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MEMORANDUM

To: Commissioners

From: Eileen Fleck, Program Manager E.F.

Date: May 20, 2010

Re: Kaiser Permanente Gaithersburg Surgical Center
Docket No. 09-15-2303

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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 Largo, Maryland. The proposed facility will include two operating rooms and shell space for one additional operating room. It will also include the necessary preoperative, postoperative, storage, and support spaces. The facility will be used almost exclusively for members of Kaiser health plans.

The project is estimated to cost $9,549,090. 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
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KAISER PERMANENTE	*	MARYLAND HEALTH
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GAITHERSBURG SURGICAL	*	CARE COMMISSION
	*	
CENTER	*	
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DOCKET NO. 09-15-2303	*	
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Staff Report and Recommendation

May 20, 2010

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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 purchase an existing six story medical office building that is 200,000 square feet in order to establish a large, comprehensive medical office. Kaiser proposes the re-design approximately 17,353 square feet of the building as an outpatient surgical facility with two operating rooms and shell space for one additional operating room. The facility will be named Kaiser Permanente Gaithersburg Surgery Center ("KPGSC"). There will be four procedure rooms located on the same floor as KPGSC in the medical office building to be purchased by Kaiser. However, these procedure rooms have not been incorporated into the space designated as KPGSC. The cost of constructing and operating the procedure rooms is not reflected in the budget for KPGSC. 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#2, page 9). Upon opening KPGSC, Kaiser will close two operating rooms at its existing facility located in Kensington, Montgomery County, Maryland (DI#2, page 9).

Table 1: Proposed Facility Capacity for Kaiser Permanente Gaithersburg 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).

The total estimated capital cost of the project is $9,495,188. The cost of renovations is the largest component of the project, at $5,317,163. Equipment costs (major and minor equipment and radiology equipment) are the second largest expense, at $3,940,346. The source of project funding is $9,549,090 in cash. (DI#10, Exhibit 2).

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. 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 Montgomery County increased at an average annual rate of 3.2 percent between 2001 and 2008.

- The number of outpatient surgeries at Maryland hospitals for residents in the primary service area of KPGSC increased from 2001-2008 at an average annual rate of 10.2 percent.

Projected Utilization

- Recent trends in Kaiser's membership levels for those in the primary service area of KPGSC suggest that KPGSC will not 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. However, Kaiser has shown that limiting the facility to one operating room would result in operation above optimal utilization.

Impact on Existing Programs

- The impact of the proposed new facility on existing surgical facilities in Maryland is likely to be minimal because the facility will be shifting cases from several locations. The greatest impact will be on an existing Kaiser location. In addition, no person sought interested party status in this review or otherwise raised objections to the proposed project.

Availability of More Cost-Effective Alternatives

- Kaiser reasonably rejected the alternative of building an addition to the Kensington facility because the facility would be unable to accommodate CT/MRI imaging equipment, which may be needed for some patients receiving care, including surgeries, in Kaiser's medical office building.

- Shifting surgical cases that are currently performed in hospitals to KPGSC would likely reduce the cost of these cases.

Viability of the Proposal

- KPGSC has projected costs per surgical case that are in line with the average cost per case at other freestanding ambulatory surgical facilities. The capital costs are below the Marshall Valuation Service benchmark, and therefore are reasonable. 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 October 5, 2009, Commission staff acknowledged Kaiser's submission of a Letter of Intent to apply for a CON to construct a freestanding ambulatory surgery facility in Gaithersburg. [Docket Item (DI) # 1].

Kaiser filed its Certificate of Need application for a new facility to be located in Montgomery County on December 4, 2009 (DI#2). Acknowledgement of receipt of the application was sent on December 10, 2009 (DI#4), and a notice was published in the Maryland Register Electronic Filing System on December 10, 2009 (DI#6).

On December 10, 2009, the Commission requested that the *Washington Examiner* publish notice of the receipt of the KPGSC application (DI#5). On December 18, 2009, Commission staff received a copy of the notice of receipt of application that was published in the *Washington Examiner* (DI#7).

On December 18, 2009, Commission staff requested that the applicant provide information based on a completeness review of the application (DI#8). On December 28, 2009, Commission staff received the applicant's e-mail request for an extension to respond to completeness questions by January 22, 2010 (DI#9) and granted the requested extension.

KPGSC filed its its response to the completeness questions on January 22, 2010 (DI#10).

On January 27, 2010, Commission staff received a request from MedStar Health to receive notification on the review (DI#11). On the same date, Commission staff received a request from Adventist HealthCare for notification regarding the review (DI#12).

On February 1, 2010, Commission staff requested that notice be provided in the Maryland Register Electronic Filing System that the application for KPGSC would be docketed as of February 12, 2010 (DI#13).

Commission staff notified KPGSC on February 4, 2010 that its application would be docketed effective the February 12, 2010 publication of a notice of docketing in the *Maryland Register*, and requested additional information (DI#14).

On February 18, 2010, the Commission requested that notice of the docketing of KPGSC's application be published in the next edition of the *Washington Examiner* (DI#15). On February 28, 2010, Commission staff provided a copy of the notice of the formal start of the review that was published in the *Washington Examiner* (DI#16).

KPGSC filed its responses to additional information questions on March 24, 2010 (DI#17).

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

Local Health Department Review and Comment

The Montgomery County Health Department expressed support for the project on May 13, 2010.

Community Support

Letters of support were submitted by Rob Garagiola, Senator for Montgomery County (District 15), Jennie Forehand, Senator for Montgomery County (District 17), and George L. Leventhal, Montgomery County Council Member. (DI#2, Exhibit 7).

William G. Robertson, President and C.E.O. of Adventist HealthCare, and Kevin J. Sexton, President and C.E.O. of Holy Cross Hospital, also provided letters of support. (DI#2, Exhibit 7).

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 once limited to provision on an inpatient basis are now performed as outpatient surgeries.

Since 1995, Maryland law has exempted surgical facilities with a single operating room from CON regulation. Prior to that time, it exempted single-specialty facilities 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 freestanding facilities 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.

In the two Maryland counties identified as the primary service area for KPGSC, the historic trend in case volume for ambulatory surgery differs. In Montgomery County, the number of ambulatory surgery cases increased from 75,138 cases to 76,708 cases from 2001 to 2008; this is an average annual growth rate of 0.3 percent a year. The number of operating room cases at ambulatory surgical centers in Montgomery County showed stronger growth for this period; operating room cases increased at an average annual rate of 3.2 percent between 2001 and 2008. In Frederick County, the total case volume decreased from 2001 to 2008, at an average annual rate of 1.9 percent; the total number of cases declined from 12,947 to 11,316. Similarly, the number of operating room cases at ambulatory surgical centers in Frederick County declined at an average annual rate of 1.7 percent. Statewide, between 2001 and 2008, the average annual rate of growth in case volume for ASCs, 8.3 percent, was much greater than in Montgomery and Frederick Counties.

At acute care hospitals located in Montgomery and Frederick Counties, the number of ambulatory surgery cases performed generally declined between 2001 and 2008. Collectively, at the six hospitals located in either Montgomery or Frederick County, a total of 58,141 ambulatory surgeries were performed in 2001, but only 55,355 were performed at those locations in 2008, as shown in Table 2. Statewide hospitals in Maryland have seen an increase of 27 percent in ambulatory surgical case volume for this period.

Table 2: Ambulatory Surgery Cases in Hospitals Located in Montgomery County and Frederick County, CY2001 and CY2008

Hospital Name	Number of Cases		Percent Change
	2001	2008	2001-2008
Montgomery County			
Holy Cross Hospital	11,014	15,222	38.2%
Washington Adventist Hospital	6,574	4,850	-26.2%
Montgomery General Hospital	4,626	4,701	1.6%
Suburban Hospital	11,642	8,396	-27.9%
Shady Grove Adventist Hospital	15,168	13,671	-9.9%
Frederick County			
Frederick Memorial Hospital	9,117	8,515	-6.6%
Total	58,141	55,355	-4.8%

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

Although the number of ambulatory surgical cases has declined at the majority of hospitals in the counties identified as part of the primary service area for KPGSC, the number of outpatient surgeries at Maryland hospitals for residents in the primary service area of KPGSC increased from 2001 to 2008, at an average annual rate of 10.2 percent. These residents are having their surgeries at hospitals outside their counties of residence. This may be the result of either individual decisions or referral patterns.

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. Therefore, this standard is not applicable. (DI#2, page 17).

(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.

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. For 2009, Kaiser forecasted expenditures of $843,472 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. KPGSC complies with this standard. (DI#2, 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 KPGSC will be licensed by the State and will be Medicare certified. KPGSC will also comply with all mandated federal, State, and local health and safety regulations. KPGSC is consistent with this standard. (DI#2, page 21).

(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 KPGSC will be licensed by the State and will be Medicare certified. In addition, the applicant states that KPGSC will obtain accreditation from the Accreditation Association for Ambulatory Health Care (DI#2, page 22). With regard to Medicaid certification, the applicant stated that KPGSC should not be required to obtain the certification because KPGSC 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#2, pages 22-23). KPGSC 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 would not enhance the safety of patients.

Kaiser's existing Kensington facility has not been accredited, although the facility is in the process of applying for accreditation from AAAHC. Therefore, Commission staff recommends the following condition:

> *KPGSC 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.

KPGSC 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#2, Exhibit 4). The applicant also noted that ambulance service will be provided by the Emergency Medical System through calling 911 (DI#2, 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 KPGSC, 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 KPGSC will have a utilization review and control program. A detailed description of the program is included in the CON application (DI#2, 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#2, page 25). KPGSC 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#2, 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 Frederick and Montgomery Counties. The vast majority of Kaiser members served by KPGSC are expected to be residents of Montgomery County (84.0 percent) (DI#17, page 2). 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 KPGSC does not charge for procedures except in rare circumstances (DI#2, 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 Montgomery County who had surgeries at Maryland hospitals. The highest number of these cases were performed at Holy Cross Hospital (601) or 63 percent of the total number of ambulatory surgical cases performed on Kaiser members from Montgomery County in CY2008 (DI#2, pages 28-29). The average charge across all Maryland hospitals, for Kaiser members residing in Montgomery County, is $2,951. (DI#2, page 28). In contrast, the applicant noted that the average cost per case at KPGSC is projected to be $2,356 in 2011 (DI#2, page 29).

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 KPGSC may be a comparison of the estimated expense per case for KPGSC 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 KPGSC ($2,356) is higher than the average for multispecialty ambulatory surgery facilities with only operating room cases reported ($1,359). Notably though, the cost per case ranges widely among freestanding ambulatory surgery facilities, as shown in Table 3.

Table 3: Comparison of Average Expense Per Case for Select Locations, CY2008

Comparison Facility	Number of Locations Included	Average Expense Per Case	Range
KPGSC	1	$2,531	N/A
Multi-specialty with only ORs*	10	$1,359	$610- $22,688

Source: Staff analysis of MHCC Survey of Freestanding Ambulatory Surgery Facilities for CY2008 and DI#2, page 29.
*Note: Information on the MHCC Survey of Freestanding Ambulatory Surgery Facilities is self-reported.

