IN THE MATTER OF	*	BEFORE THE
	*	
ROCKVILLE EYE SURGERY, LLC	*	MARYLAND
	*	
d/b/a PALISADES EYE SURGERY	*	HEALTH CARE
	*	
CENTER	*	COMMISSION
	*	
DOCKET NO. 14-15-2352	*	

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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 opthalmic 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 accurate[3], 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 article[5] 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	*	**BEFORE THE**
	*	
ROCKVILLE EYE SURGERY, LLC	*	**MARYLAND**
	*	
d/b/a PALISADES EYE SURGERY	*	**HEALTH CARE**
	*	
CENTER	*	**COMMISSION**
	*	
DOCKET NO. 14-15-2352	*	

* *

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 *Washington Times(Montgomery county)* and the *Maryland Register* 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 *Maryland Register* on April 4, 2014	03/24/2014
13	Commission requested publication of notification of formal start of review for the PESC proposal in the *Washington Times(Montgomery county)*	03/24/2014
11	Commission requested publication of notification of formal start of review for the PESC proposal in the *Maryland Register* 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)

STATE OF MARYLAND

Craig Tanio, M.D.
CHAIR

Ben Steffen
ACTING EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION

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

MEMORANDUM

TO: Commissioners

FROM: Paul E. Parker, Director PEP
Center for Hospital Services

DATE: July 19, 2012

SUBJECT: Massachusetts Avenue Surgery Center, LLC
Addition of an Operating Room
Docket No. 12-15-2328

Massachusetts Avenue Surgery Center, LLC ("MASC") is a licensed ambulatory surgery center located in Bethesda, Montgomery County. MASC requests CON approval to add a third operating room through conversion of 435 square feet of "shell space."

MASC is owned by 25 physicians and their specialties include general surgery, gynecology, orthopedics, pain management, plastic surgery, podiatry, and urology. The Center expects to add three new physicians whose applications for privileges are currently in process and expected to be approved this Summer. MASC operates a non-sterile procedure room in addition to its two operating rooms. The total estimated project cost is $780,682. The anticipated source of project funding is a mortgage loan of $730,682 and $50,000 in cash.

Staff recommends approval of this project.

IN THE MATTER OF	*	BEFORE THE
	*	
MASSACHUSETTS AVENUE	*	MARYLAND HEALTH
	*	
SURGICAL CENTER, LLC	*	CARE COMMISSION
	*	
DOCKET NO. 12-15-2328	*	
	*	

****

Staff Report and Recommendation

July 19, 2012

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APPENDIX – Floor Plan

I. INTRODUCTION

Project Description

Massachusetts Avenue Surgery Center, LLC ("MASC" or the "Center") is a licensed ambulatory surgery center located at 6400 Goldsboro Road, Suite 400, Bethesda, Montgomery County, Maryland. Established in 2004 through a Certificate of Need ("CON") exemption, with one operating room and two procedure rooms, MASC received a CON in 2006 to convert one of the procedure rooms into a second operating room and is now requesting the addition of a third operating room through conversion of 435 square feet of "shell space." Appendix 1 shows the facility with the project area designated as one of the three storage areas, immediately adjacent to an existing OR and across the hall from sterile processing. (DI#4, Exhibit 1).

MASC is owned by 25 physicians, one of whom is a part owner in Fairfax Surgery Center and three others have small equity positions at various other surgery centers based in Virginia. Currently, 48 physicians either have or had privileges during the past 12 months or are just joining MASC. These surgeons' specialties include: general surgery, gynecology, orthopedics, pain management, plastic surgery, podiatry, and urology. The Center expects to add three new physicians whose applications for privileges are currently in process and expected to be approved this summer.

MASC leases the surgery center for $29.83 per square foot. Its current lease expires on February 28, 2025 with an option to renew for an additional ten years. MASC's capacity before and after the project is summarized in Table 1 below. The project is expected to take 12 months to complete.

Table 1: Existing and Proposed Capacity at Massachusetts Avenue Surgery Center

Room Type	Current Capacity	Proposed Capacity
Operating Room	2	3
Procedure Room	1	1

Source: MASC's application, DI#4, page 3.

The total estimated capital cost of the project is $710,682, with almost $565,000 being for major and minor movable equipment. Loan placement fees of $5,000 and consulting and legal fees of $65,000 increase the total project cost to $780,682. No new lease costs are projected. The source of project funding is $730,682 in a mortgage and $50,000 in cash. (DI#13, Exhibit 2). BB&T Bank is the source for MASC's mortgage.

Summary of Recommended Decision

Commission staff has evaluated the proposed project's compliance with the Certificate of Need CON review criteria at COMAR 10.24.01.08G(3)(a)-(f) and the applicable standards in COMAR 10.24.11, the State Health Plan ("SHP") chapter for Ambulatory Surgical Services. Commission staff has concluded, based on this review, that the project is compliant with the applicable SHP standards, that the applicant has documented a need for the project, and the project should not have a significant negative impact on existing surgical facilities. Commission

staff recommends approval of the project. A summary of the Commission staff's analysis is provided below.

Projected Utilization

- Community support and recent growth in surgical case volume for the operating rooms at MASC, driven by growth in physicians' practices and the acceptance of additional insurance carriers, suggests that MASC will be able to operate its proposed operating room capacity at an optimal level of utilization, as defined in the SHP, within two years of opening a third operating room.

Impact on Existing Programs

- The impact of the proposed new facility on existing surgical facilities in Montgomery County is likely to be minimal because the facility's primary service area will not change, and the cases expected to be transferred from other facilities represent only a very small proportion of the case volume for those facilities.

Availability of More Cost-Effective Alternatives

- Commission staff evaluated the cost-effectiveness of the alternatives proposed by the applicant, acquiring either a freestanding ambulatory surgery center with one operating room or a low-volume facility with multiple operating rooms. This analysis suggests that building a third operating room at MASC is more cost-effective. Both alternatives would add to the cost of the proposed project because the cost of acquiring another facility would not offset the construction costs for the proposed project.

Viability of the Proposal

- MASC has demonstrated that its charges for the most frequently performed procedures are in line with the charges for facilities that frequently perform similar surgical procedures. MASC has operated profitably for the past two years. In addition, MASC has demonstrated the financial feasibility of the proposed project.

II. PROCEDURAL HISTORY

Review of the Record

Massachusetts Avenue Surgery Center, LLC filed a letter of intent for this project on October 7, 2011; staff acknowledged receipt of the letter of intent on October 12, 2011 (Docket Item ["D.I."] #1).

On October 27, 2011, a Request for Determination of Non-Coverage was filed by John J. Eller, Esq. on behalf of Massachusetts Avenue Surgery Center, LLC regarding the leasing of and the capital costs of renovating adjacent space to expand the operations of the existing surgery center (D.I. #2).

On January 20, 2012, staff filed a memo for the record that clarifies Massachusetts Avenue Surgery Center is an existing ambulatory surgery center that did not have to file a certificate of need application in accordance with the MHCC's review schedule for new ambulatory surgery projects, and had 180 days from the filing date of the letter of intent to submit the CON application (D.I. #3).

On January 20, 2012, John J. Eller, Esq., filed a CON application on behalf of Massachusetts Avenue Surgery Center, LLC (D.I. #2) and assigned Matter No. 12-15-2328.

On January 18, 2012, the accounting firm of Snyder Cohn submitted a letter on behalf of Massachusetts Avenue Surgery Center confirming the availability of financial resources for the proposed CON application (D.I. #5).

On January 26, 2012, staff acknowledged receipt of the CON application. (D.I. # 6). On that same day, staff requested that the *Washington Examiner* and the *Maryland Register* publish notice of receipt of the application. (D.I. #s 7-8).

On February 2, 2012, the *Washington Examiner* sent confirmation regarding publication of the notice of receipt for the application on February 6, 2012. On February 27, 2012, the Washington Examiner submitted proof of publication regarding receipt of the application (D.I. # 9).

On February 7, 2012, staff asked completeness questions (D.I. # 10).

On February 22, 2012, staff received an email from John J. Eller, Esq. in response to a question regarding patient utilization at the surgery center (D.I. # 11).

On February 14, 2012, the applicant requested an extension to respond to the completeness questions until March 16, 2012. On February 24, 2012, staff granted the extension of time to respond to completeness questions to March 16, 2012 (D.I. # 12).

On March 16, 2012, the applicant submitted responses to MHCC completeness questions from February 7, 2012 (D.I. # 13).

On April 23, 2012, staff requested the *Maryland Register* publish notice of the docketing of the application. (D.I. #14)

On May 2, 2012, staff sent a letter informing the applicant that the CON application would be docketed for formal review on May 4, 2012 and a request for additional financial information (D.I. # 15).

On May 3, 2012, staff requested that the *Washington Examiner* publish notice of docketing of the application (D.I. # 16).

On May 3, 2012, staff submitted a request for review and comment, along with a copy of the application, to the Montgomery County Health Department (D.I. #17).

On May 8, 2012, the *Washington Examiner* submitted confirmation regarding the publication of the notice of docketing on May 10, 2012 (D.I. #18)

On May 11, 2012, the Montgomery County Health Officer submitted a fax response indicating no comment to the MHCC's request on May 3, 2012 for review and comment on the application (D.I. # 19).

On May 14, 2012, John J. Eller, Esq. submitted the response to the May 2, 2012 request for additional financial information (D.I. #20).

On May 24, 2012, the *Washington Examiner* submitted proof of publication regarding notice of docketing on notice of docketing of the CON application (D.I. #21).

Local Government Review and Comment

The Montgomery County Health Department did not provide comments on the application.

Community Support

Twenty five letters of support were received from the following physicians who perform surgery at MASC:

John Losee, MD; Urologic Surgeons of Washington
Peter E. Lavine, MD; Orthopedic Surgery and Sports Medicine
James Francis Barter, MD
Lee E. Firestone, DPM; DC Foot and Ankle
Jason E. Engel, MD; Urologic Surgeons of Washington
Marc B. Danziger, MD; Office of Orthopaedic Medicine and Surgery, PC
Murray Lieberman, MD; Urological Consultants, PA
Mark Rosenblum, MD; Urological Consultants, PA
Pamela Coleman, MD; Assistant Professor of Urology, Howard University Hospital
Paul Shin, MD; Urologic Surgeons of Washington
Edward Dunne, Jr., MD; Foxhall Urology
Joseph Shrout, MD; Metro Orthopedics & Sports Therapy
Lewis R. Townsend, MD; Capital Women's Care
James Gilbert, MD; Metro Orthopedics & Sports Therapy
Mark Scheer, MD; Office of Orthopaedic Medicine and Surgery, PC
Louis Levitt, MD; Office of Orthopaedic Medicine and Surgery, PC
Derek Ochiai, MD; Nirschl Orthopaedic Center for Sports Medicine & Joint Reconstruction
Bartholomew Radolinski, MD; Urological Consultants, PA
Matthew Buchanan, MD; The Orthopaedic Foot & Ankle Center

Steven K. Neufeld, MD; The Orthopaedic Foot & Ankle Center
Eric Guidi, MD; Nirschl Orthopaedic Center for Sports Medicine & Joint Reconstruction
James M. Weiss, MD; Specialist in the Practice of Orthopaedic Surgery
Juan Litvak, MD; Urological Consultants, PA
Nizamuddin Maruf, MD; Urological Consultants, PA
Andrew Wolff, MD; Nirschl Orthopaedic Center for Sports Medicine & Joint Reconstruction

IV. COMMISSION REVIEW AND ANALYSIS

The Commission reviews projects proposed for CON authorization under six criteria outlined at COMAR 10.24.01.08G (3):

- Consideration of the relevant standards, policies, and criteria of the State Health Plan;
- Consideration of the applicable need analysis of the State Health Plan or the applicant's demonstration of an unmet need of the population to be served and the project's capability and capacity to meet that need;
- Comparison of the cost effectiveness of providing proposed services through the proposed project with the cost effectiveness of providing the service at alternative existing facilities or alternative facilities submitting a competitive application for comparative review;
- Consideration of the availability of financial and nonfinancial resources, including community support, necessary to implement the project on a timely basis and the availability of resources necessary to sustain the project;
- Consideration of the compliance of the applicant in all conditions applied to previous CONs and compliance with all commitments made that earned preference in obtaining CONs; and
- Consideration of the impact of the proposed project on existing health care providers in the proposed project's service area, including the impact on access to services, occupancy, and costs and charges of other providers.

A. The State Health Plan

The relevant State Health Plan chapter is COMAR 10.24.11, Ambulatory Surgical Services.

> ***COMAR 10.24.11.06 A. <u>System Standards</u>: All hospital-based ASFs and all freestanding ambulatory surgical facilities (FASFs) including HMOs sponsoring an FASF, shall meet the following standards, as applicable.***

(1) Information Regarding Charges

Each hospital-based ASF and each FASF shall provide to the public, upon inquiry, information concerning charges for and the range and types of services provided.

The applicant states that it "provides to the public, upon inquiry, information concerning charges and the range and types of services provided." MASC provided a copy of its Facility Fee Statement. (DI#4, Exhibit 2). MASC complies with this standard.

(2) Charity Care Policy

(a) Each hospital-based ASF and FASF shall develop a written policy for the provision of complete and partial charity care for indigent patients to promote access to all services regardless of an individual's ability to pay.

