.

E. Compliance with Conditions of Previous Certificates of Need

An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

This applicant has never received a CON in the past.

F. Impact on Existing Providers

An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

PESC identified three facilities that will be materially affected by a loss of case volume if the project is authorized and physicians that have expressed interest in using the expanded capacity being created by PESC follow through on those intentions as projected. These include Friendship Ambulatory Surgery Center (“Friendship”), located south of Bethesda near the Western Avenue/D.C. border (136 cases), Shady Grove Adventist Hospital (SGAH) in Rockville (271 cases) and Providence Hospital in D.C. (800 cases). It estimated that these losses represented 2.8% of Friendship’s caseload and 4.5% of Providence Hospital’s surgical minutes. PESC reports the same-day surgery caseload of SGAH as over 12,000 cases. MHCC data sources indicate a volume of over 14,000 ambulatory surgical cases at SGAH currently.

PESC’s description of the project indicates that the project will have the impact of enabling access to its facilities for physicians serving patients in Montgomery County and D.C. that want to treat patients at PESC but cannot now be accommodated in its single OR. The application indicates a very slight increase in financial access to eye surgery for the indigent is planned by PESC (see the earlier review of the SHP Charity Care Policy standard), but this is a very small impact in terms of patient numbers.

Approximately half of PESC’s patients are covered by Medicare and its reimbursement levels per case and Medicare patient out-of-pocket expenses would not be affected by this project. If PESC is successful in using this project to enable the increase in the market share of eye surgery cases that it is pursuing, it may have a marginal gain in negotiating leverage for higher prices from private payers in the future but the private insurance market in Maryland is highly concentrated, so relative changes in market power may be small.

There are no impact implications of this project that serve as a basis for denial of the project.

IV. SUMMARY AND STAFF RECOMMENDATION

Rockville Surgery Center, LLC seeks, in essence, to reestablish itself at its current location as an upgraded and expanded surgical facility that will make substantial growth in revenue possible. This will be generated through higher volumes of surgery provided by its principal surgeons and physicians that have documented an interest in participating in the PESC growth plan. The relocation and replacement comes after a successful nine years of operation at this location that has resulted in very high use of its single OR.

Staff finds that the proposed project has demonstrated need, cost-effectiveness, and viability under the applicable standards of the SHP and the applicable review criteria at COMAR 10.24.01.08G(3). It will not have an impact on other facilities or on costs and charges that pose a barrier to approval. Staff recommends conditional approval of this project.

IN THE MATTER OF

ROCKVILLE EYE SURGERY, LLC

d/b/a PALISADES EYE SURGERY

CENTER

DOCKET NO. 14-15-2352

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BEFORE THE

MARYLAND

HEALTH CARE

COMMISSION

FINAL ORDER

Based on an analysis that finds compliance with applicable criteria and standards, it is on this 17th day of July, 2014 **ORDERED**, that the application for a Certificate of Need by Rockville Surgery Center, LLC to relocate and replace its existing physicians office surgery center with a three-operating room ASF at a total project cost of \$3,637,235 be **APPROVED** with the following condition:.

Prior to first use approval, Rockville Eye Surgery, LLC d/b/a Palisades Eye Surgery Center will provide an updated and more detailed plan to MHCC for: (1) targeting indigent adults who reside in Montgomery County and qualify for charitable service under the facility's policy; (2) collaborating with Montgomery County public health agencies and nonprofit organizations to better reach indigent adults who reside in Montgomery County and qualify for charitable service under the facility's policy; and (3) promoting scheduling of charity care cases at PESC by all affiliated physicians and physician practices using PESC facilities.

Appendix A: PESC Principal Physicians and Affiliated Physician Groups

APPENDIX B: Record of the Review

Docket Item #	Description	Date
1	On November 1, 2013 PESC submitted a Letter of Intent to apply for a CON to add two operating rooms to its existing facility and relocate to a new location. Commission acknowledge receipt of PESC Letter of Intent and notified the applicant of the Pre-Application Conference scheduled for November 13, 2013	11/07/2013
2	PESC submitted a revised Letter of Intent	12/18/2013
3	PESC submitted a Certificate of Need application proposing the expansion of two operating rooms to its existing ASF and relocation to a new location on 4831 Cordell Avenue, Bethesda 20814	01/03/2014
4	Commission acknowledged receipt of the application in a letter to PESC and assigned it Matter No.14-15-2352.	01/06/2014
5	Commission requested publication of notification of receipt of the PESC proposal in the <i>Washington Times(Montgomery county)</i> and the <i>Maryland Register</i> to be published on January 24,2014	01/06/2014
6	Commission received additional documentation from PESC of full size drawings required with the submission of the CON application	01/10/2014
7	Notification published in the Washington Time (Montgomery county) on January 15,2014	01/17/2014
8	Following a completeness review, Commission staff requested addition information needed before a formal review of the CON application can begin	01/17/2014
9	On February 3, 2014 the Commission received an extension request from PESC to respond to Completeness questions and on that same date the Commission granted PESC an extension to the completeness questions due date of February 3, 2014 to February 18, 2014	02/03/2014
10	Commission received responses to the letter of January 17, 2014 request for additional information due February 18, 2014	02/14/2014
11	Commission acknowledged receipt of PESC's February 18, 2014 responses and sent a second set of Completeness questions to PESC	03/05/2014
12	Commission received PESC's response to the March 5, 2014 request for additional information	03/17/2014
14	Commission notified PESC that its application was received and reviewed for completeness and would be docketed for formal review in the <i>Maryland Register</i> on April 4, 2014	03/24/2014
13	Commission requested publication of notification of formal start of review for the PESC proposal in the <i>Washington Times(Montgomery county)</i>	03/24/2014
11	Commission requested publication of notification of formal start of review for the PESC proposal in the <i>Maryland Register</i> with the date of publication on April 4, 2014	

Appendix C: Floor Plan

Appendix D:
Historic and Projected Revenues, Expenses, and Income,
2011-2018 (current year dollars)