Although there are not any comparable charge data for KPGSC, 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. KPGSC 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. Other services, such as imaging or additional laboratory services will be located elsewhere in the same building as KPGSC. Pathology services will be provided through a regionally centralized pathology service located in Rockville that is also operated by Kaiser. KPGSC is consistent with this standard. (DI#2, page 29).

(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 KPGSC 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. KPGSC will also obtain accreditation from the Accreditation Association for Ambulatory Health Care. The applicant requested that Medicaid certification not be required because KPGSC 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. Commission staff agrees Medicaid certification should not be required because the vast majority of patients to be served by KPGSC 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 acceptable. (DI#2, pages 21-22).

(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#2, page 30). 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#2, page 31). Kaiser stated that these projections show a need for 1.84 operating rooms in 2013, the second year of operation for KPGSC (DI#2, page 32). Kaiser also provided a conservative estimate, assuming that membership levels remain the same in 2013 as they were in 2009. Under this assumption, 1.42 operating rooms will be needed (DI#2, page 32).

Commission staff regards the conservative estimate provided by Kaiser as more appropriate, based on the historical levels of Kaiser members for the primary service area of KPGSC 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 KPGSC, refer to the "Need" section of this report. Commission staff concludes that two operating rooms will not be used at optimal capacity by the second full year of operation. However, Kaiser has shown that more than one operating will likely be used at greater than optimal capacity within two years of opening KPGSC. For this reason, two operating rooms are appropriate for the 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.

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 the projected membership levels for residents in the primary service area of KPGSC, an estimated rate of ambulatory surgery per 1,000 Kaiser members, and the estimated procedure time for ambulatory surgery cases (DI#2, 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#2, page 36). Table 4 below shows the historical number of Kaiser members in the primary service area for KPGSC from 2004-2009 and the projected number of members for 2010-2013.

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

	History						Forecast			
Area	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**
Frederick	--	--	482	3,828	5,158	5,266	7,176	8,091	9,052	10,138
Gaithersburg	21,305	21,353	19,329	17,412	17,601	16,466	17,424	17,984	18,699	19,573
Germantown	5,493	6,422	6,911	6,086	6,112	5,762	6,121	6,362	6,658	7,026
Shady Grove	6,033	6,513	7,571	6,665	5,531	5,408	5,415	5,543	5,719	5,833
Total	32,831	34,288	34,293	33,991	34,402	32,902	36,137	37,981	40,129	42,570

Source: DI#2, page 31

The applicant calculated the projected number of surgery cases for 2010-2013 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 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 KPGSC by analyzing its surgical data for the Mid-Atlantic Region, including both cases performed at Kaiser facilities and non-Kaiser facilities (DI#2, 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#2, page 31). 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 2013. Kaiser calculated the need for operating rooms using the projected membership for 2013, 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 concludes that two operating rooms are needed in 2013.

Table 5: Projected Need for Operating Rooms at KPGSC at 2013 Kaiser Membership Level

Specialty	Average Case Time (minutes)	Rate per 1,000 Members	Cases, 2013 Forecast	Surgical Minutes	Turnaround Minutes	Total Minutes	Operating Room Need
Ear, Nose, Throat	66	6.1	260	17,139	7,790	24,929	
General Surgery	66	9.5	404	26,691	12,132	38,823	
Gastroenterology	36	1.3	55	1,992	1,660	3,652	
OB-GYN	60	4.6	196	11,749	5,875	17,624	
Ophthalmology	36	6.6	281	10,115	8,429	18,544	
Orthopedic	60	10.7	455	27,330	13,665	40,995	
Plastic Surgery	90	0.9	38	3,448	1,149	4,597	
Podiatry	78	3.6	153	11,954	4,598	16,552	
Retinal Service	72	0.2	9	613	255	868	
Urology	54	3.8	162	8,735	4,853	13,588	
Total	59.5	47.3	2,014	119,766	60,407	180,173	1.84

Source: DI#2, page 32, except "Total Minutes" were calculated by Commission staff.

As shown in Table 5, the overall ambulatory surgery rate per 1,000 members that Kaiser uses to justify a need for two operating rooms is 47.3. The applicant subsequently estimated the surgical case rate per 1,000 members in the primary service area of KPGSC and Kaiser's Kensington location by counting hospital cases with Kaiser as the payer in the outpatient database of the Health Services Cost Review Commission (HSCRC that have an operating room charge over one dollar and an encounter type of "Outpatient Surgery" or "Other." In addition, the applicant included CY2008 cases for Kaiser members who live within the primary service area of KPGSC and had surgeries performed in Washington, D.C. hospitals, at Kaiser's Kensington facility, at other freestanding non-Kaiser ambulatory surgery centers, and at Kaiser's facility in Falls Church, Virginia. The total cases from each source are shown in Table 6. The Kaiser member count used in the denominator reflects the number of Kaiser members in the primary service area for KPGSC and Kensington in CY2008, a total of 85,652 members. Kaiser notes that the data for Washington, D.C. facilities is likely incomplete, resulting in a lower case rate. (DI#10, pages 9-10).

Table 6: Calculation of Overall Ambulatory Surgery Rate for KPGSC Service Area, CY2008

Category	Number of Cases
Maryland Hospitals	1,161
Kaiser's ASC in Falls Church, Virginia	78
Non-Kaiser Freestanding ASCs	98
Washington, DC Hospitals	237
Kaiser's Kensington ASC	2,101
Total Cases	3,675
Membership for KPGSC and Kensington Service Areas	85,652
Cases per 1,000 Members	42.9

Source: DI#10, pages 9-10.

Kaiser did not update its need projection based on the surgery rate shown in Table 6 because it believes that the cases performed in Washington, D.C. hospitals are undercounted (DI#10 , page 8). However, Kaiser also created a projection of operating room capacity needed, assuming membership level are only at the 2009 level. This estimate shows a need for 1.42 operating rooms, and Kaiser considers it appropriate to round up to two operating rooms. (DI#2, page 32).

For Kaiser's Kensington facility, Kaiser presents information that two operating rooms will be needed after KPGSC is built. Kaiser's Kensington facility has four operating rooms now, but fewer operating rooms will be needed if KPGSC is built because its primary service area overlaps with the current service area for Kaiser's Kensington facility. Kaiser projects that 2.25 operating rooms will be needed in 2013, using the optimal capacity standard for an operating room in the SHP (97,920 minutes), a surgery rate of 47.3, an average case time of 59.5 minutes, and 30 minutes of turnaround time per case. Kaiser also assumes that membership will grow from 48,502 in 2009 to 51,965 in 2013 (DI#2, pages 33-34.) As a result of the reduced need for operating rooms at Kaiser's Kensington facility, Kaiser intends to close two of the four operating rooms at its Kensington facility.

With regard to membership growth, Kaiser justifies the projected membership growth by citing an anticipated increase in consumer satisfaction. Kaiser noted that Northern California's scores for the overall health plan on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) were three percent higher than the Mid-Atlantic region, and scores for overall health care were six percent higher. In addition, the member termination rate for the Northern California members was more than three percent less than the Mid-Atlantic's rate. Kaiser links the difference in member termination rates to the differences in consumer satisfaction, noting that the Mid-Atlantic's termination rate improved 0.7 percent over the previous year as satisfaction scores increased. (DI#17, pages 10-11).

Kaiser also presented information on an internal consumer satisfaction survey for spring and fall of both 2008 and 2009, conducted with a random sample of adult members who had

been Kaiser members for at least 12 months, in order to demonstrate the connection between member satisfaction and growth in membership. The results from this survey (METEOR) show that the overall health plan rating was 66 percent in spring of 2008, fall of 2008, and Spring of 2009. In the fall of 2009, the overall health plan rating increased to 73 percent. Kaiser attributes the increased satisfaction and greater retention to implementation of its business strategy. (DI#17, pages 11-12).

Kaiser provides an additional reason why KPGSC will meet the needs of its members: improved access. Kaiser performed a travel time analysis to identify the number of Kaiser members in the primary service area of KPGSC that are within a 15-minute drive of KPGSC. Approximately 75 percent of these members are within a 15-minute drive of KPGSC. (DI#2, pages 35 -37).

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 KPGSC and a projection of the surgical case rate. Kaiser relies on historic information as well as other research to justify its need projections. The use of historic trends to create future projections is consistent with the approach of Commission staff to CON requests. Although Commission staff disagrees with some of the conclusions reached by Kaiser, regarding both the projections for Kaiser members and the surgical rates cited, Commission staff concludes that two operating rooms are justified.

The historic information provided by Kaiser on its membership levels indicates membership growth has been flat, 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 five locations listed and average annual growth at the other two locations of one percent or less, as shown in Table 8.

Table 7: Kaiser Membership, Actual and Projected for KPGSC and Kensington Service Areas

	Actual						Forecast			
Location	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**
Frederick	--	--	482	3,828	5,158	5,266	7,176	8,091	9,052	10,138
Gaithersburg	21,305	21,353	19,329	17,412	17,601	16,466	17,424	17,984	18,699	19,573
Germantown	5,493	6,422	6,911	6,086	6,112	5,762	6,121	6,362	6,658	7,026
Shady Grove	6,033	6,513	7,571	6,665	5,531	5,408	5,415	5,543	5,719	5,833
Subtotal	32,831	34,288	34,293	33,991	34,402	32,902	36,137	37,981	40,129	42,570
Kensington	32,763	32,832	33,452	32,140	32,927	31,200	32,517	31,824	32,725	33,062
Silver Spring	17,054	17,815	18,543	18,194	18,323	17,302	18,178	18,529	18,970	18,904
Subtotal	49,817	50,647	51,995	50,334	51,250	48,502	50,695	50,353	51,695	51,965
Total	82,648	84,935	86,288	84,325	85,652	81,404	86,832	88,334	91,824	94,535

Source: DI#2, pages 31 and 33.

Table 8: Historic Level of Membership Change

Location	Average Annual Change 2004-2009
Frederick	NA
Gaithersburg	-5.0%
Germantown	1.0%
Shady Grove	-2.2%
Subtotal	0.0%
Kensington	-1.0%
Silver Spring	0.3%
Subtotal	-0.5%
Total	-0.3%

Source: MHCC staff analysis of DI#2, pages 31 and 33.

Despite the historic level of decline in Kaiser's membership for the KPGSC and Kensington service areas overall (-0.3 percent), Kaiser projects average annual growth of 3.8 percent for these locations. 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 1.5 percent annually, and increased growth in the federal workforce (DI#10, pages 10-11).

With regard to member satisfaction, Kaiser noted that Northern California's scores for the overall health plan on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) were three percent higher than the Mid-Atlantic region, and scores for overall health care were six percent higher. In addition, the member termination rate for the Northern California members was over three percent less than its Mid-Atlantic's rate. Kaiser links the difference in member termination rates to the differences in consumer satisfaction, noting that the Mid-Atlantic's termination rate improved 0.7 percent over the previous year as satisfaction scores increased. Kaiser also presented information on an internal consumer satisfaction for Spring and Fall of both 2008 and 2009. (DI#17, pages 10-11).