(b) Public notice and information regarding a hospital or a freestanding facility's charity care policy shall include, at a minimum, the following:

(i) Annual notice by a method of dissemination appropriate to the facility's patient population (for example, radio, television, newspaper);

(ii) Posted notices in the admission, business office, and patient waiting areas within the hospital or the freestanding facility; and

(c) Within two business days following a patient's request for charity care services, application for Medicaid, or both, the facility must make a determination of probable eligibility.

MASC provided a copy of its charity care policy and a copy of a public notice regarding the availability of financial assistance. (DI#4, Exhibit 3). The applicant stated that this notice is run annually in the *Washington Post.* MASC also stated that it "posts notices in the admission, business office, and patient waiting areas." In addition, its policy states that a determination of probable eligibility is made within two business days. MASC is consistent with this standard.

(3) Compliance with Health and Safety Regulations

Unless exempted by an appropriate waiver, each hospital-based ASF and FASF shall be able to demonstrate, upon request by the Commission, compliance with all mandated federal, State, and local health and safety regulations.

The applicant provided a copy of its Maryland Department of Health and Mental Hygiene's letter licensing MASC as a freestanding ambulatory surgery center and stated that it is "in compliance with all mandated federal, State and local health and safety regulations." (DI#4, Exhibit 4). MASC is consistent with this standard.

(4) Licensure, Certification and Accreditation

(a) Existing FASFs and HMOs that sponsor FASFs shall obtain state licensure from the Maryland Department of Health and Mental Hygiene, certification from the Health Care Financing Administration as a provider in the Medicare program, and from the Maryland Department of Health and Mental Hygiene as a provider in the Medicaid program.

(b) Except as provided in (c), existing FASFs and HMOs that sponsor FASFs shall obtain accreditation from either the Joint Commission on Accreditation of Healthcare

Organizations (JCAHO) or the Accreditation Association for Ambulatory Health Care (AAAHC).

(c) If another accrediting body exists with goals similar to JCAHO and AAAHC, and is acceptable to this Commission, accreditation by this organization may be substituted.

MASC is licensed by the Maryland Department of Health and Mental Hygiene and certified as a provider in the Maryland Medicaid program. It is also certified by the Health Care Financing Administration (CMS) as a provider in the Medicaid program and has received documented accreditation by the Accreditation Association for Ambulatory Health Care, Inc. ("AAAHC") until February 22, 2014. (DI#4, Exhibit 5). MASC complies with this standard.

(5) Transfer and Referral Agreements

(a) Each hospital-based ASF shall have written transfer and referral agreements with:

(i) Facilities capable of managing cases which exceed its own capabilities; and

(ii) Facilities that provide inpatient, outpatient, home health, aftercare, follow-up, and other alternative treatment programs appropriate to the types of services the hospital offers.

(b) Written transfer agreements between hospitals shall meet the requirements of the Department of Health and Mental Hygiene regulations implementing Health-General Article, §19-308.2, Annotated Code of Maryland.

(c) Each FASF shall have written transfer and referral agreements with one or more nearby acute general hospitals.

(d) For both hospital-based ASFs and FASFs, written transfer agreements shall include, at a minimum, the following:

(i) A mechanism for notifying the receiving facility of the patient's health status and services needed by the patient prior to transfer;

(ii) That the transferring facility will provide appropriate life-support measures, including personnel and equipment, to stabilize the patient before transfer and to sustain the patient during transfer;

(iii) That the transferring facility will provide all necessary patient records to the receiving facility to ensure continuity of care for the patient; and

(iv) A mechanism for the receiving facility to confirm that the patient meets its admission criteria relating to appropriate bed, physician, and other services necessary to treat the patient.

(e) If an FASF applying for a Certificate of Need has met all standards in this section except (c)-(d) of this standard, the Commission may grant a waiver upon:

(i) Demonstration that a good-faith effort has been made to obtain such an agreement; and

(ii) Documentation to the Commission of the facility's plan regarding transfer of patients.

(f) An FASF shall establish and maintain a written transportation agreement with an ambulance service to provide emergency transportation services.

MASC provided a copy of a signed transfer agreement with Sibley Hospital. (DI#4, Exhibit 6). The applicant indicates that ambulance service is provided by the local Emergency Medical System by calling 911. MASC is compliant with this standard.

(6) Utilization Review and Control Program
Each hospital and FASF shall participate in or have utilization review and control programs and treatment protocols, including a written agreement with the Peer Review Organization contracting with the Health Care Financing Administration, or other private review organizations.

MASC states that it has utilization review and control programs and treatment protocols, as well as a "Performance Improvement Plan." (DI#4, Exhibit 7). The applicant did not include a written agreement with a Peer Review Organization or other private review organization. Such an agreement is no longer required by Delmarva, the Medicare Quality Improvement Organization for the District of Columbia and Maryland. MASC is consistent with this standard.

2. COMAR 10.24.11.06 B. Certificate of Need Standards. An applicant proposing to establish or expand a hospital-based ASF or an FASF, including an HMO sponsoring and FASF, shall demonstrate compliance with the following standards, as appropriate:

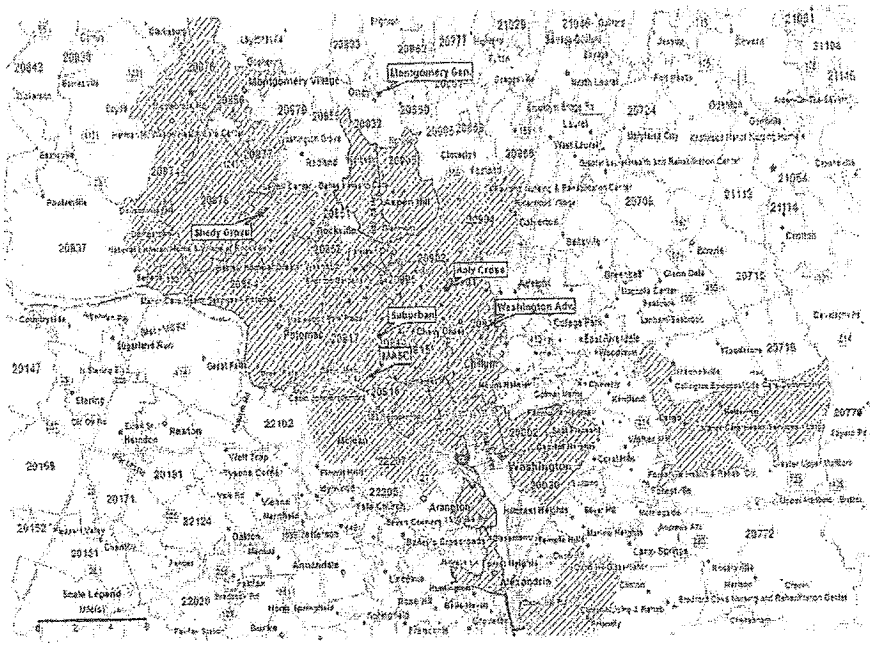
(1) Compliance with System Standards
(a) Each applicant shall submit, as part of its application, written documentation of proposed compliance with all applicable standards in section A of this regulation.
(b) Each applicant proposing to expand its existing program shall document ongoing compliance with all applicable standards in section A of this regulation, including meeting standard A(4) within 18 months of first opening.

The applicant complies with all system standards and is, therefore, consistent with this standard.

(2) Service Area
Each applicant shall identify its proposed service area, consistent with its proposed location.

The primary service area, which is defined as the most frequent zip codes where patients reside, covering 60% of patients served, spans a large geographic area of 42 zip code areas. It includes portions of Montgomery County, Washington, D.C., Northern Virginia, and Prince George's County, as shown in Exhibit 1. (DI#4, page 29). None of the aforementioned areas represents more than a quarter of the utilization at MASC.

Exhibit 1: Map of the Primary Service Area of MASC (Shaded Area)



Source: DI#4, page 6.

The applicant states that the primary service area for the expanded MASC will remain the same. (DI#4, page 18). The applicant notes that its expansive service area reflects the locations of the physicians practicing at MASC. The largest number of patients currently come from Washington, D.C. (465) with Montgomery County being a close second (445), as shown in Table 2. These two areas represent slightly less than half of MASC's patients.

Table 2: MASC Patient Origin, CY2010

Patient Residence	Number of Cases	Percent of Total
District of Columbia	465	23.5%
Montgomery County	445	22.5%
Prince George's County	29	1.5%
Virginia	50	2.5%
All Others	990	50.0%
Total	**1,979**	**100%**

Source: MHCC Freestanding Ambulatory Surgery Survey, 2010

(3) Charges

Each applicant shall submit a proposed schedule of charges for a representative list of procedures and document that these charges are reasonable in relation to charges for similar procedures by other freestanding and hospital providers of ambulatory surgery in its jurisdiction.

In response to this standard, the applicant provided a proposed schedule of charges and its average revenue collections for the 25 most frequent procedures performed at MASC for the period from November 2010 to October 2011. (DI#4, page 20). Often, the average revenue collection was a quarter to a third of the average charge, or even less. The applicant explained that "the Gross Charge is not meaningful as payors will continue to reimburse at the lesser of billed charges or reasonable and customary rates." MASC also provided comparative gross charge information for two ambulatory surgical facilities in Montgomery County for some of the 25 most frequent procedures performed at MASC. (DI#4, pages 21-22).

In order to assess the reasonableness of charges for MASC further, Commission staff compared MASC's average charge per case with other facilities that appeared to have a similar case-mix, based on the specialties reported on the Maryland Health Care Commission's Survey of Freestanding Ambulatory Surgical Facilities for 2011. This analysis is shown in Table 3. Commission staff also compared the average charge per case to those for outpatient surgeries at hospitals in Montgomery County, as shown in Table 3.

Although there are not any directly comparable data for MASC and a similar ASC within Montgomery County, the available comparative information suggests that the charges for a representative list of procedures is reasonable in relation to other freestanding facilities with a similar case-mix. The project is consistent with this standard.

Table 3
Charge and Revenue Comparisons, Proposed Facility and Selected Hospitals, CY 2009 and 2010, and Montgomery County FASFs, CY 2010

Hospital Charges from the HSCRC Ambulatory Surgery Data Set, 2009 and 2010		
Facility	**Average Outpatient Surgery Charge/Case CY 2009**	**Average Outpatient Surgery Charge/Case CY 2010**
Holy Cross	$3,401	$3,441
MedStar Montgomery General	$3,345	$3,808
Shady Grove Adventist	$3,426	$3,232
Suburban	$3,557	$4,179
Washington Adventist	$4,466	$3,831
Average Montgomery County	$3,639	$3,698
All Maryland hospitals	**$2,716**	**$2,834**

Montgomery County freestanding ambulatory surgical facilities reporting 6 or more specialties from MHCC FASF Survey, 2005	
Average Billed Charges per Case, CY 2010	
Facility A	$8,702
Facility B	$7,179
Facility C	$5,344
Facility D	$1,906
Facility E	$4,449
Facility F	$2103
Average of 6 reporting facilities	**$4,956**
Average Net Revenue per Case, CY 2010	
Facility A	$2,016
Facility B	$1,779
Facility C	$1,143
Facility D	$1,011
Facility E	$2,014
Facility F	$1,474
Average of 6 reporting facilities	**$1,573**

Source: MHCC, Annual FASF Survey CY2010, and HSCRC, Hospital Ambulatory Surgery Data Base
Hospital Charges are from the HSCRC Ambulatory Outpatient Data Set, 2009 and 2010,

(4) Minimum Utilization for the Expansion of Existing Facilities
Each applicant proposing to expand its existing program shall document that its operating rooms have been, for the last 12 months, operating at the optimal capacity stipulated in Regulation .05A(3) of this Chapter, and that its current surgical capacity cannot adequately accommodate the existing or projected volume of ambulatory surgery.

Based on 2011 utilization data reported to MHCC and detailed in this report, MASC's two operating rooms are currently utilized at 98% of capacity, based on a 40 hour work week per operating room and the applicant's estimated 30 minutes per case clean up time. MASC is consistent with this standard.

Table 4: Operating Room Cases and Utilization Measures, CY2011

Number of Cases	2,161
Surgical Hours	2,392
Surgical Minutes	143,520
Clean Up Minutes	64,830
Total Minutes Utilized	208,350
Full Capacity Operating Room Standard (2 ORs)	244,800
Percent Utilization	98.0%

Source: DI#4, page 35; MHCC Ambulatory Surgery Survey Data 2011

(5) Support Services.

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

MASC states that it uses the services of Landauer for Radiation Dosimetry services, Labcorp for laboratory services, and Dianon for pathology services. MASC reports that it provides its own radiology services. (DI#4, page 25).

(6) Certification and Accreditation

Except as provided in (c), each new FASF applicant or HMO that sponsors a new FASF shall agree to seek and to obtain, within 18 months of first opening, licensure, certification and accreditation from the following organizations:

(a) The Maryland Department of Health and Mental Hygiene for state licensure, the Health Care Financing Administration for certification as a provider in the Medicare program, and the Maryland Department of Health and Mental Hygiene for certification in the Medicaid program; and

(b) Accreditation from either the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care.

If an applicant can demonstrate that an alternative accrediting body exists with goals similar to JCAHO and AAAHC, and is otherwise acceptable to the Commission, accreditation by this organization may be substituted

The applicant is appropriately licensed, accredited, and certified. (DI#4, pages 25-26). MASC complies with this standard.