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. 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. Given the level of consumer satisfaction, as noted for these measures, across time and relative to other health plans, it is not surprising that Kaiser's membership had not been growing.

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. Commission staff assigns greater weight to longer term trends, rather than a change from one year to the next. Therefore, Commission staff is skeptical that growth in the federal workforce by itself will result in a greater number of Kaiser members.

Population growth is another factor Kaiser expects to result in membership growth. Historically, from 2005 to 2010, the population in Montgomery County is projected to have increased from 929,106 to 965,996, based on data supplied by the Maryland Department of Planning in February 2009. However, Kaiser membership for those in the service area of KPGSC and Kensington has generally declined, in spite of population growth. Consequently, Commission staff is skeptical that population growth itself will lead to an increase in the number of Kaiser members.

The surgical case rates per 1,000 members calculated by Kaiser are too high to use to project the utilization of operating rooms at KPGSC. The initial estimated surgical rates, by specialty, result in a significantly higher rate of surgery than suggested by the HSCRC data. The initial forecast rate is 47.3 compared to 42.9, as calculated by Kaiser based on its review of HSCRC data (DI#10, pages 9-10). Commission staff's own analysis concludes that even 42.9 is too high to use as the surgical rate for Kaiser members in the primary service area of KPGSC. The rate Kaiser uses to project future utilization of operating rooms at KPGSC (47.3) does not account for the ambulatory surgical cases that are likely to continue being performed in hospitals due to patient characteristics. Kaiser estimates that 4.5 cases per 1,000 members may have outpatient surgery in a hospital setting because of significant medical co-morbidities (DI#19, page 5). An adjustment should be made to account for cases that will be performed in hospitals, even if new Kaiser facilities are built.

[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.

Commission staff also concluded that further adjustment of the surgical rate used for projections regarding operating room utilization at KPLSC is appropriate. 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).

Commission staff regards the appropriate rate of surgery for projecting the surgical case volume at KPGSC to be somewhere between 38.4 and 42.6 surgeries per 1,000 members. These values were calculated by subtracting 4.5 cases per 1,000 members from the surgery rate calculated from HSCRC data and Kaiser records (42.9) and from the adjusted surgery rate for Kaiser's Virginia members, which is also the projected rate for KPGSC (47.1).

The surgical rate per 1,000 Kaiser members calculated by staff reduces the need for operating rooms, but still results in a need for more than one operating room within two years of opening KPGSC. Depending on the number of Kaiser members who are assumed to be served by KPGSC, Commission staff calculates between 1.2 and 1.5 operating rooms will be needed, assuming 38.4 ambulatory surgeries per 1,000 members. The low end of the range assumes the number of Kaiser members in 2013 is the same level as in 2008 (34,402). The high end of the range assumes that the number of Kaiser members is 42,570, the estimate given by the applicant for KPGSC in 2013 (DI#2, page 32). If a higher surgery rate is assumed, 42.6 surgeries per 1,000 members, Commission staff calculates between 1.3 and 1.7 operating rooms will be needed.

Although Kaiser notes that the data from hospitals located in Washington, D.C. likely understates the number of surgeries, Commission staff does not have sufficient information to evaluate the extent to which surgeries may have been undercounted. Kaiser also did not attempt to quantify the extent to which cases may be undercounted. In addition, even if the data from hospitals in Washington, D.C. understates the number of surgical cases, Commission staff has found that the HSCRC data may overstate the number of ambulatory operating room cases. Data collected by the Maryland Health Care Commission on the annual survey of acute care hospitals regarding the number of cases for each type of operating room indicate a much lower number of surgical cases are performed in operating rooms than the number of cases in the HSCRC outpatient data with an operating room charge and an encounter type of "outpatient surgery" or "other outpatient." For example, the total number of surgery cases (both inpatient and outpatient) in operating rooms at one hospital was reported as 11,999 for CY2008. However, HSCRC data indicate a total of 22,224 such cases were performed in CY2008. Similar large discrepancies were noted in the vast majority of Maryland's hospitals. Consequently, Commission staff does not agree with Kaiser's assumption of 47.3 ambulatory surgeries per 1,000 members.

Commission staff concludes that the applicant may not achieve use of two operating rooms at optimal capacity within two years of completing KPGSC; however, the applicant has justified the construction of two operating rooms because more than one operating room will be needed within two years of opening KPGSC.

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's Response

Kaiser considered two alternative options to the proposed project. First, Kaiser considered creating an addition to its existing Kaiser facility located in Kensington. Second, Kaiser considered continuing to perform cases in acute care hospitals and other non-Kaiser setting. Kaiser concluded that neither of those options is cost-effective.

Kaiser considered adding a two story addition to its existing ambulatory surgery center in Kensington and renovating existing space for the addition of seven operating rooms. The preliminary estimate for the project was $19,621,725. Kaiser compared the project cost to the Marshall Valuation Service (MVS) benchmark and found that the project cost was below the MVS benchmark. However, Kaiser rejected this alternative because the building would not be large enough to accommodate CT/MRI imaging, and the project would not improve access to ambulatory surgery for Kaiser members by reducing the driving time to a Kaiser location. (DI#2, pages 39-42).

Kaiser also noted that performing cases in existing facilities, such as hospitals, is much more expensive that performing surgeries at Kaiser facilities. Using data from HSCRC, Kaiser analyzed the average charges for patients with Kaiser insurance who reside in Montgomery County and who had ambulatory surgeries at hospitals. For CY2008, Kaiser counted 951 surgeries at hospitals for Kaiser patients from the primary service area for KPGSC (DI#2, pages 28-29). The average charge for these cases was $2,951 compared to an estimated cost per case of $2,356 for KPGSC in 2013 (DI#2, pages 28-29). Kaiser also then analyzed HSCRC data for Kaiser members who reside in the service area of either Kaiser's Kensington location or KPGSC. For those Kaiser members, Kaiser counted 1,161 surgeries at hospitals in CY2008 (DI#10, pages 3-4). The average charge for those surgeries was $4,260, which is more than 50 percent higher than the estimated cost per case for KPGSC ($2,356).

Kaiser attempted to adjust for case mix by matching the primary ICD-9 code for each of the 1,161 surgical cases in the HSCRC data to a specialty and calculating the average charge for each specialty (DI#10, pages 4-5). Using this method, the average charge of hospital ambulatory surgery cases for patients with Kaiser insurance located within the primary service area of KPGSC was estimated to be a bit lower $3,975 (DI#10, page 4). However, Kaiser also noted that approximately 39 percent of the 1,161 cases identified as Kaiser patients within the service area of KPGSC and Kaiser's Kensington location could not be matched to a specialty, and the ICD-9 code may not accurately reflect the nature of the surgery (DI#10, page 5).

Staff Analysis

Commission staff concludes that Kaiser reasonably rejected the alternative of building an addition to the Kensington facility. Although it appears that building an addition to the Kensington facility and renovating space there would cost slightly less than the proposed project, assuming the equipment costs for each project are the same, the inability to accommodate CT/MRI imaging equipment is a legitimate reason to reject this alternative. Kaiser explained that the location of the Kensington facility is in a densely populated neighborhood, thereby restricting Kaiser's ability to expand both the facility and parking. If adequate parking is not available, it may not be convenient for Kaiser members to receive care at an expanded Kaiser Kensington facility. Kaiser also explained that the existing Imaging Center is located in the basement, making it challenging to place new MRI equipment in that space (DI#10, page 17). The CT/MRI imaging equipment may be needed for some patients receiving care, including surgeries, in Kaiser's medical office building. Efficiency or Kaiser members' satisfaction may be compromised if there is insufficient imaging equipment at Kaisers' medical buildings.

With regard to cost of Kaiser cases performed in hospitals, Commission staff believes the cost of performing surgical cases in hospitals is not as great as suggested by Kaiser's analysis. The costs included in the field "total costs" of the HSCRC data may include therapeutic services (physical, speech, occupational), diagnostic radiology tests, and diagnostic scans (MRI, CAT, etc). These are costs that were not counted as costs in the KPGSC budget. After eliminating many types of costs from the HSCRC data for ambulatory surgical cases, Commission staff calculates the average cost per case for cases that Kaiser anticipates moving to KPGSC is $3,647. This is significantly lower than the value calculated by Kaiser including all types of charges, $4,260 (DI#10, page 4). It is also lower than the cost per case estimated by Kaiser ($3,975), based on categorizing cases into medical specialties according to the primary diagnosis code (DI#10, page 5). The cost per ambulatory surgical case calculated by Commission staff may also be high compared to the estimated expense per case at KPGSC because a profit margin is built into hospital changes, 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. 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 KPGSC.

As an alternative to performing cases at KPGSC, Kaiser could continue to operate all four operating rooms at its Kensington location. There is likely greater efficiency in relying on a single Kaiser site with four operating rooms, rather than two sites, each with two operating rooms in use. The estimated staffing per operating room required for KPGSC, which would have two operating rooms in use, is slightly higher than at Kensington, which currently has four operating rooms in use. Commission staff calculated that KPGSC will have 3.9 percent more full-time equivalent staff (FTEs) per operating room than Kensington. In addition, the cost per case for Kensington in CY2008 ($1,717), calculated by staff from the information submitted on the annual survey of ambulatory surgery centers, is higher than the expense per case projected for KPGSC in its second year of operation ($2,356) (DI#2, page 29).

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

Based on the projected case volume for KPGSC and the amount of surgery time for those cases, staff concludes that the proposed two operating rooms at KPGSC would be under utilized for at least the first few years of operation. As previously shown in Table 5, KPGSC has projected a need for two ORs in 2013 based on the estimated rate of surgery and membership growth trends. The applicant has provided information on the capital cost of providing the surgical services through renovations at Kaiser's Kensington location and the alternative of continuing to use existing non-Kaiser facilities. As discussed above, renovating Kaiser's Kensington location would not meet the need to accommodate CT/MRI imaging equipment or for greater access of Kaiser members. In addition, continuing to use alternative non-Kaiser locations would likely be more expensive than handling surgical cases at a Kaiser facility. On this basis, the applicant has demonstrated that KPGSC 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.

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 $9,594,090 (DI#10, Exhibit 2). 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#2, Exhibit 6). In addition, two hospital executive and three local government representatives submitted letters of support (DI#2, Exhibit 7).

Staff Analysis

As shown in Table 9, the projected capital costs for KPGSC are higher than the range of costs per surgical room seen in other surgical projects reviewed by MHCC in the past three years. However, all of these projects include construction of both operating rooms and procedure rooms. Kaiser's proposed project involves only building operating rooms, which would be expected to be more expensive.

Table 9: Costs of FASF Projects Recently Filed for CON Review

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
Average (3 Projects)	**2007-2009**	**17 Total Surgical Rooms**	**$4,333,347**	**$820,392**
Kaiser Permanente Gaithersburg Surgery Center	2010	3 ORs (1 Shelled)	$9,594,090	$3,198,030

Source: MHCC CON Files

Staff analyzed the project costs and compared them to the MVS guidelines for construction, as shown in Table 11. 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 $334.99 by the amount of $28.57.

Table 10: MVS Analysis of KPGSC Construction Costs

Project Information	Cost ($)
Building	4,995,663
Fixed Equipment	-
Normal Site Prep.	-
Arch./Eng. Fees	261,500
Permits	60,000
Cap. Const. Int.	-
Total Project Costs	5,317,163
Square Footage	17,353
Cost Per Square Ft.	306.41
Adj. MVS Cost/Square Foot	334.99
Over(Under)	(28.57)

Source: Commission staff analysis of DI#2., pages 43-44 and DI#10, Exhibit 2.

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 much more expensive than the projected expenses estimated by Kaiser (DI#2, page 29 and DI#10, page 4). By shifting Kaiser members' surgeries to a less expensive setting, Kaiser will likely be able to reduce costs (DI#2, page 40). In addition, the costs per surgical case projected by Kaiser ($2,357) are within the range of the average cost per case reported by other multispecialty freestanding ambulatory surgical facilities, suggesting that the projected expenses for KPGSC are reasonable. As indicated by the audited financial statements submitted by Kaiser, Kaiser realized a profit in both 2008 and 2007.

KPGSC has projected costs per surgical case that are in line with 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 Kaiser has demonstrated that it will be a viable facility 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 has not applied for or received any CONs. 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 addition 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 planned to seek any third party reimbursement for surgical services at a new surgical facility, Maryland statute required 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 will be Kaiser's Kensington facility. Approximately 34 percent of the cases performed at the Kensington facility in CY2008 were for residents from the primary service area of KPGSC. The other facilities that Kaiser expects will be most affected are Washington Hospital Center, George Washington University Hospital, and Holy Cross Hospital. Internal Kaiser data show that, in 2008, a total of 1,254 surgeries were performed on Kaiser members at Washington Hospital Center; 290 ambulatory surgery cases were performed on Kaiser members at George Washington University Hospital; and 270 ambulatory surgery cases were performed on Kaiser members at Holy Cross Hospital who reside in the primary service area of KPGSC. In addition, Kaiser

estimates that about 884 other cases were performed on Montgomery County residents, dispersed among 19 other freestanding centers and non-Maryland hospitals. (DI#2, page 50).

Kaiser also states that travel time will be reduced for Kaiser members, resulting in a substantial benefit for Kaiser members. For Kaiser members living in the service area of KPGSC, 74.1 percent will be within a 15-minute drive time from the KPGSC (DI#2, page 38).

Kaiser does not anticipate that recruitment of personnel will be a problem. The administrator for Kaiser's ambulatory surgical facility in Kensington 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. (DI#2, page 51).

Staff Analysis

Commission staff agrees that the proposed project will not negatively affect geographic and demographic access to services. The case volume to be shifted away from Washington Hospital Center likely accounts for about one operating room, and the volume shifted away from George Washington University Hospital and Holy Cross Hospital is likely less than half the capacity of an operating room for each location, based on the typical volume and case times for use of operating rooms in Maryland, as reported to MHCC for CY2008. A representative for MedStar Health reported that Washington Hospital Center has 35 operating rooms and performed 13,026 inpatient surgeries and 11,594 ambulatory surgeries in CY2008. Consequently, Commission staff concludes that the reduction in surgical volume resulting from the shifting of Kaiser patients will have little impact on Washington Hospital Center, George Washington University Hospital, and Holy Cross Hospital.

Kaiser's plans to shift surgical case volume away from its existing facility in Kensington to KPGSC significantly reduces the need for surgical capacity at Kaiser's Kensington facility. In conjunction with opening KPGSC, as previously mentioned, Kaiser intends to close two operating rooms at its Kensington facility and use the rooms as procedure rooms for colonoscopies and other minor procedures (DI#2, page 9). Commission staff is not concerned about KPGSC negatively affecting Kaiser's Kensington facility because the facility is owned and operated by Kaiser and the operating room capacity will be adjusted to optimize their use.

No objections have been raised to the proposed project. Both the President and C.E.O. for Adventist HealthCare and the President and C.E.O. of Holy Cross Hospital wrote letters of support for the proposed facility (DI#2, Exhibit 7). In addition, the facility anticipated to be most impacted, an ambulatory surgical facility in Kensington, is owned by Kaiser (DI#2, page 50).

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 where Kaiser members currently go for surgery, not just Kaiser's facility in Kensington, Maryland. Some of these hospitals appear to be within the service area of KPGSC. Thus, many members may already have a short drive-time to a surgery center.

With regard to costs for consumers, the proposed project is unlikely to alter pricing power or price positions because many of the cases for the proposed facility are ones that would otherwise have been performed at Kaiser's Kensington location or that represent a small proportion of surgical cases at other locations. 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. Kaiser also reported that ambulatory surgery is a small part of its total health care expenditures on members, so it does not expect that premiums will be significantly affected by moving surgical cases from non-Kaiser locations to KPGSC (DI#17, page 14). In addition, the surgical capacity in Montgomery County will not change as a result of the proposed project; two operating rooms at Kaiser's Kensington location will close if the KPGSC is approved and built (DI#2 , page 9).

Commission staff concludes that the proposed project will not have an undue 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.

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.

- KPGSC has demonstrated that establishing two operating rooms at a new location is reasonable and that it will require the use of more than one operating room within two years of opening the new facility, based on estimates of the surgery rate per 1,000 Kaiser members and Kaiser membership projections.

- KPGSC has demonstrated that the proposed new facility is a more cost-effective approach to expanding surgical capacity and access of Kaiser members than building an addition to Kaiser's Kensington location or 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 KPGSC.

- 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 be minimal. Cases will also be shifted away from an existing Kaiser facility located in Kensington, and two operating rooms at Kensington will be taken out of service to eliminate excess operating room capacity.

IN THE MATTER OF	*	**BEFORE THE**
	*	
KAISER PERMANENTE	*	**MARYLAND HEALTH**
	*	
GAITHERSBURG SURGICAL	*	**CARE COMMISSION**
	*	
CENTER	*	
	*	
	*	
DOCKET NO. 09-15-2303	*	
	*	

* *

FINAL ORDER

Based on the analysis and findings contained in the Staff Report and Recommendation, it is this 20th day of May, 2010, by a majority of the Maryland Health Care Commission, **ORDERED:**

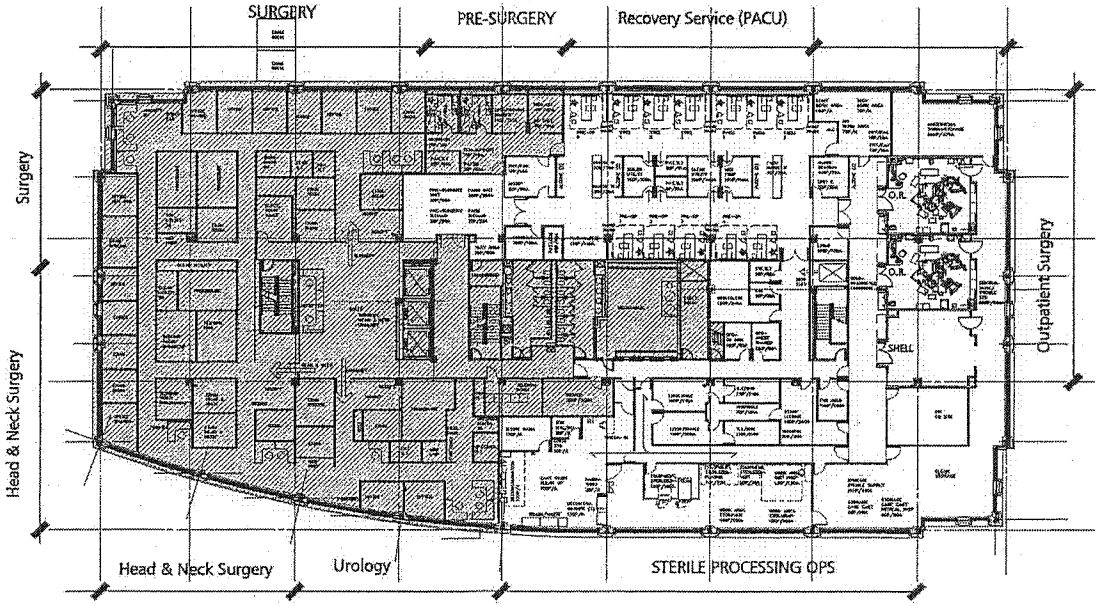
That the application of Kaiser Permanente for a Certificate of Need to establish a freestanding ambulatory surgery facility, Kaiser Permanente Gaithersburg Surgical Center with two operating rooms at 655 Watkins Mill Road, Gaithersburg, Maryland, at a cost of $9,594,090 is **APPROVED**, with the following conditions:

1. KPGSC 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 KPGSC, 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

APPENDIX A



SIXTH FLOOR

NOVEMBER 20, 2009

SCALE: 1" = 1/16"

KAISER PERMANENTE

KAISER PERMANENTE Full Service MOB - Gaithersburg

0' 5' 10' 20' 50'