(7) Minimum Utilization for New Facilities

Each FASF applicant shall demonstrate, on the basis of the documented caseload of the surgeons expected to have privileges at the proposed facility, that, by the end of the second full year of operation, the facility can draw sufficient patients to utilize the optimal capacity of the proposed number of operating rooms, measured according to Regulation .05A of this Chapter.

This standard is not applicable. MASC is an existing facility.

(8) Reconfiguration of Hospital Space

Each hospital applicant proposing to develop or expand its ASF within its current hospital structure shall document plans for the reconfiguration of hospital space for recovery beds, preparation rooms, and waiting areas for persons accompanying patients.

The proposed project is a freestanding ambulatory surgical facility. This standard is not applicable.

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.

Applicant Response

MASC projects a need for operating room capacity at its facility based on three factors: population growth, growth in the physicians' practices that utilize MASC, and acceptance of more insurance carriers. MASC also explains that physicians want to put their patients on the surgery schedule as soon as possible and will seek operating room time at another facility if their requests for posting times cannot be met. According to MASC, the Center has increasingly been unable to meet physicians' requests for posting time. Furthermore, the applicant states that patients experiencing higher deductibles and co-insurances are looking for "a less costly option than utilizing a hospital for their outpatient surgery" as well as trying to avoid exposure to a sicker patient population and "increased hospital infection rates." (DI#4, pages 27-28).

With regard to population growth, MASC presents data for those ages 15 and older residing in the zip code areas comprising its service area. (DI#4, pages 29-30). The data shows overall estimated population growth of 12% from 2010 to 2011 and projected growth of 3.3% from 2011 to 2016. However, MASC notes that its case volume is primarily driven by factors other than population growth. (DI#4, page 29).

MASC states that it has experienced case volume growth since opening in 2005, as shown in Table 5. MASC attributes the case volume growth to population growth, growth in physicians' practices, and acceptance of more insurance plans. (DI#4, page 27).

Table 5: MASC OR Cases, CY2005-11

Year	Cases
2005	844
2006	975
2007	1,396
2008	1,523
2009	1,495
2010	1,529
2011	2,161

Source: DI#4, page 27.

For 2012, MASC projects an increase of 618 operating room cases compared to the number of cases performed in 2011 (2,079 cases). MASC justifies the anticipated growth case volume by showing the number of cases performed by 34 physicians with privileges at MASC in the last 12 months, as well as their projected new cases for the coming year and case volume expected to be transferred from other locations. (DI#4, pages 31-32). These projections show a total of 2,907 cases are expected to be performed at MASC by these physicians, with approximately half of the increase stemming from new cases and half stemming from cases transferred from other facilities. (DI#4, page 32).

MASC states that the projected case volumes of 2,779 cases in 2012 and 2,797 cases in 2013 exceed the SHP optimal utilization standard of 1,152 cases per operating room. MASC also notes that the average time per operating room case at MASC of 65.3 minutes is comparable to the average time per case of multi-specialty ambulatory surgery centers in Montgomery County that it calculated from the Maryland Health Care Commission's public use data set of ambulatory surgery centers for 2009 (1.08 hours). (DI#4, pages 32-35).

MASC concludes that three operating rooms are needed in 2012 based on its current average case time of 65.3 minutes, assumed turnaround time of 30 minutes, a projected case volume of 2,779 cases, and the optimal capacity standard for dedicated outpatient operating rooms (97,920 minutes) in the SHP. These assumptions and the calculated need for three operating rooms are shown in Table 6 below.

Table 6: Projected Operating Room Cases, Surgical Time, and Capacity Utilization, CY2012

Surgical Minutes per Case	65.3
Clean-up Minutes per Case	30
Total Time per Case	95.3
Number of Cases	2,779
Total Minutes	264,838.7
Optimal Capacity per Operating Room (minutes)	97,920
Number of ORs Needed at Optimal Capacity	2.7

Source: DI#4, page 35

Staff Analysis

In order to evaluate the need for a third operating room at MASC, Commission staff examined each of the factors cited by MASC to justify the need for a third operating room. These factors were population growth in the primary service area of MASC, growth in physicians' practices, and acceptance of more insurance carriers. Of the three factors cited by MASC to justify a third operating room, population growth appears to have the least influence. In contrast, it appears that growth in physicians' practices and acceptance of more insurance carriers are regarded as the primary drivers of growth.

With regard to population growth, as shown below in Table 7, the areas in which almost half of MASC's patients reside (District of Columbia and Montgomery County) are growing more than twice as fast as the State of Maryland and the nation's population. In addition, approximately three-quarters of MASC's patients are adults between the ages of 18-64 years, and

the District of Columbia's representation of this age group is significantly higher than other jurisdictions. Although strong population growth in MASC's primary service area is a reasonable basis for some growth in case volume, the case volume increase projected by MASC far exceeds the approximate 2% growth expected for its service area. As noted previously, appropriately, MASC did not state that its projected surgical case volume is based primarily on population growth.

Table 7: Current and Projected Population for Select Jurisdictions, 2010 and 2011

Jurisdiction	2010 Population	2011 Population Estimate	% Change 2010-11	% Pop 18-64 Years (2011)
District of Columbia	601,723	617,996	2.7%	71.6%
Montgomery Co.	971,777	989,794	1.9%	63.7%
Maryland	5,773,552	5,828,289	0.9%	64.4%
United States	308,745,538	311,591,917	0.9%	63.0%

Source: US Census Bureau QuickFacts

In large measure, MASC relies on the significant jump in operating room utilization from 2010 to 2011 to justify the need for a third operating room. As shown in Table 8, the number of operating room cases increased from 1,529 cases in 2010 to 2,161 cases in 2011. MASC primarily attributes the large increase in operating room case volume to physician referrals and becoming "in network" with CareFirst early in 2011. To the extent that MASC's surgical case volume growth is driven by accepting additional insurance carriers, MASC may be expected to again dramatically increase it surgical case volume in 2012 and 2013 because MASC expects to become "in network" with two additional insurers, United and Cigna, in 2012.

Table 8: MASC Surgical Utilization, CY2009-2011

Year	Total Cases	OR Cases	OR Hours	OR Hours /Case	PR Cases	PR Hrs	PR Hours/ Case
2009	2,160	1,495	1,594	1.07	665	233	0.35
2010	1,979	1,529	1,775	1.16	450	127	0.28
2011	2,671	2,161	2,392	1.11	510	178	0.35
Percent Change	23.7%	44.5%	50.1%	3.8%	-23.3%	-23.6%	-0.4%

Source: MHCC Freestanding Ambulatory Surgery Survey, 2009-11

In addition to MASC becoming "in network" with more insurance carriers, MASC attributes its projected surgical case volume growth to physicians' referral practices. MASC presents historical and projected case volume data for 34 individual physicians with privileges at MASC to justify the need for a third operating room. These projections show a total of 2,907 cases committed to MASC by these physicians, with approximately half of the increase stemming from new cases and half stemming from cases transferred from other facilities. (DI#4, pages 31-32). In addition, MASC submitted letters of support from physicians practicing at MASC attesting to the number of surgeries that they had performed at MASC and other surgical facilities and making projections of their future case volume and utilization of MASC's operating rooms. (DI#4, Exhibit 9). The letters are compelling evidence of MASC's ability to realize its future projections for surgical case volume.

Although MASC anticipates large increases in surgical case volume, it does not expect the average case times to change in its projections for 2012 and 2013. As shown in Table 8, the time per operating room case did not appear to change significantly between 2009 and 2011. The average operating room time of 1.11 hours in 2011 is slightly higher than for 2009 (1.07 hours), but less than the average time in 2010 (1.16 hours). The historic average cases times are consistent with the surgical case time used by MASC for its projections of future utilization of its operating rooms. In addition, MASC examined the surgical case times for other Maryland FASFs that had a comparable case-mix to MASC. As shown in Table 9, more than 50% of MASC's cases are orthopedic, so it analyzed the average operating room time for Maryland FASFs with at least one OR and a mix of between 30% and 70% orthopedic specialty cases. This analysis of FY2010 utilization shows an average case time of 1.11 hours per case. This analysis resulted in exactly the same average operating room case time as MASC used in the development of its projections. Therefore, Commission staff concludes that the projected time per case is reasonable.

Table 9: MASC Cases by Specialty, CY2010

Specialty	Number of Cases	Percent of Cases
OB/GYN	172	8.7%
Orthopedics	1,042	52.7%
Pain Management	360	18.2%
Plastic Surgery	1	0.1%
Podiatry	93	4.7%
Urology	311	15.7%
Total	**1,979**	**100.0%**

Source: MHCC Freestanding Ambulatory Surgery Survey 2010.

As shown in Table 10, MASC projects 2,779 cases in 2012. This would be an increase of 618 cases compared to 2011 or a case volume increase of 29%. The projected number of additional cases for 2012 is similar to the actual increase in case volume from 2010 to 2011 (632 cases). Although the projected case volume growth for the next two years is very aggressive, the applicant has presented sufficient evidence to justify such increases. The growth projections are supported by the apparent boost in case volume due to accepting additional insurance carriers and physicians' letters of support attesting to their historic case volumes and commitment to use MASC for future surgical cases.

Table 10: MASC Surgical Utilization & Projections, CY2011-2013

Year	Total Cases	OR Cases	OR Hours	PR Cases	PR Hours
2011	2,671	2,161	,2392	510	178
2012 (projected)	3,229	2,779	3,089	450	158
2013 (projected)	3,261	2,797	3,110	463.5	162
% Change 2011-13	22.1%	29.4%	30.0%	-9.1%	-8.9%

Sources: MHCC Freestanding Ambulatory Surgery Survey, 2011; DI#4, page 36.

In evaluating the need for a third operating room at MASC, Commission staff relies on the State standard for optimal capacity of a dedicated outpatient general-purpose operating room, which is 80% of full capacity. The State Plan defines the full capacity of such operating rooms as 2,040 hours, so the optimal capacity standard is 1,632 hours. Commission staff accepts the applicant's projected case volume, clean-up time, and time per case as reasonable. As illustrated below, based on Staff's analysis, the 2012 projections would result in a need for 2.7 operating rooms at optimal capacity. Therefore, the applicant has demonstrated a need for a third operating room at its facility.

Table 11: Projected Operating Room Cases, Surgical Time, and Capacity Utilization, CY2012

Operating Room Cases	2,779
Operating Hours (1.11/case)	3,085
Clean Up Hours (0.5/case)	1,390
Total Hours	4,475
Optimal Capacity in Hours per Operating Room	1,632
Number of ORs Needed at 80% of Capacity	2.7

Source: DI#4, pages 25-36; DI#13, page 7.

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.

Applicant Response

MASC outlines three different alternatives to the proposed project. The first alternative would be to purchase a single-OR freestanding ASC and re-locate it to the MASC site. This option was rejected because the proposed project would still require a CON and would cost more than the proposed project due to the added cost of acquisition. The second alternative presented is to purchase a low volume existing facility with multiple operating rooms in MASC's service area, closing it, and re-locating the multi-OR ASC to the MASC site. The applicant notes that this would be higher cost for the same reason as the first alternative.

A third alternative outlined by the applicant is to do nothing. MASC states that it is not cost effective for surgeons to perform surgeries at many sites. MASC cites the burden of travel time on physicians' efficiency and the impact of limited capacity on patient choice and delays in scheduling.

MASC also notes that the project has a cost of $638,250, with only $555,750 for capital costs. It also states that the project cost per square foot ($204.60) is lower than the MVS benchmark for outpatient surgery centers ($478.88). (DI#4, pages 39-40).

Staff Analysis

Commission Staff notes that it is highly unlikely that many of MASC's physicians are performing the majority of their surgeries at MASC. Only four physicians are performing 100 or more surgeries annually at MASC and only thirteen projected that they will perform 100 or more surgeries in 2012. In fact, given the distance that many patients travel from areas outside of Montgomery County, it may be more convenient for their physicians to practice at multiple locations.

The capital costs associated with this project are minimal because of existing shell space at MASC. As noted by the applicant the cost per square foot of the project is well below the MVS benchmark. In addition, the transfer of cases away from other facilities is expected to have minimal financial impact on those facilities. Therefore, the applicant has demonstrated that the proposed project appears is the most cost effective alternative.

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.

MASC states that it does not have audited financial statements but did include its Profit and Loss and Balance Sheets for 2009 and 2010. (DI#4, Exhibit 8). MASC has net income of $1.88 million in 2009 and $1.90 million in 2010 on revenue of $6.04 in 2009 and $6.45 in 2010. In both years MASC realized significant profit margins. The 2010 Balance Sheet shows assets of $2.35 million, with $1.66 million being fixed assets, with $669 thousand in liabilities and $1.68 million in equity. In addition, a letter from MASC's Certified Public Accountant states that the cash for the project is on hand and the bank for loan financing and concludes that adequate financial resources for the operating room project. (DI#4, Exhibit 8).

The project will require only a few additional staff including one administrative full-time equivalent employee (FTE), 2.65 FTE clinical staff, and 0.5 FTE support staff. (DI#13, Exhibit 5). Given the current economic environment and the relatively few additional staff required, Commission Staff do not anticipate that the applicant will have difficulty procuring these

resources. Moreover, MASC states that "working in an ASC often affords an opportunity for a surgical nurse who has taken a sabbatical from the field to reenter." (DI#4, page 59). The applicant notes that the best source for recruitment has been from its physician members, and open positions usually fill within one or two weeks. MASC states that it has a quarterly bonus plan that it offers to key employees and makes "a substantial annual profit sharing contribution to all of the employees that participate in the company's retirement plan" in which they are vested after five years. Commission staff concludes that MASC has reasonably demonstrated that the project is viable and financially feasible.