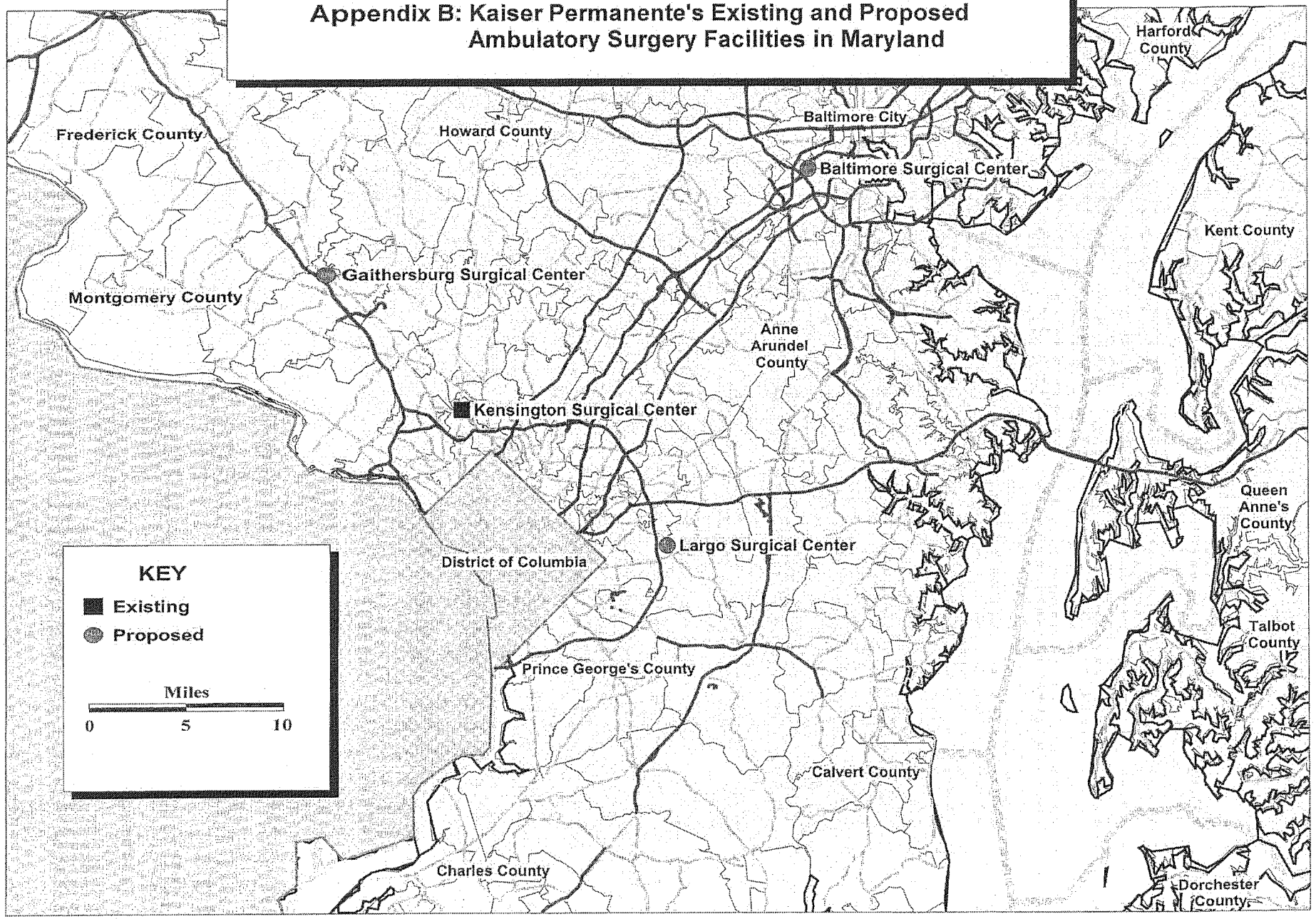
TRUE NORTH

PLAN NORTH

ELLERBE

APPENDIX B

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



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: May 20, 2010

Re: Kaiser Permanente Largo Surgical Center
Docket No. 09-10-2302

****

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 Largo, Maryland. The proposed facility will include six operating rooms. It will also include the necessary preoperative, postoperative, storage, and support spaces. The facility will be used almost exclusively for members of Kaiser health plans.

The project is estimated to cost $16,961,961. 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 LARGO SURGICAL CENTER	*	MARYLAND HEALTH
	*	
	*	CARE COMMISSION
DOCKET NO. 09-10-2302	*	
	*	

****

Staff Report and Recommendation

May 20, 2010

TABLE OF CONTENTS

I. INTRODUCTION

Project Description

The applicant, Kaiser Permanente ("Kaiser") is a health maintenance organization that provides health care services to persons enrolled in Kaiser health plans. Services for Kaiser members are funded primarily through health plan premiums, co-payments, and deductibles. Kaiser proposes to add a four-story addition to an existing Kaiser medical office building. The addition will include an outpatient surgical facility with six operating rooms, and it will be named Kaiser Permanente Largo Surgery Center (KPLSC). Although a total of 128,000 square feet will be added, only 31,604 square feet will be used to create KPLSC (DI#2, page 9). Non-sterile procedure rooms will be located elsewhere in the building, will not be part of KPLSC, and are not included in the project budget for KPLSC. In addition to the six proposed operating rooms ("ORs"), there will be a preoperative area, a postoperative area that includes a 12-bay post-anesthesia care unit (PACU) and 12 recovery bays. The facility will also include the necessary patient registration and waiting areas, staff locker rooms, and equipment storage. (DI#2, page 10).

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

Room Type/Other Space	Proposed Capacity
Operating Rooms	6
PACU Bays/Patient Holding Bays*	12
Recovery Bays	12

Source: DI#2, page 10.
* Note: The applicant has indicated that the PACU will also be used as a Pre-Op area.

The total estimated capital cost of the project is $16,916,103. The cost of renovations is the largest component of the project, at $9,041,297. Although KPLSC will occupy newly constructed space, Kaiser views the creation of KPLSC as a fit-out project because the building addition will be built regardless of whether KPLSC is approved (DI#10, page 1). Equipment costs (both major and minor equipment combined) are the second largest expense, at $6,769,478. The single source of project funding is $16,961,103 in cash. (DI#10, Exhibit 2).

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. 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 a cost-effective alternative to updating an existing Kaiser facility. The project will not have a negative impact on the cost or charges for ambulatory surgery in Maryland or on existing surgical facilities. Commission staff recommends approval of the project. A summary of the Commission staff's analysis is provided below.

Projected Utilization

- Kaiser membership decreased in the primary service area for KPLSC between 2004 and 2009. However, Kaiser has demonstrated some progress in reversing this trend.

- The surgery rate for Kaiser members is sufficient to conclude that between five and six operating rooms will be needed within two years of opening KPLSC.

Impact on Existing Programs

- The impact of the proposed new facility on existing surgical facilities in Maryland is likely to be minimal because the facility will be shifting cases from several locations. The greatest impact will be on a facility in Kensington that is owned and operated by Kaiser.

- No person sought interested party status in this review or otherwise raised objections to the proposed project.

Availability of More Cost-Effective Alternatives

- Kaiser reasonably rejected the alternative of building an addition to its existing Kensington facility because the facility would be unable to accommodate CT/MRI imaging equipment, which may be needed for some patients receiving care, including surgeries, in Kaiser's medical office building.

- Shifting surgical cases that are currently performed in hospitals to KPLSC would likely reduce the cost of these cases.

Viability of the Proposal

- KPLSC has projected costs per surgical case that are in line with the average cost per case at other freestanding ambulatory surgical facilities. The capital costs are below the Marshall Valuation Service benchmark, and therefore are reasonable. 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 October 5, 2009, Commission staff acknowledged that Kaiser submitted a Letter of Intent to apply for a CON to construct a freestanding ambulatory surgery facility. [Docket Item (DI) #1].

Kaiser filed its Certificate of Need application on December 10, 2009 (DI#2). Acknowledgement of receipt of the application was sent on December 10, 2009 (DI#4), and a

notice was published in the Maryland Register Electronic Filing System on December 10, 2009 (DI#6).

On December 10, 2009, the Commission sent a request for publication of the receipt of the KPLSC application to the *Washington Examiner* (DI#5). On December 18, 2009, Commission staff received a notice of receipt of application, as published in the *Washington Examiner* (DI#7).

On December 18, 2009, Commission staff notified the applicant that its application was incomplete and requested responses to completeness questions (DI#8). On December 28, 2009, the applicant sent an e-mail request for an extension until January 22, 2010 to respond to completeness questions (DI#9). Commission staff granted the requested extension and, on January 22, 2010, the applicant filed responses to the completeness questions. (DI#10).

On January 27, 2010, Commission staff received a request from Pat Cameron to receive notification on review for MedStar Health (DI#11). On the same date, Commission staff received a request from Adventist HealthCare to receive notification regarding the review (DI#12).

On February 1, 2010, Commission staff requested that notice be provided in the Maryland Register Electronic Filing System that the application for KPLSC would be docketed as of February 12, 2010 (DI#13).

On February 4, 2010, Commission staff notified KPLSC that its application would be docketed effective upon the February 12, 2010 publication of a notice of docketing in the *Maryland Register* and requested additional information (DI#14).

On February 18, 2010, the Commission also requested that notice of the docketing of KPLSC's application be published in the next edition of the *Washington Examiner* (DI#15). The requested notice was published in the *Washington Examiner* on February 28, 2010 (DI#16).

KPLSC filed responses to additional information questions on March 24, 2010 (DI#17).

On April 12, 2010, Commission staff requested additional information regarding KPLSC and Kaiser Permanente Gaithersburg Surgical Center (DI#18). The applicant filed responses to the additional information questions on April 30, 2010 (DI#19).

Local Health Department Review and Comment

Donald Shell, M.D., Health Office for Prince George's County, expressed his support for the project on May 12, 2010.

Community Support

Letters of support were submitted by Michael L. Vaughn, Delegate for Prince George's County, Jack B. Johnson, County Executive, Prince George's County Government, and Samuel H. Dean, Council Member, 6th District, Prince George's County Council (DI#2, Exhibit 7).

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 once limited to provision on an inpatient basis are now performed as outpatient surgeries.

Since 1995, Maryland law has exempted single operating room surgical facilities from CON regulation. Prior to that time, it exempted single-specialty facilities with up to four operating rooms. Maryland has more Medicare-certified ambulatory surgery centers ("ASCs") per capita than any other state, and a very high proportion of its total freestanding facilities have a single operating room (49 percent) or no operating rooms at all (34 percent), based on data for CY2008. 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, outpatient 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 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 just 0.6 percent.

In two of four Maryland counties identified as part of the primary service area for the proposed facility in Largo, the number of ambulatory surgery cases performed at ASCs has increased rapidly. In Prince George's County, these cases almost doubled from 2001 through 2008, increasing from 24,544 cases to 48,896 cases; this is an average annual growth rate of 10.3 percent a year. Similarly, in Calvert County cases grew rapidly, increasing from 7,276 to 22,643 from 2001 to 2008. In Charles County, the caseload grew, but at a much slower rate; the caseload increased from 5,413 cases in 2001 to 6,038 in 2008, an average annual growth rate of 1.6 percent. In Anne Arundel County, the overall surgical caseload decreased from 34,881 to 27,895 cases. Statewide, the average annual growth in case volume for ASCs from 2001 to 2008 was 8.3 percent.

In contrast to the growth at ambulatory surgery centers in the primary service area of KPLSC, the number of ambulatory surgery cases performed in acute care hospitals generally declined in three of the four counties. Among the four acute care general hospitals in Prince George's County, all but one hospital experienced a significant decline in outpatient surgery case volume between 2001 and 2008, as shown in Table 2. Similarly, the single hospitals in Calvert and Charles Counties experienced a decline in outpatient surgical case volume, as shown in Table 2. In contrast, the surgical case volume increased at both hospitals in Anne Arundel County and offsets the decreases in the other three counties sufficiently to produce net growth of five percent for the four counties identified as part of the primary service area of KPLSC, as shown in Table 2. Statewide, hospitals in Maryland have seen much higher growth in ambulatory surgical case volume for this period, 27 percent.