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.

MASC received a condition with the approval of its 2006 CON for its second operating room (Docket No. 06-15-2181) requiring it to obtain accreditation by the JCAHO or the Accreditation Association for Ambulatory Health Care and become a participating Maryland Medicaid provider within 18 months of approval. The applicant provided copies documenting compliance with this standard. (DI#4, Exhibit 5).

Commission Staff concludes that MASC is compliant with this standard. However, Commission Staff notes that while the applicant obtained a Maryland Medicaid provider number as required to meet the condition of its 2006 CON, only $6,780 of its revenue, or 0.11% of total revenues came from Maryland Medicaid. Medicaid patients comprise only a small proportion of MASC's patients (0.5%).

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.

In responding to this criterion, the applicant states that the project "will not materially affect any other facility." (DI#4, page 54). The applicant reports that it projects 368 cases will be transferred from other facilities, and no one facility will be single facility will be significantlyly adversely affected. The applicant provided, by physician and facility, the projected cases to be transferred. Those facilities most likely to be impacted include Suburban Hospital (172 cases), Surgery Center of Chevy Chase (53 cases), and Washington Adventist Hospital (37 cases). The applicant provided ambulatory surgical case data for hospitals from MHCC's 2005 Guide to Ambulatory Surgery Facilities which showed Suburban's outpatient surgical utilization at 9,216 cases and Washington Adventist Hospital's utilization at 7,213. (In 2010, Suburban Hospital

reported an outpatient caseload of 9,024 cases; Washington Adventist Hospital reported 4,387 in that year.) The applicant shows that the projected transferred cases from The Surgery Center of Chevy Chase represent 1.3% of that facility's 2009 utilization. (This percentage would be very similar, considering 2010 case volumes reported by this facility.) Therefore, the cases to be transferred would have minimal impact on these facilities use.

Commission staff concludes that the proposed project will not have a substantial negative impact on existing health care providers in the service area or on geographic and demographic access to ambulatory surgical services. It is not likely to have a negative impact on costs and charges of other providers of ambulatory surgical services.

IN THE MATTER OF	*	BEFORE THE
	*	
MASSACHUSETTS AVENUE	*	MARYLAND HEALTH
	*	
SURGICAL CENTER, LLC	*	CARE COMMISSION
	*	
DOCKET NO. 12-15-2328	*	
	*	

****

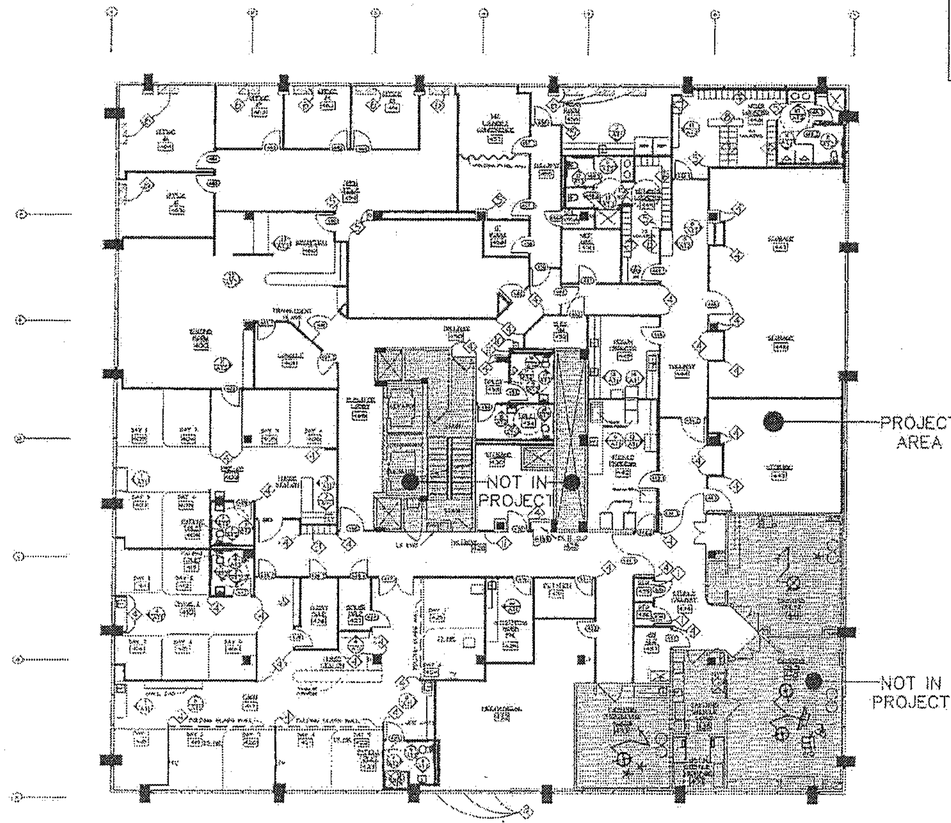
FINAL ORDER

Based on the analysis and findings contained in the Staff Report and Recommendation, it is this 19th day of July 19, 2012, by a majority of the Maryland Health Care Commission, **ORDERED:**

That the application for a Certificate of Need to add a third operating room at the Massachusetts Avenue Surgical Center LLC, an existing freestanding ambulatory surgery facility, in leased space at 6400 Goldsboro Road, Suite 400, Bethesda, Maryland, at a cost of $780,682 is **APPROVED.**

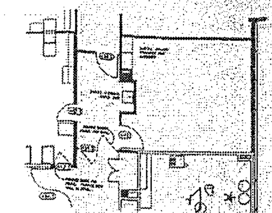
APPENDIX

FLOOR PLAN



FLOOR PLAN - NEW WORK

SCALE: 1/8" = 1'-0"



FLOOR PLAN
ADD ALTERNATE

SCALE: 1/8" = 1'-0"

PARTITION GRAPHIC:

NEW PARTITIONS

EXISTING PARTITIONS

GENERAL NOTES:

1. CONTRACTOR TO FAMILIARIZE THEMSELVES WITH THE SCOPE OF WORK & TO IMMEDIATELY NOTIFY THE ARCHITECT WITH ANY DISCREPANCIES.
2. GENERAL CONTRACTOR TO COORDINATE WITH SPRINKLER CONTRACTOR. SPRINKLER HEAD LOCATIONS TO COMPLY WITH CURRENT APPLICABLE CODES.
3. SEE DRAWING A5.1 FOR LAYOUT DIMENSIONS & PARTITION TYPES.

FLOOR PLAN - NEW WORK NOTES:

1. Provide 5 adj shelves
2. Reinstall ex equip
3. Reinstall ex lockers
4. Corner guard CG-1
5. Corner guard CG-2
6. New PTAC, see Mechanical dwgs
7. New lockers
8. New locker bench
9. New louvers in ex opening, match ex
10. New EWC, see Mechanical dwgs
11. New fire extinguisher cabinet

KMD Architects, LLC
106 Rosewood Drive
Greenbelt, MD 20770
301-787-2380
ken@kmdarchitects.net

Lasch Wallace Associates, Inc
Consulting Engineers

MASSACHUSETTS AVENUE SURGERY CENTER

MASSACHUSETTS AVENUE
SURGERY CENTER
EXPANSION & RENOVATION

FLOOR PLAN - NEW WORK

A4.1

STATE OF MARYLAND

Marilyn Moon, Ph.D.
CHAIR

Rex W. Cowdry, M.D.
EXECUTIVE DIRECTOR

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

MEMORANDUM

To: Commissioners

From: Eileen Fleck, Program Manager E.F.

Date: June 17, 2010

Re: Kaiser Permanente Baltimore Surgical Center
Docket No. 10-03-2306

Enclosed is a staff report and recommendation for a Certificate of Need ("CON") application filed by Kaiser Permanente ("Kaiser") for a freestanding ambulatory surgical facility located in southwest Baltimore County, Maryland. The proposed facility will include two operating rooms and shell space for a third. It will also include the necessary preoperative, postoperative, storage, and support spaces. The facility will be used almost exclusively by members of Kaiser health plans.

The project is estimated to cost $8,906,397. Kaiser plans to fund the project with cash.

Commission staff analyzed the proposed project's compliance with the applicable State Health Plan criteria and standards and the other applicable CON review criteria at 10.24.01.08 and recommends that the project be **APPROVED** with two conditions. First, before first use approval of the facility, Kaiser shall submit a transfer agreement that meets the requirements of the Department of Health and Mental Hygiene regulations implementing Health-General Article, §19-308.2, Annotated Code of Maryland. Second, the facility must provide the Commission with documentation that it has obtained accreditation from the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care within 18 months of first use approval.

IN THE MATTER OF	*	BEFORE THE
	*	
KAISER PERMANENTE	*	MARYLAND HEALTH
	*	
BALTIMORE SURGICAL	*	CARE COMMISSION
	*	
CENTER	*	
	*	
DOCKET NO. 10-03-2306	*	
	*	

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Staff Report and Recommendation

June 17, 2010

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FINAL ORDER

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Appendix B: Kaiser's Existing and Proposed Ambulatory Surgical Facilities in Maryland

I. INTRODUCTION

Project Description

The applicant, Kaiser Permanente ("Kaiser") is a health maintenance organization that provides health care services to persons enrolled in a Kaiser health plan. Services for Kaiser members are funded primarily through health plan premiums, co-payments, and deductibles. Kaiser is planning to construct a new medical office building at 1601 Odensos Lane, Baltimore, Maryland (Baltimore County), and seeks a Certificate of Need ("CON") to design approximately 16,987 square feet of the building as an outpatient surgical facility. The facility will be named Kaiser Permanente Baltimore Surgery Center ("KPBSC") and is proposed to have two operating rooms and shell space for one additional operating room. There will be procedure rooms constructed as part of the medical office building. However, these procedure rooms have not been incorporated into the space designated as KPBSC. The cost of constructing and operating the procedure rooms is not reflected in the budget for KPBSC. In addition to the two proposed operating rooms, there will be a preoperative area with six bays, a postoperative area that includes three bays in a post-anesthesia care unit (PACU) and three Stage 2 recovery bays. The facility will also include the necessary patient registration and waiting areas, staff locker rooms, and equipment storage. (DI#4, page 9).

Table 1: Proposed Facility Capacity for Kaiser Permanente Baltimore Surgery Center

Room Type/Other Space	Proposed Capacity
Operating Rooms	2
Pre-OP Bays	6
PACU Bays/Patient Holding Bays*	3
Recovery Bays	3

Source: CON application (DI#2, page 9).

There are no capital construction costs because Kaiser is planning to construct the building whether or not the project is approved. The building costs for the project are characterized as renovations. The cost of renovations is the largest component of the project, at $4,763,179. Equipment costs (major, minor, and radiology equipment) are the second largest expense, at $3,940,136. The source of project funding is $8,906,397 in cash. (DI#11, Exhibit 1).

Summary of Recommended Decision

Commission staff has evaluated the proposed project's compliance with the Certificate of Need review criteria at COMAR 10.24.01.08G(3)(a)-(f) and the applicable standards in COMAR 10.24.11, the State Health Plan ("SHP") chapter for Ambulatory Surgical Services. Based on this review, Commission staff has concluded that the project is consistent with the applicable SHP standards, that the applicant has documented a need for the project, and that the project is an alternative for increasing Kaiser's surgical capacity and improving its operational effectiveness and efficiency at a reasonable cost. The project will not have a negative impact on the cost or charges for ambulatory surgery in the counties to be served by the proposed facility or

on existing surgical facilities. Commission staff recommends approval of the project. A summary of the Commission staff's analysis is provided below.

Ambulatory Surgery Utilization Trends

- The number of operating room cases at freestanding ambulatory surgical centers in Baltimore City and the five counties identified as the primary service area of KPBSC increased at an average annual rate of 1.4 percent between 2001 and 2008.

- The number of outpatient surgeries at Maryland hospitals for residents in the primary service area of KPBSC increased from 2001-2008 at an average annual rate of 4.5 percent.

Projected Utilization

- Recent increases in Kaiser's membership levels for those in the primary service area of KPBSC suggest that KPBSC will be able to operate its proposed two operating rooms at an optimal level of utilization, as defined in the SHP, within two years of opening the proposed facility.

Impact on Existing Programs

- The impact of the proposed new facility on existing surgical facilities in Maryland is likely to be minimal because even the facility most affected will lose a relatively small volume of surgical cases. In addition, no persons raised objections to the proposed project.

Availability of More Cost-Effective Alternatives

- Kaiser reasonably rejected the alternative of using existing hospitals for surgeries. Shifting surgical cases that are currently performed in hospitals to KPBSC would likely reduce the cost of these cases.

Viability of the Proposal

- KPBSC has projected costs per surgical case that are in line with the average cost per case at other freestanding ambulatory surgical facilities. The construction costs are reasonable, when evaluated using the construction cost guidelines of the Marshall Valuation Service. In addition, Kaiser has demonstrated that it has the resources and community support necessary for the proposed project to be financially feasible.

II. PROCEDURAL HISTORY

Review Record

On November 10, 2009, Commission staff acknowledged Kaiser's submission of its Letter of Intent filed that same day to apply for a CON to construct a freestanding ambulatory surgery facility in Baltimore County. [Docket Item (DI) # 1].

On December 9, 2009, Kaiser filed an amended Letter of Intent (DI#2), and on December 16, 2009, Kaiser sent a second amended Letter of Intent (DI#3).