Table 2: Ambulatory Surgery Cases in Hospitals Located in Prince George's, Charles, Calvert, and Anne Arundel Counties, CY2001 and CY2008

Hospital Name	Number of Cases		Percent Change
	2001	2008	2001-2008
Prince George's County			
Prince George's Hospital	7,131	2,887	-60%
Doctor's Community Hospital	9,072	9,052	0%
Southern Maryland Hospital	10,670	7,453	-30%
Laurel Regional Hospital	5,277	3,907	-26%
Charles County			
Civista Medical Center	4,867	3,785	-22%
Calvert County			
Calvert Memorial Hospital	4,771	7,148	50%
Anne Arundel County			
Anne Arundel Medical Center	13,176	21,330	62%
Baltimore Washington Medical Center	8,690	11,244	29%
Total	63,654	66,806	5%

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

Although the number of ambulatory surgical cases has declined at most hospitals in the counties identified as part of the primary service area for KPLSC, the number of outpatient surgeries at Maryland hospitals for residents in the primary service area of KPLSC increased from 2001-2008, at an average annual rate of 0.7 percent. These residents are having their surgeries at hospitals outside their counties of residence. This may be the result of either individual decisions or steering by health maintenance organizations.

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 facility generally will not charge patients or bill an insurance company except in rare cases. There may be co-payments and deductibles, but the cost of care is generally covered by members' health plan premiums. Therefore, this standard is not applicable. (DI#2, page 17).

(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.

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 the children enrolled with free or reduced cost primary care. Both Kaiser members and non-members are eligible for CHCP. For 2009, Kaiser forecasted expenditures of $843,472 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 website 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. KPLSC complies with this standard. (DI#2, 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 KPLSC will be licensed by the State and will be Medicare certified. KPLSC will also comply with all mandated federal, State, and local health and safety regulations. KPLSC is consistent with this standard. (DI#2, page 21).

(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 KPLSC will be licensed by the State and will be Medicare certified. In addition, the applicant states that KPLSC will obtain accreditation from the Accreditation Association for Ambulatory Health Care (DI#2, page 21). With regard to Medicaid certification, the applicant stated that KPLSC should not be required to obtain the certification because KPLSC 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#2, pages 21-22). KPLSC 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 would not enhance the safety of patients.

Kaiser's existing Kensington facility has not been accredited, although the facility is in the process of applying for accreditation from AAAHC. Therefore, Commission staff recommends the following condition:

> *KPLSC 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.

KPLSC does not currently have a transfer agreement, but the applicant anticipates that an agreement similar to the one for Kaiser's Kensington facility will be created (DI#2, page 24). A copy of this agreement was provided (DI#2, Exhibit 4). The applicant also noted that ambulance service will be provided by the Emergency Medical System through calling 911 (DI#2, page 24). The applicant has agreed to comply with this standard, but has not yet created a transfer agreement. Therefore, Commission staff recommends the following condition addressing the transfer agreement:

> *Before first use approval of KPLSC, 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 KPLSC will have a utilization review and control program. A detailed description of the program is included in the CON application (DI#2, 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. KPLSC complies with this standard. (DI#2, page 24).

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#2, page 25). 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 Prince George's, Calvert, Charles, and Anne Arundel Counties and Washington, D.C. The vast majority of Kaiser members served by KPLSC are expected to be residents of either Prince George's County (67.4 percent) or Washington, D.C. (30.5 percent) (DI#17, page 2). 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 KPLSC does not charge for procedures except in rare circumstances. However, Kaiser does pay other providers when Kaiser members receive surgical services at non-Kaiser locations. Kaiser provided a table with average hospital charges for Kaiser members from the primary service area for KPLSC who had surgeries at Maryland hospitals. The highest number of these cases were performed at Holy Cross Hospital (1,295) or 69 percent of the total number of ambulatory surgical cases performed at Maryland hospitals in CY2008 on Kaiser members from the primary service area for KPLSC. (DI#10, pages 4-5). The average charge for these cases is $4,732. (DI#10, page 4). In contrast, the applicant noted that the average cost per case at KPLSC is projected to be $1,531 in 2013 (DI#2, page 29).

In lieu of comparing charges at KPLSC and other facilities, Commission staff chose to evaluate the reasonableness of costs at KPLSC by comparing the estimated expense per case for KPLSC 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 KPLSC ($1,531) is higher than the average cost per case compared to multispecialty ambulatory surgery facilities with only operating rooms ($1,359), but not exceptionally higher.

Table 3: Comparison of Average Cost Per Case for Select Locations, CY2008

Comparison Facility	Number of Locations Included	Average Expense Per Case	Range
KPLSC	1	$1,531	N/A
Multi-specialty with only ORs*	10	$1,359	$610- $22,688

Source: Staff analysis of MHCC Survey of Freestanding Ambulatory Surgery Facilities for CY2008 and DI#2, page 29.

*Note: Information on the MHCC Survey of Freestanding Ambulatory Surgery Facilities is self-reported.

Although there are no comparable charge data for KPLSC, the response provided by the applicant is reasonable. Information submitted regarding the expense per case appears similar to other multi-specialty facilities with only operating room cases reported. The expense per case at KPLSC is also projected to be much lower than the expense per case performed in a hospital setting. 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. KPLSC 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. Other services, such as imaging or additional laboratory services, will be located elsewhere in the same building as KPLSC. Pathology services will be provided through a regionally centralized pathology service located in Rockville that is also operated by Kaiser. KPLSC is consistent with this standard. (DI#2, page 29).

(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 KPLSC 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. KPLSC will also obtain accreditation from the Accreditation Association for Ambulatory Health Care. The applicant requested that Medicaid certification not be required because KPLSC 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. Commission staff agrees that Medicaid certification should not be required because the vast majority of patients to be served by KPLSC 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. For this reason, Commission staff considers Kaiser's level of compliance with this standard to be acceptable. (DI#2, pages 21-22).

(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#2, page 30). 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#2, page 31). Kaiser stated that its projections show a need for 6.7 operating rooms in 2013, the second year of operation for KPLSC (DI#2, page 32). Kaiser also provided a conservative projection of operating room utilization; Kaiser assumed that membership in 2013 would be the same as in 2009. Under this assumption, 5.9 operating rooms would be utilized at optimal capacity in 2013 (DI#2, page 33).

Commission staff regards the operating room utilization estimate provided by Kaiser as too high. Historical changes in the number of Kaiser members do not support the strong growth in membership that Kaiser has projected. In addition, Kaiser uses a surgical rate that does not account for the ambulatory surgical cases that will be performed in a hospital setting, rather than a freestanding ambulatory surgery center, because of patient characteristics. For a full discussion of the conclusions of Commission staff regarding the projected utilization of operating rooms at KPLSC, refer to the "Need" section of this report. Commission staff concludes that six operating rooms will not be used at optimal capacity by the second full year of operation; however, Kaiser has shown that more than five operating rooms will likely be used at greater than optimal capacity within two years of opening KPLSC.

(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, and the facility was not 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 the projected membership levels for residents in the primary service area of KPLSC, an estimated rate of ambulatory surgery per 1,000 Kaiser members, and the estimated procedure time for ambulatory surgery cases. The applicant then uses the definition of optimal utilization of operating rooms included in the State Health Plan (SHP) to show that six 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#2, page 37). Table 4 below shows the historical number of Kaiser members in the primary service area for KPLSC from 2004-2009 and the projected number of members for 2010-2013.

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

	History						Forecast			
Area	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Camp Springs	36,375	36,207	36,010	34,651	33,515	32,180	32,682	32,306	32,341	31,844
Largo	39,587	39,497	39,623	38,272	38,932	37,315	39,965	40,569	39,245	40,137
Marlow Heights	11,494	11,735	12,025	11,784	11,218	10,940	11,096	11,266	9,668	9,901
Prince George's	13,010	13,608	14,335	13,508	13,495	12,455	13,379	13,576	12,513	12,803
Subtotal	100,466	101,047	101,993	98,215	97,160	92,890	97,122	97,717	93,767	94,685
North Capitol*	30,150	29,152	29,137	27,803	27,564	26,736	27,347	-	-	-
West End*	20,276	20,293	19,856	19,130	18,381	17,709	18,320	12,637	-	-
NW DC*									13,199	13,218
Capitol Hill*								35,790	42,413	47,224
Subtotal	50,426	49,445	48,993	46,933	45,945	44,445	45,667	48,427	55,612	60,442
Total	150,892	150,492	150,986	145,148	143,105	137,335	142,789	146,144	149,379	155,127

Source: DI#2, page 32

*Note: Kaiser is planning to open another full service medical center in Washington, D.C. in 2011. The membership changes reflect this shifting of members.

The applicant calculated the projected number of surgery cases for 2010-2013 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 defined in the SHP for Ambulatory Surgical Services. The applicant estimated the surgical case rate per 1,000 members in the primary service area of KPLSC by analyzing its surgical data for the Mid-Atlantic Region, including both cases performed at Kaiser facilities and non-Kaiser facilities (DI#2, 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#2, page 31). 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 2013. Kaiser calculated the need for operating rooms using the projected membership for both 2009 and 2013. The 2009 membership level (137,335) was used to calculate a conservative estimate of the need for operating rooms in 2013. As shown in Table 5, this results in an estimated need of 5.9 operating rooms. If the projected Kaiser membership in 2013 is used to calculate the need for operating rooms (155,127), then 6.7 operating rooms are needed (DI#2, page 33).

Table 5: Projected Need for Operating Rooms at KPLSC at 2009 Kaiser Membership Level

Specialty	Average Case Time (minutes)	Rate per 1,000 Members	Cases, 2013 Forecast	Surgical Minutes	Turnaround Minutes	Total Minutes	Operating Room Need[1]
Ear, Nose, Throat	66	6.1	838	55,308	25,140	80,448	
General Surgery	66	9.5	1,305	86,130	39,150	125,280	
Gastroenterology	36	1.3	179	6,444	5,370	11,814	
OB-GYN	60	4.6	632	37,920	18,960	56,880	
Ophthalmology	36	6.6	906	32,616	27,180	59,796	
Orthopedic	60	10.7	1,469	88,140	44,070	132,210	
Plastic Surgery	90	0.9	124	11,160	3,720	14,880	
Podiatry	78	3.6	494	38,532	14,820	53,352	
Retinal Service	72	0.2	27	1,944	810	2,754	
Urology	54	3.8	522	28,188	15,660	43,848	
Total	59.5	47.3	6,496	386,512	194,880	581,392	5.9

Source: DI#2, page 33.
[1]Operating room need is calculated using the optimal capacity standard in the SHP: 97,920 minutes per operating room.

As shown in Table 5, the overall ambulatory surgery rate per 1,000 members that Kaiser uses to justify a need for six operating rooms is 47.3. The applicant subsequently estimated the surgical case rate per 1,000 members in the primary service area of KPLSC by counting CY2008 hospital cases with Kaiser as the payer in the outpatient database of the Health Services Cost Review Commission (HSCRC) that have an operating room charge over one dollar and an encounter type of "outpatient surgery" or "other." In addition, the applicant counted the CY2008 cases for Kaiser members who live in the primary service area of KPLSC who had surgeries performed in Washington, D.C. hospitals, at Kaiser's Kensington facility, at other freestanding non-Kaiser ambulatory surgery centers, and at Kaiser's facility in Falls Church, Virginia. Lastly, Kaiser includes Virginia residents who will be directed to KPLSC for surgeries. The total cases from each source are shown in Table 6. The Kaiser member count used to calculate the surgery rate per 1,000 members is the number of Kaiser members in the primary service area for KPLSC in CY2008, a total of 143,105. Kaiser notes that the data for Washington, D.C. facilities is likely incomplete, resulting in a lower case rate. Kaiser did not change its need projection based on the surgery rate shown in Table 5 because it believes that cases performed in Washington, D.C. hospitals are undercounted (DI#10, pages 6-11).

Table 6: Calculation of Overall Ambulatory Surgery Rate for KPLSC Service Area, CY2008

Category	Number of Cases
Maryland Hospitals	1,888
Virginia Membership Cross Over	221
Kaiser's ASC in Falls Church, Virginia	102
Non-Kaiser Freestanding ASCs	747
Washington, DC Hospitals	76
Kaiser's Kensington ASC	2,817
Total Cases	5,851
Membership for KPLSC Service Area	143,105
Cases per 1,000 Members	40.9

Source: Completeness Response page 11.

With regard to membership growth, Kaiser justifies the projected membership growth by citing an anticipated increase in consumer satisfaction. Kaiser noted that Northern California's scores for the overall health plan on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) were three percent higher than the Mid-Atlantic region, and scores for overall health care were six percent higher. In addition, the member termination rate for the Northern California members was more than three percent less than the Mid-Atlantic's rate. Kaiser links the difference in member termination rates to the differences in consumer satisfaction, noting that the Mid-Atlantic's termination rate improved 0.7 percent over the previous year as satisfaction scores increased. (DI#17, page 12).

Kaiser also presented information on an internal consumer satisfaction survey for spring and fall of both 2008 and 2009, conducted with a random sample of adult members who had been Kaiser members for at least 12 months, in order to demonstrate the connection between member satisfaction and growth in membership. The results from this survey (METEOR) show that the overall health plan rating was 66 percent in spring of 2008, fall of 2008, and spring of 2009. In the fall of 2009, the overall health plan rating increased to 73 percent. Kaiser attributes the increased satisfaction and greater retention to implementation of its business strategy. (DI#17, pages 12-13).

In addition to citing increased consumer satisfaction as the basis for future membership growth, Kaiser notes that an anticipated population growth of 1.5 percent annually, Kaiser's more affordable price for members, and expected growth in the number of federal employees are other factors that will promote membership growth (DI#10, page 13). Kaiser also notes that its model of providing health care, owning and operating full service medical centers, has allowed it to reach market shares of 15-40 percent in some places, and it currently holds only an 8 percent market share in Washington, D.C. (DI#10, pages 12-13).

Besides meeting Kaiser members' need for surgical services, Kaiser states that the proposed project will improve access to such services. Kaiser performed a travel time analysis to identify the number of Kaiser members within a 15-minute drive of a Kaiser ambulatory surgery center. Kaiser found that only 15.2 percent of the Kaiser members in the Washington,

D.C./Southern Maryland areas are within a 15-minute drive of Kaiser's Kensington surgical facility; the Kensington location is the only existing Kaiser site in the Washington, D.C./Southern Maryland area. Kaiser determined that, by locating ambulatory surgical facilities in both Gaithersburg and Largo, the percentage of Kaiser members in Washington, D.C./Southern Maryland within a 15-minute drive of a Kaiser surgical facility would increase to 50 percent. For the Largo location specifically, the percentage of Kaiser members who would be within a 15-minute drive of KPLSC is 38 percent. (DI#2, pages 35 -37).

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 KPLSC and a projection of the surgical case rate. Kaiser relies on historic information as well as other research to justify its need projections. The use of historic trends to create future projections is consistent with the approach of Commission staff to CON requests. Although Commission staff disagrees with some of the conclusions reached by Kaiser, regarding both the projections for Kaiser members and the surgical rates cited, Commission staff concludes that six operating rooms are justified.

The historic information provided by Kaiser on its membership levels indicates a declining trend, as shown in Table 7. Commission staff calculated the average annual change in membership from 2004-2009, for the Kaiser medical center locations listed. This analysis shows a decline in membership, ranging from 0.9 to 2.7 percent on an average annual basis, as shown in Table 8.

Table 7: Kaiser Membership, Actual and Projected for Largo

Location	Actual						Forecast			
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Camp Springs	36,375	36,207	36,010	34,651	33,515	32,180	32,682	32,306	32,341	31,844
Largo	39,587	39,497	39,623	38,272	38,932	37,315	39,965	40,569	39,245	40,137
Marlow Heights	11,494	11,735	12,025	11,784	11,218	10,940	11,096	11,266	9,668	9,901
Prince George's	13,010	13,608	14,335	13,508	13,495	12,455	13,379	13,576	12,513	12,803
Subtotal	100,466	101,047	101,993	98,215	97,160	92,890	97,122	97,717	93,767	94,685
North Capitol*	30,150	29,152	29,137	27,803	27,564	26,736	27,347	-	-	-
West End*	20,276	20,293	19,856	19,130	18,381	17,709	18,320	12,637	-	-
NW DC*									13,199	13,218
Capitol Hill*								35,790	42,413	47,224
Subtotal	50,426	49,445	48,993	46,933	45,945	44,445	45,667	48,427	55,612	60,442
Total	150,892	150,492	150,986	145,148	143,105	137,335	142,789	146,144	149,379	155,127

Source: CON application, page 32

*Note: Kaiser is planning to open another full service medical center in Washington, D.C. in 2011. The membership changes reflect this shifting of members

Table 8: Historic Level of Membership Change

Area	Average Annual Change 2004-2009
Camp Springs	-2.4%
Largo	-1.2%
Marlow Heights	-1.0%
Prince George's	-0.9%
Subtotal	-1.6%
North Capitol	-2.4%
West End	-2.7%
NW DC	N/A
Capitol Hill	N/A
Subtotal	N/A
Total	N/A

Source: MHCC staff analysis of DI#2, page 32

Despite the historic level of decline in Kaiser membership for Camp Springs, Largo, Marlow Heights, and Prince George's, Kaiser projects average annual growth of 3.1 percent for these locations collectively. 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 1.5 percent annually, and increased growth in the federal workforce (DI#10, page 13).

With regard to member satisfaction, Kaiser noted that Northern California's scores for the overall health plan on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) were three percent higher than the Mid-Atlantic region, and scores for overall health care were six percent higher. In addition, the member termination rate for the Northern California members was over three percent less than its Mid-Atlantic rate. Kaiser links the difference in member termination rates to the differences in consumer satisfaction, noting that the Mid-Atlantic termination rate improved 0.7 percent over the previous year as satisfaction scores increased (DI#17, page 12). Kaiser also presented information on an internal consumer satisfaction for spring and fall of both 2008 and 2009 and membership levels between 2007 and 2010 (DI#19, page 7).

Commission staff reviewed data reported by Kaiser on the Consumer Assessment of Healthcare Providers and Systems (CAHPS) 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 about average 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. 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. Given the level of consumer satisfaction, as noted for these measures, across time and relative to other health plans, it is not surprising that Kaiser's membership had not been growing.

Kaiser reported that it implemented changes in the fall of 2008 that resulted in better service, which in turn increased member retention (DI#17, page 7). Kaiser showed that membership increased from July 2009 to December of 2009 and continued to increase through March 2010 (DI# 17, page 7 and DI#19, page 7). However, Commission staff notes that the most recent membership level reported (March 2010) is still below the number of members in

December 2008 (482,045 versus 484,401). Therefore, Commission staff regards a conservative estimate for membership growth as appropriate for calculating the future utilization of operating rooms at KPLSC.

Commission staff reviewed the historical and projected population estimates for both Prince George's County and Washington, D.C. because Kaiser cites population growth as a factor that will increase the number of Kaiser members in future years. Kaiser estimates that about 67 percent of the members served by KPLSC will be from Prince George's County and 31 percent will be from Washington, D.C. (DI#17, page 2). Based on Commission staff's review, membership levels are not closely linked to population growth; in spite of average annual population growth of 0.5 percent between 2005 and 2010 in Prince George's County and statewide population growth in Maryland, Kaiser's membership levels declined. In addition, population growth in the primary service area of KPLSC is not as high as cited by Kaiser. In Washington, D.C., the population is expected to decrease between 2010 and 2015, at an average annual rate of one percent a year. In Prince George's County, the population is projected to grow at an average annual rate of less than one percent (0.7) between 2010 and 2015. Commission staff concludes that population changes are unlikely to increase the number of Kaiser members served at KPLSC.

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 9-10), 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. Commission staff assigns greater weight to longer term trends, rather than a change from one year to the next. Therefore, Commission staff is skeptical that growth in the federal workforce by itself will result in a greater number of Kaiser members.

The surgical case rates per 1,000 members calculated by Kaiser are too high to use to project the utilization of operating rooms at KPLSC. The initial estimated surgical rates, by specialty, result in a significantly higher rate of surgery than suggested by the HSCRC data. The initial forecast rate is 47.3 compared to 40.9, as calculated by Kaiser based on its review of HSCRC data. Commission staff's own analysis concludes that even 40.9 may be too high to use as the surgical rate for Kaiser members in the primary service area of KPLSC. When Kaiser calculated a surgical rate of 40.9 for the service area of KPLSC, it assumed that all outpatient surgical cases performed at hospitals may be shifted to Kaiser surgical facilities. An adjustment should be made to account for cases that will be performed in hospitals because of the urgency of the case or patient characteristics. Kaiser estimates that 4.5 cases per 1,000 members may have

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

outpatient surgery in a hospital setting because of significant medical co-morbidities (DI#19, page 5). Reducing the ambulatory surgical rate for Kaiser members assigned to KPLSC to account for hospital cases results in an estimated rate of 36.4 to 42.8 surgeries per 1,000 Kaiser members. These values were calculated by subtracting 4.5 cases per 1,000 members from the surgery rate calculated from HSCRC data and Kaiser's internal records (40.9) and from the surgery rate for Kaiser's Virginia members, which is also the projected rate for KPLSC (47.3).

Commission staff also concluded that further adjustment of the surgical rate used for projections regarding operating room utilization at KPLSC is appropriate. 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).

The surgical rate per 1,000 Kaiser members calculated by Commission staff reduces the projected need for operating rooms at KPLSC in 2013. Depending on the number of Kaiser members who are assumed to be served by KPLSC, Commission staff calculates the need for operating rooms as ranging from 4.6 to 6.0. The low end of the range assumes the number of Kaiser members in 2013 is the same as the level in 2009 and a surgery rate of 36.4 per 1,000 members. The high end of the range assumes the number of Kaiser members is 155,127, the estimate given by the applicant for 2013, and a surgery rate of 42.6 cases per 1,000 members (DI#2, page 32). The surgery rate of 42.6 accounts for the needed corrections related to the calculated surgical rate for Kaiser's Virginia members and cases that will still likely be performed in hospitals, even if a freestanding Kaiser facility is available.