Kaiser filed its Certificate of Need application for a new facility to be located in Baltimore County on January 8, 2010 (DI#4). Acknowledgement of receipt of the application was sent on January 12, 2010 (DI#5), and a notice was submitted to the Maryland Register Electronic Filing System on January 12, 2010 (DI#7).

On January 12, 2009, the Commission requested that the *Baltimore Sun* publish notice of the receipt of the KPBSC application (DI#6). On January 20, 2010, Commission staff received a copy of the notice that was published in the *Baltimore Sun* on January 20, 2010 (DI#9).

On January 15, 2010, Commission staff requested that the applicant provide information based on a completeness review of the application (DI#10). On February 12, 2010, Commission staff received the applicant's response to completeness questions (DI#11).

Commission staff notified Kaiser on February 26, 2010 that its application would be docketed effective with the March 12, 2010 publication of a notice of docketing in the *Maryland Register* and requested additional information (DI#12).

On February 26, 2010, Commission staff requested that notice of the docketing of KPBSC's application be published in the next edition of the *Baltimore Sun* (DI#13). On March 11, 2010, Commission staff received a copy of the notice of the formal start of the review that was published on March 9, 2010 in the *Baltimore Sun* (DI#15).

On February 26, 2010, Commission staff requested that notice be published in the Maryland Register Electronic Filing System that the application for KPBSC would be docketed as of March 12, 2010 (DI#14).

Commission staff sent the Baltimore County Health Department a request for comments on the application of KPBSC, on March 29, 2010. (DI#16).

KPBSC filed its responses to additional information questions on March 31, 2010 (DI#17).

On April 12, 2010 Commission staff requested additional information regarding Kaiser Permanente Baltimore Surgical Center (DI#18). On April 30, 2010, Commission staff received responses to its additional information questions (DI#19).

On May 26, 2010, the Baltimore County Health Department sent notice to Commission Staff that it has chosen not to comment on the proposed project (DI#20).

Local Health Department Review and Comment

The Baltimore County Health Department did not submit any comments on the proposed project (DI#20).

Community Support

Letters of support were submitted by: James T. Smith, Jr., Baltimore County Executive; Kenneth N. Oliver, Councilman for Baltimore County; Bonnie Phipps, President and C.E.O. of Saint Agnes Health Care; Edward J. Kasemeyer, Senator for Baltimore and Howard Counties (District 12); John R. Saunders, Jr., M.D., Interim President and C.E.O. of Greater Baltimore Medical Center; Steven J. DeBoy, Sr., State Delegate; and James E. Malone, Jr., State Delegate (DI#8).

III. BACKGROUND

Ambulatory or outpatient surgery is surgery that does not require overnight hospitalization for recovery or observation. Preparation of the patient for the surgical procedure, the procedure itself, post-operative recovery, and discharge of the patient from the surgical facility are accomplished on a single day. Outpatient surgery has been increasing in recent decades. Strong growth has been driven by changes in technology, including both surgical and anesthetic techniques, patient preferences, cost control efforts, and the development of new procedures. Many surgical procedures that were once limited to provision on an inpatient basis are now performed as outpatient surgeries.

Since 1995, Maryland law has exempted surgical centers with a single operating room from CON regulation. Prior to that time, it exempted single-specialty centers with up to four operating rooms. Maryland has more Medicare-certified ambulatory surgery centers ("ASCs") per capita than any other state. Based on data collected by the Maryland Health Care Commission for CY2008, a very high proportion of Maryland's surgical centers have a single operating room (49 percent) or no operating rooms at all (34 percent). Freestanding centers without operating rooms have non-sterile procedure rooms that are suitable for closed endoscopic or urologic procedures and needle injection or biopsy procedures. A high proportion of Maryland's freestanding centers also identify themselves as single-specialty (81 percent).

Statewide, from 2001 to 2008, ambulatory surgery case volume at acute care hospitals increased at an average annual rate of approximately 3.6 percent compared to an annual growth rate of approximately 8.3 percent at freestanding ambulatory surgery centers. The number of operating and procedure rooms also grew during this time period at an average annual rate of 4.1

percent. This increase has been primarily driven by an increase in procedure rooms; the number of operating rooms increased at an average annual rate of 0.6 percent.

For residents from Baltimore City or one of the five Maryland counties identified as the primary service area for KPBSC, the volume of outpatient surgical cases performed at hospitals increased from 2001 to 2008. The average annual increase in outpatient surgical case volume for residents from each of the six localities was strong, ranging from 3.2 percent to 12.9 percent, as shown in Table 2. With regard to the number of operating room cases at ambulatory surgical centers in these six localities, collectively the average annual growth has been 1.4 percent between 2001 and 2008. However, the six localities had average annual growth rates ranging from -10.8 percent in Baltimore City to +11.1 percent in Anne Arundel County. Statewide, between 2001 and 2008, the average annual rate of growth in case volume for ASCs was 8.3 percent.

Table 2: Ambulatory Surgery Cases at Maryland Hospitals for Residents from the Primary Service Area of KPBSC, CY2001 and CY2008

City/County	Number of Cases		Average Annual Percent Change
	2001	2008	2001-2008
Anne Arundel County	23,205	30,345	3.9%
Baltimore City	50,184	62,399	3.2%
Baltimore County	64,628	80,936	3.3%
Carroll County	6,845	12,195	8.6%
Harford County	14,279	23,070	7.1%
Howard County	7,866	18,420	12.9%
Total	167,007	227,365	4.5%

Source: MHCC staff analysis of HSCRC data for Hospitals CY2001 and CY2008.

IV. COMMISSION REVIEW AND ANALYSIS

The Commission reviews projects proposed for CON authorization under six criteria outlined at COMAR 10.24.01.08G (3):

- Consideration of the relevant standards, policies, and criteria of the State Health Plan;
- Consideration of the applicable need analysis of the State Health Plan or the applicant's demonstration of an unmet need of the population to be served and the project's capability and capacity to meet that need;
- Comparison of the cost effectiveness of providing proposed services through the proposed project with the cost effectiveness of providing the service at alternative existing facilities or alternative facilities submitting a competitive application for comparative review;

- Consideration of the availability of financial and nonfinancial resources, including community support, necessary to implement the project on a timely basis and the availability of resources necessary to sustain the project;

- Consideration of the compliance of the applicant in all conditions applied to previous CONs and compliance with all commitments made that earned preference in obtaining CONs; and

- Consideration of the impact of the proposed project on existing health care providers in the proposed project's service area, including the impact on access to services, occupancy, and costs and charges of other providers.

A. The State Health Plan

The relevant State Health Plan chapter is COMAR 10.24.11, Ambulatory Surgical Services.

> ***COMAR 10.24.11.06 A. <u>System Standards:</u> All hospital-based ASFs and all freestanding ambulatory surgical facilities (FASFs) including HMOs sponsoring an FASF, shall meet the following standards, as applicable.***
>
> ***(1) <u>Information Regarding Charges</u>***
> ***Each hospital-based ASF and each FASF shall provide to the public, upon inquiry, information concerning charges for and the range and types of services provided.***

The applicant has explained that the proposed facility will not charge most patients, except for co-payments and deductibles because the cost of Kaiser members' care is covered by their health plan premiums (DI#4, page 17). Therefore, this standard is not applicable.

> ***<u>(2) Charity Care Policy</u>***
> ***(a) Each hospital-based ASF and FASF shall develop a written policy for the provision of complete and partial charity care for indigent patients to promote access to all services regardless of an individual's ability to pay.***
> ***(b) Public notice and information regarding a hospital or a freestanding facility's charity care policy shall include, at a minimum, the following:***
> ***(i) Annual notice by a method of dissemination appropriate to the facility's patient population (for example, radio, television, newspaper);***
> ***(ii) Posted notices in the admission, business office, and patient waiting areas within the hospital or the freestanding facility; and***
> ***(c) Within two business days following a patient's request for charity care services, application for Medicaid, or both, the facility must make a determination of probable eligibility.***

Kaiser provides charitable care by enrolling individuals with low income as Kaiser members, rather than providing a particular medical service. Kaiser works with community organizations and local governments to enroll individuals. Kaiser's largest charitable programs

are the Bridge Plan and the Children's Health Care Partnership. The Bridge Plan helps those who cannot afford health care coverage because of a change in employment or income. Members in the Bridge Plan pay a subsidized premium for up to three years. For 2009, Kaiser forecasted an investment of $10,104,584 for Maryland members in the Bridge Plan. The Children's Health Care Partnership (CHCP) is a program that provides children enrolled with free or reduced cost primary care. Both Kaiser members and non-members are eligible for CHCP. In 2009, Kaiser forecasted that it would have expenditures of $843,472 that year for Maryland children enrolled in CHCP. In addition to these two programs, Kaiser has a Medical Financial Assistance Program for its members who cannot afford out-of-pocket costs for health care services. Information on this program is posted on Kaiser's web site and displayed on posters and brochures in Kaiser's medical offices. A determination of probable eligibility for the program is made within two business days. KPBSC complies with this standard. (DI#4, pages 18-20).

(3) Compliance with Health and Safety Regulations

Unless exempted by an appropriate waiver, each hospital-based ASF and FASF shall be able to demonstrate, upon request by the Commission, compliance with all mandated federal, State, and local health and safety regulations.

The applicant states that KPBSC will be licensed by the State and will be Medicare certified (DI#4, page 21). KPBSC will also comply with all mandated federal, State, and local health and safety regulations (DI#4, page 21). KPBSC is consistent with this standard.

(4) Licensure, Certification and Accreditation

(a) Existing FASFs and HMOs that sponsor FASFs shall obtain state licensure from the Maryland Department of Health and Mental Hygiene, certification from the Health Care Financing Administration as a provider in the Medicare program, and from the Maryland Department of Health and Mental Hygiene as a provider in the Medicaid program.

(b) Except as provided in (c), existing FASFs and HMOs that sponsor FASFs shall obtain accreditation from either the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the Accreditation Association for Ambulatory Health Care (AAAHC).

(c) If another accrediting body exists with goals similar to JCAHO and AAAHC, and is acceptable to this Commission, accreditation by this organization may be substituted.

The applicant states that KPBSC will be licensed by the State and will be Medicare certified. In addition, the applicant states that KPBSC will obtain accreditation from the Accreditation Association for Ambulatory Health Care (DI#4, page 22). With regard to Medicaid certification, the applicant stated that KPBSC should not be required to obtain the certification because KPBSC will provide services primarily to Kaiser members and Medicaid certification does not impose quality requirements above and beyond those required to obtain a State license (DI#4, pages 22-23). KPBSC does not fully comply with this standard because it will not be Medicaid certified; however, Commission staff agrees with Kaiser that Medicaid certification should not be required because the vast majority of persons served are Kaiser members and Medicaid certification requirements would not enhance the safety of patients at a facility that is Medicare-certified and appropriately accredited.

Kaiser's existing Kensington facility was established more than ten years ago and has not been accredited. This suggests that Kaiser does not regard accreditation as essential Although Kaiser indicated that the Kensington facility intends to begin the process of applying for accreditation from AAAHC, Commission staff believe it is important to emphasize that obtaining accreditation is essential. Therefore, Commission staff recommends the following condition:

> *KPBSC must provide the Commission with documentation that it has obtained accreditation from the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care within 18 months of first use approval.*

(5) <u>Transfer and Referral Agreements</u>
(a) Each hospital-based ASF shall have written transfer and referral agreements with:
(i) Facilities capable of managing cases which exceed its own capabilities; and
(ii) Facilities that provide inpatient, outpatient, home health, aftercare, follow-up, and other alternative treatment programs appropriate to the types of services the hospital offers.
(b) Written transfer agreements between hospitals shall meet the requirements of the Department of Health and Mental Hygiene regulations implementing Health-General Article, §19-308.2, Annotated Code of Maryland.
(c) Each FASF shall have written transfer and referral agreements with one or more nearby acute general hospitals.
(d) For both hospital-based ASFs and FASFs, written transfer agreements shall include, at a minimum, the following:
(i) A mechanism for notifying the receiving facility of the patient's health status and services needed by the patient prior to transfer;
(ii) That the transferring facility will provide appropriate life-support measures, including personnel and equipment, to stabilize the patient before transfer and to sustain the patient during transfer;
(iii) That the transferring facility will provide all necessary patient records to the receiving facility to ensure continuity of care for the patient; and
(iv) A mechanism for the receiving facility to confirm that the patient meets its admission criteria relating to appropriate bed, physician, and other services necessary to treat the patient.
(e) If an FASF applying for a Certificate of Need has met all standards in this section except (c)-(d) of this standard, the Commission may grant a waiver upon:
(i) Demonstration that a good-faith effort has been made to obtain such an agreement; and
(ii) Documentation to the Commission of the facility's plan regarding transfer of patients.
(f) An FASF shall establish and maintain a written transportation agreement with an ambulance service to provide emergency transportation services.

KPBSC does not currently have a transfer agreement, but the applicant anticipates that an agreement similar to the one for Kaiser's Kensington location will be created. A copy of this

agreement was provided (DI#4, Exhibit 4). The applicant also noted that ambulance service will be provided by the Emergency Medical System through calling 911 (DI#4, page 24). The applicant has indicated this it will comply with this standard, but has not created a transfer agreement. Therefore, the following condition addressing the transfer agreement is recommended for inclusion, if the project is awarded a CON:

> *Before first use approval of KPBSC, Kaiser shall submit a transfer agreement that meets the requirements of the Department of Health and Mental Hygiene regulations implementing Health-General Article, §19-308.2, Annotated Code of Maryland.*

(6) Utilization Review and Control Program
Each hospital and FASF shall participate in or have utilization review and control programs and treatment protocols, including a written agreement with the Peer Review Organization contracting with the Health Care Financing Administration, or other private review organizations.

The applicant states that KPBSC will have a utilization review and control program. A detailed description of the program is included in the CON application (DI#4, Exhibit 5). Although the applicant did not include a written agreement with a Peer Review Organization or other private review organization, such an agreement is no longer required by Delmarva, the Medicare Quality Improvement Organization for the District of Columbia and Maryland (DI#4, page 25). KPBSC complies with this standard.

COMAR 10.24.11.06 B. Certificate of Need Standards. An applicant proposing to establish or expand a hospital-based ASF or an FASF, including an HMO sponsoring and FASF, shall demonstrate compliance with the following standards, as appropriate:

(1) Compliance with System Standards
(a) Each applicant shall submit, as part of its application, written documentation of proposed compliance with all applicable standards in section A of this regulation.
(b) Each applicant proposing to expand its existing program shall document ongoing compliance with all applicable standards in section A of this regulation, including meeting standard A(4) within 18 months of first opening.

The applicant states that it will comply with all system standards (DI#4, page 26). Based on this assurance, the application is consistent with this requirement.

(2) Service Area
Each applicant shall identify its proposed service area, consistent with its proposed location.

The applicant defines the primary service area of the proposed ambulatory surgical facility as including Baltimore City and Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties (DI#4, page 26). The applicant also provided a specific list of zip code areas that

define the primary service area for KPBSC (DI#19, page 11). The applicant has complied with this standard.

(3) Charges

Each applicant shall submit a proposed schedule of charges for a representative list of procedures and document that these charges are reasonable in relation to charges for similar procedures by other freestanding and hospital providers of ambulatory surgery in its jurisdiction.

In response to this standard, the applicant stated that KPBSC does not charge for procedures except in rare circumstances (DI#4, pages 10-11). However, Kaiser does pay other providers when Kaiser members receive surgical services at non-Kaiser locations. Kaiser provided a table with average hospital charges by hospital for Kaiser members from the primary service area of KPBSC at Maryland hospitals in CY2008. The highest number of these cases were performed at Greater Baltimore Medical Center, which had 1,918, or 61 percent, of the total number of Kaiser ambulatory surgical cases for members in the proposed facility's primary service area. (DI#4, pages 27-28). The average charge across all Maryland hospitals, for Kaiser members in the primary service area of KPBSC is $2,628. (DI#4, page 28). In contrast, the applicant noted that the average cost per case at KPBSC is projected to be $1,810 in 2014 (DI#4, page 28).

Charges do not generally reflect the actual payment for surgical services at health care facilities, such as freestanding ambulatory surgical facilities, and Kaiser does not charge for procedures. Therefore, the best source for evaluating the reasonableness of costs at KPBSC may be a comparison of the estimated expense per case for KPBSC and the reported average cost per case at other multispecialty surgical facilities with only operating room cases reported. As shown in Table 3, the average expense per case estimated by Kaiser for KPBSC ($1,810) is higher than the average for all Maryland multispecialty ambulatory surgery facilities with only operating rooms and cases reported ($969). Among the ten facilities with only operating rooms, there are just three that reported a similar level of utilization as KPBSC projects; the surgical minutes per operating room for these three facilities ranged from 62,400 to 99,600 surgical minutes. The expense per case at these three facilities ranged from $612 to $1,545. The facility with the highest expense per case is another Kaiser facility. The types of cases reported for the two non-Kaiser facilities are different from the likely mix of cases for KPBSC. One facility reported primarily otolaryngology cases; the other facility reported a large number of gastrological, general surgery, and pain management cases. The difference in case mixes may account for the much lower expense per case at two of the three facilities that Commission staff regard as most similar to KPBSC with regard to utilization.

Table 3: Comparison of Average Expense Per Case for Select Locations, CY2009

Comparison Facility	Number of Locations Included	Average Expense Per Case	Range
KPBSC	1	$1,810	N/A
Multi-specialty with only ORs*	10	$969	$264 -- $1,545

Source: Staff analysis of MHCC Survey of Freestanding Ambulatory Surgery Facilities for CY2008 and DI#4, page 28.
*Note: Information on the MHCC Survey of Freestanding Ambulatory Surgery Facilities is self-reported.

Although there are not any comparable charge data for KPBSC, the response provided by the applicant is acceptable. The project is consistent with this standard.

(4) Minimum Utilization for the Expansion of Existing Facilities
Each applicant proposing to expand its existing program shall document that its operating rooms have been, for the last 12 months, operating at the optimal capacity stipulated in Regulation .05A(3) of this Chapter, and that its current surgical capacity cannot adequately accommodate the existing or projected volume of ambulatory surgery.

This standard is not applicable. KPBSC will be a new facility; it is not an expansion of an existing ambulatory surgical facility.

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

The applicant states that laboratory and radiology services will be provided on site (DI#4, page 28). Other services, such as imaging or additional laboratory services will be located elsewhere in the same building as KPBSC (DI#4, page 28). Pathology services will be provided through a regionally centralized pathology service located in Rockville that is also operated by Kaiser (DI#4, page 28). KPBSC is consistent with this standard.

(6) Certification and Accreditation
Except as provided in (c), each new FASF applicant or HMO that sponsors a new FASF shall agree to seek and to obtain, within 18 months of first opening, licensure, certification and accreditation from the following organizations:
(a) The Maryland Department of Health and Mental Hygiene for state licensure, the Health Care Financing Administration for certification as a provider in the Medicare program, and the Maryland Department of Health and Mental Hygiene for certification in the Medicaid program; and
(b) Accreditation from either the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care.
If an applicant can demonstrate that an alternative accrediting body exists with goals similar to JCAHO and AAAHC, and is otherwise acceptable to the Commission, accreditation by this organization may be substituted

The applicant states that KPBSC will be licensed by the Maryland Department of Health and Mental Hygiene and will be Medicare-certified by the Department of Health and Human Services (DI#4, pages 21-23). KPBSC will also obtain accreditation from the Accreditation Association for Ambulatory Health Care. (see earlier discussion at COMAR 10.24.11.06A(4)). A recommended condition for any approval of this project concerning accreditation was previously discussed.) The applicant requested that Medicaid certification not be required because KPBSC will provide services primarily to Kaiser members and employees of self-funded groups, and Medicaid certification does not impose requirements related to quality beyond those required to obtain State licensure (DI#4, pages 21-23). Commission staff agrees Medicaid certification should not be required because the vast majority of patients to be served by KPBSC will be Kaiser members. Without Medicaid certification, the applicant does not fully comply with this standard; however, all other parts of the standard are met. Commission staff considers Kaiser's level of compliance with this standard to be appropriate.

(7) Minimum Utilization for New Facilities

Each FASF applicant shall demonstrate, on the basis of the documented caseload of the surgeons expected to have privileges at the proposed facility, that, by the end of the second full year of operation, the facility can draw sufficient patients to utilize the optimal capacity of the proposed number of operating rooms, measured according to Regulation .05A of this Chapter.

Kaiser analyzed its surgical data for the Mid-Atlantic Region and used this data to develop surgical case rates by specialty (DI#4, page 29). Kaiser also created projections for the number of Kaiser members based on population growth and initiatives that Kaiser is undertaking to increase its membership (DI#4, page 30). Kaiser stated that these projections show a need for 2.99 operating rooms in 2014, the second year of operation for KPBSC (DI#4, page 31). Kaiser also provided a conservative estimate, assuming that membership levels remain the same in 2014 as they were in 2009. Under this assumption, 2.43 operating rooms will be needed (DI#4, page 32).

Commission staff regards the conservative estimate provided by Kaiser as more likely, based on the historical levels of Kaiser members for the primary service area of KPBSC and the evidence provided to support higher growth projections. For a full discussion of the conclusions of Commission staff regarding the projected utilization of operating rooms at KPBSC, refer to the "Need" section of this report. Commission staff concludes that two operating rooms are likely to be used at optimal capacity by the second full year of operation, which is consistent with this standard.

(8) Reconfiguration of Hospital Space

Each hospital applicant proposing to develop or expand its ASF within its current hospital structure shall document plans for the reconfiguration of hospital space for recovery beds, preparation rooms, and waiting areas for persons accompanying patients.

This standard is not applicable. The proposed project is a freestanding ambulatory surgical facility that is not being developed to replace and relocate surgical space within a hospital.

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.

Applicant Response

The applicant projects a need for operating room capacity at the proposed new facility based on its projected membership levels for residents in the primary service area of KPBSC, an estimated rate of ambulatory surgery per 1,000 Kaiser members, and the estimated procedure time for ambulatory surgery cases (DI#4, pages 30-32). The applicant then uses the definition of optimal utilization of operating rooms included in the State Health Plan to show that two operating rooms are needed. The applicant also states that reducing the driving time for Kaiser members who require surgical services will improve access to Kaiser-owned and -operated surgical facilities (DI#4, page 34). Table 4 below shows the historical number of Kaiser members in the primary service area for KPBSC from 2004-2009 and the projected number of members for 2010-2014.

Table 4: Kaiser Members to Be Served at KPBSC, Historical and Projected Membership Levels by Kaiser Primary Care Medical Center

	History						Forecast				
Location	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
City Plaza	6,002	6,086	5,964	6,193	5,321	4,501	5,091	5,154	5,242	3,480	3,652
Columbia Gateway	7,588	8796	9,273	8,856	9,111	8,869	8.875	9,198	9,586	10,022	10,389
Severna Park	7,633	7,851	8,171	7,905	7,936	7,654	7,433	7,622	7,849	8,173	8,616
Towson	9,214	9,968	10,340	9,775	9,171	8,481	9,750	9,934	10,165	9,782	10,225
White Marsh	12,949	13,492	14,471	13,664	13,509	12,911	13,731	14,106	14,571	11,449	11,775
Woodlawn	13,756	14,088	14,301	13,607	12,865	11,604	13,034	13,336	13,714	13,104	13,756
Full Service MOB*										7,598	8,362
Total	57,142	60,281	62,520	60,000	54,020	57,914	59,914	59,351	61,127	63,609	66,776

Source: DI#17, page 1

*Note: Full Service MOB refers to members who are currently served by other medical centers but are expected to switch to KPBSC once it is open.

The applicant calculated the projected number of surgery cases for 2010-2014 by estimating a surgical case rate per 1,000 members, estimating the average case time for these surgeries, and assuming that turnaround time is 30 minutes. Turnaround time of 30 minutes is the standard assumption defined in the State Health Plan for Ambulatory Surgery. The applicant initially estimated the surgical case rate per 1,000 members in the primary service area of

KPBSC by analyzing its surgical data for the Mid-Atlantic Region, including both cases performed at Kaiser facilities and non-Kaiser facilities (DI#4, page 30). The rates generated by this analysis were for medical specialties, and Kaiser physicians reviewed these rates to verify the validity of them (DI#4, page 29). The average case time by specialty was also calculated. Kaiser then used the rates by specialty, average case time by specialty, and membership projections to calculate the need for operating rooms in 2014. Kaiser calculated the need for operating rooms using the projected membership for 2014, as shown in Table 5. Based on the optimal capacity standard for a mixed-use general purpose operating room in the State Health Plan (97,920 minutes), the applicant concluded that more than two operating rooms are needed in 2014.

Table 5: Projected Need for Operating Rooms at KPBSC at 2014 Kaiser Membership Level

Specialty	Average Case Time (minutes)	Rate per 1,000 Members	Cases, 2014 Forecast	Surgical Minutes	Turnaround Minutes	Total Minutes	Operating Room Need
Ear, Nose, Throat	66	6.1	407	26,884	12,220	39,104	
General Surgery	66	9.5	634	41,869	19,031	60,900	
Gastroenterology	36	1.3	87	3,125	2,604	5,729	
OB-GYN	60	4.6	307	18,430	9,215	27,645	
Ophthalmology	36	6.6	441	15,866	13,222	29,088	
Orthopedic	60	10.7	714	42,870	21,420	64,260	
Plastic Surgery	90	0.9	60	5,409	1,803	7,212	
Podiatry	78	3.6	240	18,751	7,212	25,963	
Retinal Service	72	0.2	13	962	401	1,362	
Urology	54	3.8	254	13,702	7,612	21,315	
Total	59.5	47.3	3,158	187,867	94,740	282,577	2.89

Source: DI#11, pages 11-12, except turnaround and total minutes were calculated by Commission staff.

As a conservative estimate of the need for operating rooms, Kaiser created projections using the same average case time and surgery rate per 1,000 members shown in Table 5, but assumed that Kaiser membership levels would not increase above the level in 2009. Under these assumptions, Kaiser projected a need for 2.33 operating rooms (DI#11, page 12).

With regard to membership growth, Kaiser justifies the projected membership growth of 4.7 percent on an average annual basis by citing an anticipated increase in consumer satisfaction and other factors (DI#11, page 13). These other factors include improved cost of care management, improved geographic access, and population growth of 0.5 percent annually (DI#11, page 13). In order to demonstrate the extent to which the proposed facility will improve geographic access, Kaiser performed a travel time analysis to identify the number of Kaiser members in the primary service area of KPBSC who are within a 30-minute drive of KPBSC. Approximately 93.3 percent of these members are within a 30-minute drive of KPBSC (DI#4, pages 34 -35).

Staff Analysis

Kaiser's conclusions regarding the need for additional operating room capacity primarily rely on two factors, a projection of the number of Kaiser members in the service area of KPBSC and a projection of the surgical case rate. Kaiser provided both what it regards as a realistic estimate of the future operating room utilization at KPBSC and a conservative estimate. Both of these estimates show a need for more than two operating rooms. Although Commission staff disagrees with some of the conclusions reached by Kaiser, Commission staff's own analysis indicates that two operating rooms are justified.

The historic information provided by Kaiser on its membership levels shows that, while membership grew from 2004 to 2006, it declined from 2007 to 2009, resulting in membership levels below the level in 2004, as shown in Table 7. Commission staff calculated the average annual change in membership from 2004-2009, for the locations of Kaiser medical centers listed. This analysis shows a decline in membership at three of the six locations listed, virtually no change at two locations (+/- 0.1 percent), and solid growth at just one location, Columbia Gateway, as shown in Table 8.

Table 7: Kaiser Members to Be Served at KPBSC, Historical and Projected Membership Levels by Kaiser Primary Care Medical Center

	History					
Location	2004	2005	2006	2007	2008	2009
City Plaza	6,002	6,086	5,964	6,193	5,321	4,501
Columbia Gateway	7,588	8796	9,273	8,856	9,111	8,869
Severna Park	7,633	7,851	8,171	7,905	7,936	7,654
Towson	9,214	9,968	10,340	9,775	9,171	8,481
White Marsh	12,949	13,492	14,471	13,664	13,509	12,911
Woodlawn	13,756	14,088	14,301	13,607	12,865	11,604
Total	57,142	60,281	62,520	60,000	54,020	57,914

Source: DI#11, page 11.

Table 8: Historic Level of Membership Change

Location	Average Annual Change 2004-2009
City Plaza	-5.6%
Columbia Gateway	3.2%
Severna Park	0.1%
Towson	-1.6%
White Marsh	-0.1%
Woodlawn	-3.3%
Total	-1.1%

Source: MHCC staff analysis of DI#11, page 11.

Despite the historic level of decline in Kaiser's membership for the KPBSC, Kaiser projects average annual growth of 4.7 percent for these locations (DI#11, page 13). Kaiser explained that growth in membership was expected because of improved member retention due to greater satisfaction, a more affordable price for members and employer groups, improved geographic access, population growth of 0.5 percent annually, and increased growth in the federal workforce (DI#11, pages 13-14).

Commission staff reviewed data reported by Kaiser on the CAHPS survey and published in the Commission's "Health Plan Performance Report" for years 2004-2009 in order to assess the longer term trend in member satisfaction and membership levels. In the category "Rating of Health Plan," which reflects the percentage of adults who rated their health plan a nine or ten on a ten-point scale, Kaiser scored an average mark relative to other health plans for years 2004 through 2008, and the percentage of Kaiser members who rated the health plan a nine or ten decreased from 40 percent in 2005 to 33 percent in 2008. In 2009, Kaiser was ranked above average and had the highest rating among the seven health maintenance organization (HMO) plans, with 39 percent of its members rating the health plan a nine or ten. On the measure "Getting Care Quickly," Kaiser was average for 2004 and 2005; it was below average for years 2006-2009 and ranked last among the seven plans rated for all four years. The measures for "Rating of Health Care" and "Getting Needed Care" are not available for all years reviewed. In 2004 and 2005, Kaiser members' ratings of the overall care provided by the plan was about average, compared to other health plans, and Kaiser ranked fourth among the seven other plans listed. In 2006, Kaiser members' ratings of the overall care provided by the plan was below average, compared to other plans, and Kaiser ranked 7th among the seven plans listed. In 2007, Kaiser members' rating of the plan was below average on "Getting Needed Care" compared to other plans. However, in 2008 the rating of the plan in this category was average compared to other plans. It is reasonable to conclude that the level of consumer satisfaction achieved by Kaiser, as noted for these measures, across time and relative to other health plans, may be influencing Kaiser's lack of membership growth record in recent years.

Although Kaiser expects an increase in Kaiser members as a result of growth in the federal workforce, it does not appear that Kaiser membership is tied to growth in the federal workforce living in Washington, D.C. or the Washington, D.C. metropolitan area. The number of

Kaiser members in the federal workforce generally declined between 2006 and 2010 (DI#17, pages 8-9), while the federal workforce living in Washington, D.C. or the vicinity of Washington, D.C. appears to have generally increased. The Bureau of Labor Statistics reported that the federal workforce living in Washington, D.C. in 2006 was approximately 192,800 and increased to approximately 204,600 in January 2010.[1] Although the number of Kaiser members in the federal workforce increased from 2009 to 2010, the number of Kaiser members in the federal workforce declined between 2006 and 2009. Therefore, it does not appear that Kaiser membership levels are necessarily closely tied to the size of the federal workforce.

The surgical case rates per 1,000 members calculated by Kaiser appear reasonable. HSCRC data suggests a much higher rate of surgery per 1,000 members. However, the HSCRC data likely overstates the number of ambulatory surgical cases performed in sterile operating rooms, as has been noted by Commission staff in previous reports. Overall, it appears that the HSCRC data overstates the number of operating room cases by greater than 25 percent at many hospitals. The rate chosen by Kaiser appears to be based on a more reliable source. Commission staff believes that only a small adjustment to the surgical rate that Kaiser used for its projections is required. The rate Kaiser used for its projections is the rate calculated for Kaiser members in Virginia. Kaiser included Maryland residents who had surgeries in Virginia in calculating the surgery rate, but only used the total number of Kaiser members in Virginia to calculate the rate. If the Maryland residents are excluded, then the new surgical rate is 47.1. (DI#19, pages 5-6).

Kaiser's projected case volume for KPBSC accounts for ambulatory surgical cases that are likely to continue being performed in hospitals due to patient characteristics; for some patients, a hospital is the best and safest setting for surgical procedures. Kaiser estimates that 5.4 cases per 1,000 members may take place in a hospital setting because of significant medical co-morbidities (DI#11, page 12). Commission staff agrees that Kaiser's assumption regarding continued use of hospitals for a small percentage of ambulatory surgical cases is appropriate.

Using a conservative estimate for Kaiser membership levels in 2014 and the surgery rate given by Kaiser, adjusted slightly (47.1), and accounting for surgical cases that will continue to be performed in hospitals, Commission staff calculates 1.96 operating rooms will be needed. Therefore, Commission staff concludes that the applicant will be likely to use the two proposed operating rooms at optimal capacity within two years of opening KPBSC. In addition, the applicant has demonstrated a need for ambulatory surgery by the HMO membership that it has enrolled in the Baltimore area for the two operating rooms proposed.

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.

[1] U.S. Department of Labor, Bureau of Labor Statistics. "State and Area Employment, Hours, and Earnings." http://data.bls.gov/cgi-bin/dsrv. Last accessed April 29, 2010.

Applicant's Response

Kaiser considered one alternative to the proposed project, continuing to perform cases in acute care hospitals and other non-Kaiser settings (DI#4, page 39). Kaiser has concluded that this option is no longer cost-effective.

In order to demonstrate that performing cases in existing facilities, such as hospitals, is more expensive than performing surgeries at Kaiser facilities, Kaiser analyzed data from HSCRC for residents in the primary service area of KPBSC. For these patients, Kaiser analyzed the average charges for patients with Kaiser listed as the primary payer and an operating room charge of greater than one dollar. For CY2008, Kaiser counted 3,915 surgeries at hospitals for Kaiser patients from the primary service area for KPBSC (DI#11, page 17). The average charge for these cases was $2,586 compared to an estimated cost per case of $1,810 for KPBSC in 2014 (DI#11, page 20). Because the cost of performing surgeries at KPBSC is projected to be much lower than the cost incurred by Kaiser to obtain surgical services for its members from area hospitals, the applicant believes the proposed project is cost-effective.

Kaiser attempted to adjust for case mix by matching the primary ICD-9 code for each of the 3,539 surgical cases in the HSCRC data to a specialty and calculating the average charge for each specialty (DI#11, page 3). Using this method, the average charge of hospital ambulatory surgery cases for patients with Kaiser insurance located within the primary service area of KPBSC was estimated to be higher, $3,606 (DI#11, page 4). However, Kaiser also noted that approximately 46 percent of the 3,539 cases identified as Kaiser patients within the service area of KPBSC could not be matched to a specialty, and the ICD-9 code may not accurately reflect the nature of the surgery (DI#11, page 4).

Staff Analysis

With regard to the difference in charges for Kaiser cases performed in hospitals, Commission staff believes the charges for performing surgical cases in hospitals, rather than a Kaiser facility, is not as great as suggested by Kaiser's analysis. The charges included in the HSCRC data base field named "total charges" may include non-surgical services, such as therapeutic services (physical, speech, occupational), diagnostic radiology tests, and diagnostic imaging scans (MRI, CAT, etc). These are charges that were not included in the KPBSC budget. After eliminating what staff assesses to be non-surgical services charges from the HSCRC data for ambulatory surgical cases, Commission staff calculates that the average charge per case for cases that Kaiser anticipates moving to KPBSC is $2,277. This is lower than the value calculated by Kaiser that includes all types of charges, $2,586 (DI#11, page 4). It is also lower than the hospital charge per case estimated by Kaiser ($3,606), based on categorizing cases into medical specialties according to the primary diagnosis code (DI#11, page 4). The charge per ambulatory surgical case calculated by Commission staff may also be high compared to the estimated expense per case at KPBSC because a profit margin is built into hospital charges, generally around 11 percent, and the mark-up from cost is not uniform across services.[2] Hospitals may choose to allocate overhead costs across services differently, which complicates

[2] Health Services Cost Review Commission. "Hospital Charge Targets FY2008." http://76.12.205.105/hsp_Rates3.cfm. Accessed May 4, 2010.

charge comparisons. However, the cost per case estimated by Commission staff is still well above the reported cost per case estimated by Kaiser based on the future budget of KPBSC.

Based on the projected case volume for KPBSC and the amount of surgery time for those cases, staff concludes that the proposed two operating rooms at KPBSC would be adequately utilized within the first two years of opening. The applicant has provided information on the cost of providing the surgical services at existing non-Kaiser facilities. Continuing to use non-Kaiser locations, such as hospitals, would likely be more expensive than handling surgical cases at a Kaiser facility. On this basis, the applicant has demonstrated that KPBSC is a cost-effective approach to expanding its surgical capacity and increasing access to services for its members.

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.

Applicant's Response

The applicant has provided information on the availability of resources required to develop the proposed project and sustain its operation. Kaiser plans to finance the project through cash in the amount of $8,906,397. (DI#11, Exhibit 1). It has projected utilization, staffing, revenue, and expense levels for the proposed facility. As required, Kaiser submitted audited financial statements for the previous two years, 2008 and 2007. These statements show that Kaiser generated a profit in both years and has adequate funds for the proposed project. (DI#4, Exhibit 6). In addition, one hospital executive and three local government representatives submitted letters of support. (DI#8).

Staff Analysis

Compared to other HMOs in Maryland, for CY2007 Kaiser reports the highest total asset value and revenue total.[3] Among the eight HMOS in Maryland, Kaiser has the third largest net profit. Information for more recent years is not yet available. Based on the available information, Kaiser appears to be in a strong financial position relative to other HMOs.

As shown in Table 9, the projected capital cost for KPBSC is above the average cost per surgical room of surgical projects reviewed by MHCC in the past four years. Among these projects, the projects that include construction of both operating rooms and procedure rooms have a much lower capital cost per surgical room. Kaiser's proposed project involves only building operating rooms, which would be expected to be more expensive. The cost of KPBSC is consistent with two other Kaiser projects that were recently approved by the Commission.

[3] Maryland Insurance Administration. Document emailed to Commission staff by Karen Barrow June 10, 2010.

Table 9: Costs of FASF Projects Recently Filed for CON Review and the Proposed Project

Facility	Year of Cost Estimate	Project	Estimated Capital Cost	Estimated Capital Cost per Surgical Room
Orthopaedic and Sports Medicine Center	2007	New Facility Buildout 3 ORs/2 PRs	$5,318,519	$1,063,704
Hanover Surgery Center	2007	New Facility Buildout 3 ORs/2 PRs	$5,251,982	$1,050,396
Frederick Surgical Center	2009	New Renovated Facility 4 ORs/3 PRs	$2,429,540	$347,077
Kaiser Permanente Gaithersburg Surgical Center	2010	New Facility Buildout, 3 ORs (1 Shelled)	$9,594,090	$3,198,030
Kaiser Permanente Largo Surgical Center	2010	New Facility, 6 ORs	$16,916,103	$2,819,350.50
Average (5 Projects)	**2007-2009**	**26 Total Surgical Rooms**	**$7,902,047**	**$1,695,712**
Kaiser Permanente Baltimore Surgical Center	2010	New Facility Buildout, 3 ORs (1 Shelled)	$8,861,397	$2,953,799

Source: MHCC CON Files and DI#11, Exhibit 1.

Staff analyzed the project costs and compared them to the MVS guidelines for construction. Commission staff uses the MVS guidelines to evaluate the reasonableness of construction costs for CON projects, as applicable. The MVS analysis shows that the proposed project is below the MVS benchmark of $318.56 by the amount of $38.16.

Kaiser does not charge for individual services, so charges cannot be compared to those of other existing facilities. (See earlier discussion at COMAR 10.24.11.06 on charges). The projected expenses reported by Kaiser suggest that it will realize a profit because surgical cases performed on Kaiser members in hospitals are more expensive than the projected expenses estimated by Kaiser (DI#4 page 22 and DI#19, pages 1-3). By shifting Kaiser members' surgeries to a less expensive setting, Kaiser will likely be able to reduce costs (DI#4, page 39). In addition, the costs per surgical case projected by Kaiser ($1,810) are within the range of the average cost per case reported by other multispecialty freestanding ambulatory surgical facilities, suggesting that the projected expenses for KPBSC are reasonable. As indicated by the audited financial statements submitted by Kaiser, Kaiser realized a profit in both 2008 and 2007.

KPBSC has projected costs per surgical case that are in line with similar projects recently reviewed by the Commission. The costs per case are also not excessively higher than the average cost per case calculated from the information submitted for MHCC's annual survey of freestanding ambulatory surgical facilities for CY2008. The capital costs are below the MVS benchmark, and therefore are reasonable. In addition, projections for case volume suggest that the operating rooms will be sufficiently utilized and will allow Kaiser to realize a net profit in future years. Commission staff concludes that the facility will be a viable and that the proposed project is financially feasible.

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.

The applicant applied for and received two CONs recently. On May 20, 2010, the Kaiser Gaithersburg Surgical Center (Docket No. 09-15-2303) and Kaiser Largo Surgical Center (Docket No. 09-10-2302) were approved. Conditions were included in both of these projects; however, the deadlines for meeting these conditions have not yet passed. Kaiser's only existing freestanding ambulatory surgical facility in Maryland, located in Kensington, was established prior to the passage of Certificate of Need requirements for ambulatory surgical facilities.

Following the establishment of CON requirements for ambulatory surgical facilities, in February 1995, representatives for Kaiser requested confirmation from the Maryland Health Resources Planning Commission (MHRPC) that Kaiser would be able to establish additional ambulatory surgery facilities that would not be subject to CON review. Kaiser explained that it does not seek reimbursement from third party payors except in very limited circumstances, and therefore new surgical facilities would not meet the definition of "ambulatory surgery center" used for CON reviews. At that time, the Executive Director of MHRPC agreed with the argument presented by Kaiser. However, in 2009, when Kaiser sought a determination that the proposed project would not be subject to CON review, the Executive Director of MHCC responded that if Kaiser plans to seek any third party reimbursement for surgical services at a new surgical facility, Maryland statute requires Certificate of Need review.

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.

Kaiser states that the facility that will be most affected by the proposed project is Greater Baltimore Medical Center (GBMC). Based on Kaiser's analysis of HSCRC data, it found that 2,098 ambulatory surgical cases were performed at GBMC on Kaiser members from the primary service area of KPBSC (DI#11, page 3). This represents 59 percent of all ambulatory surgical cases performed in Maryland hospitals on Kaiser members from the primary service area of KPBSC (DI#11, page 3). The other Maryland hospitals with the next highest volumes of ambulatory surgical cases performed on Kaiser members in the primary service area of KPBSC are Johns Hopkins Hospital (269 cases) and Saint Agnes Hospital (232 cases) (DI#11, page 3).

At GBMC, the hospital that will be most affected by the proposed project, Kaiser notes that 37,823 surgery cases were performed there in CY2007, according to the Commission's 2008 *Maryland Ambulatory Surgery Provider Directory* (DI#4, page 47). Kaiser mentions this to illustrate the relatively small portion of surgical volume that it will be pulling away, if the proposed project is implemented. Kaiser also states that it has a mutually beneficial relationship with GBMC; GBMC benefits from admissions of Kaiser members and GBMC's provision of other services that Kaiser does not provide (DI#4, page 47).

Kaiser also states that travel time will be reduced for Kaiser members, resulting in a substantial benefit for its members. For Kaiser members living in the service area of KPBSC, 93.3 percent will be within a 30-minute drive time from the facility (DI#4, pages 34-35).

Kaiser does not anticipate that recruitment of personnel will be a problem. The administrator for Kaiser's only existing ambulatory surgical facility in Maryland, Kaiser Permanente Kensington Surgery Center, reported that maintaining full staff levels has not been a problem. Vacancy and turnover rates are not available for only the ambulatory surgical portion of Kaiser's Kensington medical center. Vacancy and turnover rates for the entire medical center are 5.5 percent and 10.2 percent, respectively (DI#4, page 48).

Staff Analysis

Commission staff agrees that the proposed project will not negatively affect demographic and geographic access to services. The case volume to be shifted away from GBMC likely accounts for about two operating rooms, based on an average case time of 55 minutes and turnaround time of 30 minutes. Kaiser used 55 minutes in its calculations of operating room utilization for KPBSC (DI#4, page 32). For the other hospitals anticipated to be most affected by the proposed project, Johns Hopkins Hospital, Saint Agnes Hospital, and Johns Hopkins Bayview Medical Center, operating room use will be reduced by less half of one operating room. Consequently, Commission staff concludes that the reduction in surgical volume resulting from the shifting of Kaiser patients will have little impact on Johns Hopkins Hospital, Saint Agnes Hospital, and Johns Hopkins Bayview Medical Center. The impact on GBMC is greater, but relative to the number of mixed-use operating rooms at GBMC (27), two operating rooms is a small percentage. In addition, based on information reported by GBMC for CY2008, the operating rooms are currently operating over the optimal capacity standard of 97, 920 minutes per operating room; GBMC reported information that indicates use of over 110,000 minutes per mixed-use operating room.

No one raised objections to the proposed project. The President and CEO of GBMC submitted a letter of support for the proposed facility, as did the President and CEO of Saint Agnes Health Care. (DI#8). In addition, six other persons from the community wrote letters of support for the proposed facility (DI#8).

The benefit to Kaiser members of a shorter drive time is not as great as suggested by Kaiser. The alternative locations for surgical services include hospitals that appear to also be equally convenient to Kaiser members in the primary service are of KPBSC, based on Commission staff's own analysis of drive-time to GBMC and the other three hospitals with the highest volume of Kaiser members undergoing ambulatory surgery. Many Kaiser members already live in zip code areas that are within a 30 minute drive of one of the four Maryland hospitals that accounted for over 80 percent of the ambulatory surgeries in CY2008 of Kaiser members in the primary service area of KPBSC. Ninety-one of the 116 zip code areas that are part of the primary service area of KPBSC are within a 30 minute drive of the four hospitals with the highest volume of Kaiser ambulatory surgery cases. In contrast, only 76 zip code areas in the primary service area are within a 30 minute drive of the proposed site for KPBSC.

The proposed project is unlikely to alter costs for consumers generally. Many of the cases for the proposed facility are spread among multiple locations and even for the facility with the largest proportion of cases to be moved to KPBSC, the cases represent a small proportion of the hospitals' total surgical volume. As a result, neither Kaiser nor the affected hospitals will have greater influence on the price of surgical services. In addition, the unique payment structure of Kaiser is such that it does not charge patients for surgical services. Thus, the price of surgical services is not transparent for patients or readily comparable to prices at other locations.

Commission staff concludes that the proposed project will not have an undue negative impact on existing health care providers in the service area. The proposed project also will not negatively affect geographic or demographic access to ambulatory surgical services. Finally, the costs and charges of other providers will not be negatively affected by KPBSC.

V. SUMMARY AND 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, State Health Plan for Ambulatory Surgical Services, Commission staff recommends approval of the project.

- KPBSC has demonstrated that the proposed facility will be able to utilize two operating rooms within two years of opening the facility, based on estimates of the surgery rate per 1,000 Kaiser members and Kaiser membership projections.

- KPBSC has demonstrated that the proposed new facility is a more cost-effective approach than continuing to use existing facilities. In addition the proposed project will not negatively affect the availability and accessibility to surgical facilities for Kaiser members in the primary service area of KPBSC.

- The proposed new facility will not have a negative impact on other surgical facilities. The proposed project will shift cases from hospitals, but the reduction in total surgical case volume for any one hospital will not reduce the utilization of operating rooms below the optimal capacity standard.

IN THE MATTER OF	*	BEFORE THE
	*	
KAISER PERMANENTE	*	MARYLAND HEALTH
	*	
BALTMORE	*	CARE COMMISSION
	*	
CENTER	*	
	*	
	*	
DOCKET NO. 10-03-2306	*	
	*	

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FINAL ORDER

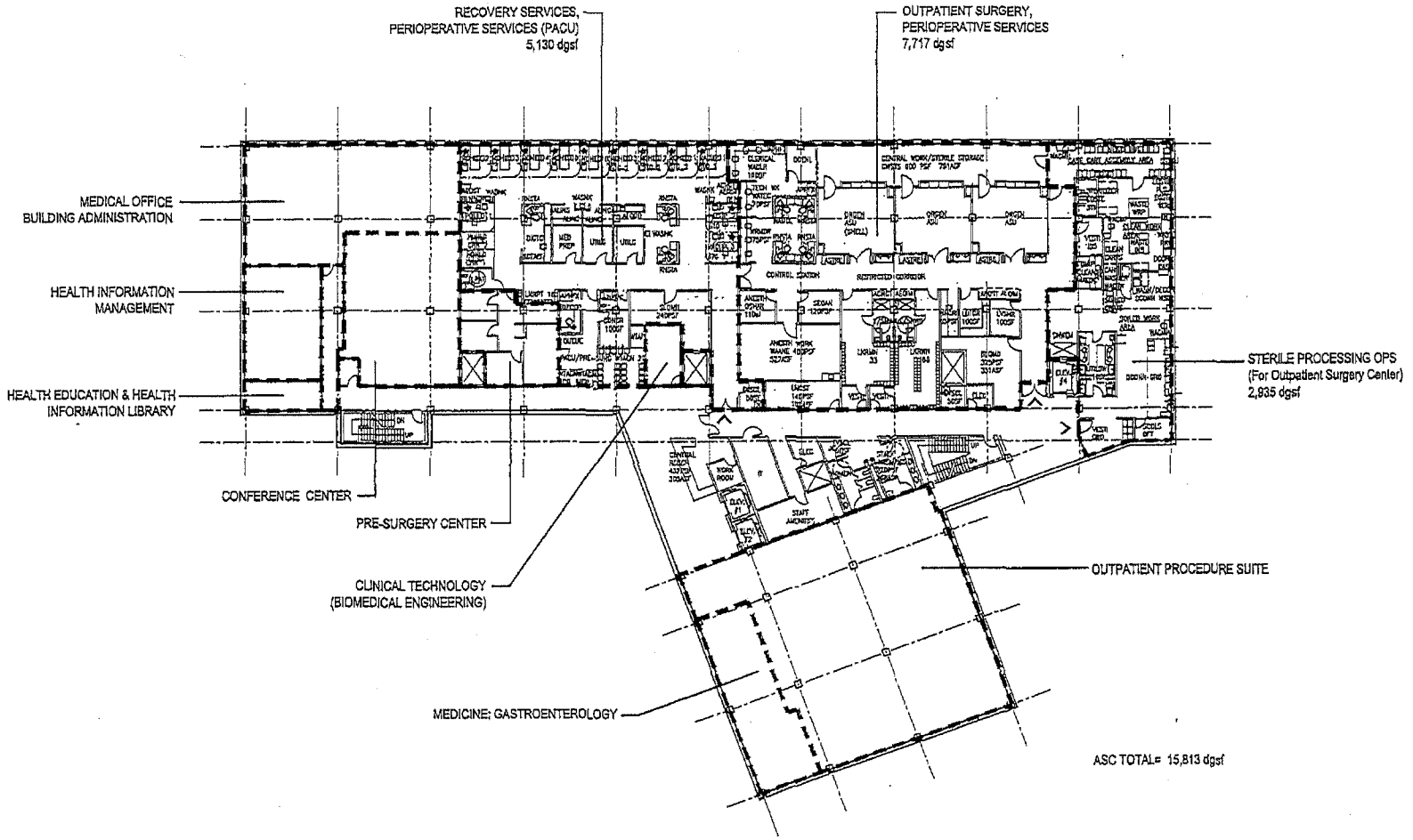
Based on the analysis and findings contained in the Staff Report and Recommendation, it is this 17th day of June, 2010, by a majority of the Maryland Health Care Commission, **ORDERED:**

That the application of Kaiser Permanente for a Certificate of Need to establish a freestanding ambulatory surgery facility, Kaiser Permanente Baltimore Surgical Center with two operating rooms at 1601 Odensos Lane, Baltimore, Maryland, at a cost of $8,906,397 is **APPROVED**, with the following conditions:

1. KPBSC must provide the Commission with documentation that it has obtained accreditation from the Joint Commission on Accreditation of Healthcare Organizations or the Accreditation Association for Ambulatory Health Care within 18 months of first use approval.

2. Before first use approval of KPBSC, Kaiser shall submit a transfer agreement that meets the requirements of the Department of Health and Mental Hygiene regulations implementing Health-General Article, §19-308.2, Annotated Code of Maryland.

Maryland Health Care Commission



South Baltimore MOB

Proposed Ambulatory Surgery Center

Certificate of Need

January 8th, 2010

KAISER PERMANENTE®

HDR

APPENDIX B

Appendix B: Kaiser Permanente's Existing and Proposed Ambulatory Surgery Facilities in Maryland