Although Kaiser notes that the data from hospitals located in Washington, D.C. likely understates the number of surgeries, Commission staff does not have sufficient information to evaluate the extent to which surgeries may have been undercounted. In addition, even if the data from hospitals in Washington, D.C. understates the number of surgical cases, Commission staff has found that the HSCRC data may overstate the number of surgical cases performed in operating rooms. Data collected by the Maryland Health Care Commission on its annual survey of acute care hospitals regarding the number of cases for each type of operating room indicate a much lower number of surgical cases are performed in operating rooms than the number of cases in the HSCRC outpatient data with an operating room charge and an encounter type of "outpatient surgery" or "other outpatient." For example, the total number of surgery cases (both inpatient and outpatient) in operating rooms at one hospital was reported as 11,999 for CY2008. However, HSCRC data indicate a total of 22,224 such cases were performed in CY2008 at this hospital. Similar, large discrepancies were noted in the vast majority of Maryland hospitals. Consequently, Commission staff does not agree with Kaiser's assumption of 47.3 ambulatory surgeries per 1,000 members.

Instead of relying on the most conservative assumptions about membership levels and surgery rates, Commission staff determined that it would be reasonable to assume that membership levels would return to the 2008 level because Kaiser has shown progress in increasing its membership levels. Commission staff also decided to use the average of the adjusted surgery rates calculated from HSCRC and internal Kaiser data (36.4) and data for

Kaiser's Virginia members (42.6). As shown in Table 9, these calculations show 5.2 operating rooms may be needed in 2013 at KPLSC.

Table 9: Calculation of OR Need for KPLSC in 2013

Projected Kaiser Members	143,105[1]
Surgery Rate Per 1,000 Members	39.5
OR Cases	5,667
Minutes, Including Turnaround Time	505,912
OR Need[2]	5.2

Source: MHCC Staff analysis.
[1] Number of Kaiser members in the service area of KPLSC in 2008.
[2] OR Need is based on optimal utilization SHP standard: 97,920 minutes per OR.

Commission staff concludes that there is sufficient evidence that the applicant can achieve optimal utilization of more than five operating rooms within two years of completing KPLSC, using the middle of the range estimated for the surgery rate per 1,000 members and assuming a modest increase in Kaiser members (one percent). The applicant has justified the construction of six operating rooms.

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's Response

The applicant considered two alternative options to the proposed project. First, Kaiser considered creating an addition to an existing Kaiser facility located in Kensington. Second, Kaiser considered continuing to perform cases in acute care hospitals and other non-Kaiser settings. Kaiser concluded that neither of those options is cost-effective.

Kaiser estimated that a two-story addition to its existing ambulatory surgery center in Kensington and renovating existing space for the addition of seven operating rooms would cost $19,621,725 (DI#2, page 42). Kaiser compared the project cost to the Marshall Valuation Service (MVS) benchmark and found that the project cost was below the MVS benchmark. The cost of the addition to the Kensington facility is very similar to the preliminary estimated cost of the proposed project ($18,655,211) (DI#2, page 14). However, Kaiser rejected the project because it would not improve access to ambulatory surgery for Kaiser members by reducing the driving time to a Kaiser location (DI#2, page 42). Kaiser also rejected this alternative because the Kensington facility would not be large enough to accommodate CT/MRI imaging equipment (DI#2, page 42).

Kaiser further explained that performing cases in existing facilities, such as hospitals, is much more expensive that performing surgeries at Kaiser facilities. Using data from HSCRC, Kaiser analyzed the average charges for patients with Kaiser insurance who had ambulatory surgeries at hospitals. For CY2008, Kaiser counted 1,888 surgeries at hospitals performed on Kaiser patients from the primary service area of KPLSC (DI#10, pages 3-5). The average charge for these cases was $4,105 compared to an estimated cost per case of $1,531 at KPLSC (DI#2, page 29 and DI#10, page 5). Kaiser attempted to adjust for case mix by matching the primary ICD-9 code for each case to a specialty and calculating the average charge for each specialty (DI#10, pages 5-6). Using this method, the average charge of hospital ambulatory surgery cases for patients with Kaiser insurance located within the primary service area of KPLSC was estimated to be $4,613 (DI#10, page 6). However, Kaiser also noted that approximately 35 percent of the 1,888 cases identified as Kaiser patients within the service area of KPLSC could not be matched to a specialty, and the ICD-9 code may not accurately reflect the nature of the surgery (DI#10, page 6).

Staff Analysis

Commission staff concludes that Kaiser reasonably rejected the alternative of building an addition to the Kensington facility. Although it appears that building an addition to the Kensington facility and renovating space there would cost slightly less than the proposed project, assuming the equipment costs for each project are the same, the inability to accommodate CT/MRI imaging equipment is a legitimate reason to reject this alternative. Kaiser explained that the location of the Kensington facility is in a densely populated neighborhood, thereby restricting Kaiser's ability to expand both the facility and parking. If adequate parking is not available, it may not be convenient for Kaiser members to receive care at an expanded Kaiser Kensington facility. Kaiser also explained that the existing Imaging Center is located in the basement, making it challenging to place new MRI equipment in that space (CON application No. 09-15-2303, DI#10, page 17). The CT/MRI imaging equipment may be needed for some patients receiving care, including surgeries, in Kaiser's medical office building. Efficiency or Kaiser members' satisfaction may be compromised if there is insufficient imaging equipment at Kaisers' medical buildings.

With regard to the cost of Kaiser cases performed in hospitals, Commission staff believes the cost of performing surgical cases in hospitals is not as great as suggested by Kaiser's analysis. The costs included in the field "total costs" for the HSCRC data may include therapeutic services (physical, speech, occupational), diagnostic radiology tests, and diagnostic scans (MRI, CAT, etc). These are costs that were not included as costs in the KPLSC budget. After eliminating many types of costs from the HSCRC data for ambulatory surgical cases, Commission staff calculates the average cost per case for cases that Kaiser anticipates moving to KPLSC is $3,552. This is significantly lower than the value calculated by Kaiser including all types of charges, $4,105 (DI#10, page 5). It is also lower than the estimate of $4,613 per case estimated by Kaiser, based on categorizing cases into medical specialties according to the primary diagnosis code (DI#10, page 6). The cost per ambulatory surgical case calculated by Commission staff may also be high compared to the estimated expense per case at KPLSC because a profit margin is built into hospital changes, 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. 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 KPLSC.

Although there is excess operating room capacity in Prince George's County at freestanding surgery centers, based on SHP assumptions regarding capacity, there are not one or two ASCs that would be able to accommodate all of the surgical cases that Kaiser intends to shift to a freestanding setting. There is likely greater efficiency in relying on a single, large site. The cost per case projected for KPLSC is lower than Kaiser's existing Kensington facility, which has four operating rooms, and much lower than the projected costs for another proposed Kaiser surgery center currently under CON review, which will have two operating rooms. This difference suggests that greater efficiencies may result from economies of scale.

Based on the projected case volume for KPLSC and the amount of surgery time for those cases, staff concludes that the proposed six operating rooms at KPLSC would be adequately utilized. As previously shown in Table 5, KPLSC has projected a need for six ORs in 2013 based on the estimated rate of surgery and membership growth trends. The applicant has provided information on the capital cost of providing the surgical services through renovations at Kaiser's Kensington location and the alternative of continuing to use existing non-Kaiser facilities. As discussed above, renovating Kaiser's Kensington location is not significantly cheaper than building KPLSC and also would not meet Kaiser's goal of increasing members' access to surgical services. In addition, continuing to use alternative non-Kaiser locations may be more expensive than handling surgical cases at a Kaiser facility. On this basis, the applicant has demonstrated that KPLSC 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.

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 $16,961,103 (DI#10, Exhibit 2). 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#2, Exhibit 6)

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

Staff Analysis

As shown in Table 10, the projected capital costs for KPLSC are higher than the range of costs per surgical room seen in other surgical projects reviewed by MHCC in the past three years. However, one of these projects, Frederick Surgical Center involved renovating space in an existing building, and the other two projects include construction of both operating rooms and procedure rooms. Kaiser's proposed project involves only building operating rooms, which would be expected to be more expensive. As previously noted, the construction costs are within the MVS benchmark adopted by Commission staff for evaluating the reasonableness of costs.

Table 10: Costs of FASF Projects Recently Filed for CON Review

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
Average (3 Projects)	**2007-2009**	**17 Total Surgical Rooms**	**$4,333,347**	**$820,392**
Kaiser Permanente Largo Surgery Center	2010	6 ORs	$16,916,103	$2,819,350.50

Source: MHCC CON Files

Kaiser does not charge for individual services, so charges for surgical services at KPLSC cannot be compared to those of other locations to evaluate the financial viability of KPLSC. (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 surgeries performed on Kaiser members in hospitals are much more expensive than the projected expenses estimated by Kaiser (DI#2, page 29). In addition, the costs per surgical case projected by Kaiser ($1,531) are similar to the cost per case of other multispecialty freestanding ambulatory surgical facilities, suggesting that the projected expenses for KPLSC are reasonable. As indicated by the audited financial statements submitted by Kaiser, Kaiser realized a profit in both 2008 and 2007 (DI#2, Exhibit 6).

Staff analyzed the project costs and compared them to the MVS guidelines for construction, as shown in Table 11. 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 $335.32 by the amount of $49.24.

Table 11: MVS Analysis for KPLSC

Project Information	Cost ($)
Building	8,330,387
Fixed Equipment	-
Normal Site Prep.	-
Arch./Eng. Fees	672,000
Permits	38,910
Cap. Const. Int.	-
Total Project Costs	9,041,297
Square Footage	31,604
Cost Per Square Ft.	286.08
Adj. MVS Cost/Square Foot	335.32
Over(Under)	(49.24)

Source: Commission staff analysis of DI#10, Exhibit 2.

KPLSC has projected costs per surgical case that are in line with the average cost per case calculated from the information submitted for MHCC's annual survey freestanding ambulatory surgical facilities. 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 Kaiser has demonstrated that KPLSC will be a viable facility 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 has not applied for or received any CONs. 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 confirmation that the proposed project would not be subject to CON review, the Executive Director of MHCC responded that, if Kaiser planned to seek any third party reimbursement for surgical services at a new surgical facility, then Maryland statute required approval through the Certificate of Need review process.

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 facilities that will be most affected by the proposed project are Kaiser's Kensington facility and Holy Cross Hospital. Approximately 60 percent of the cases performed at the Kensington facility in CY2008 were for residents from the primary service area of KPLSC. In CY2008, a total of 816 ambulatory surgical cases were performed at Holy Cross Hospital on Kaiser members from Prince George's County. Kaiser also states that a total of 1,254 ambulatory surgery cases were performed on Kaiser members at Washington Hospital Center and 290 cases performed at George Washington University Hospital. In addition, Kaiser estimates that about 884 other cases were performed on Kaiser members residing in the primary service area of KPLSC, in a total of 19 other freestanding centers and non-Maryland hospitals. (DI#2, pages 49-50).

Kaiser also states that travel time will be reduced for Kaiser members, resulting in a substantial benefit for Kaiser members. Only one zip code in Prince George's County and two zip codes in Washington, D.C. are within a 15-minute drive of Kaiser's only existing surgical center in Kensington, Maryland. (DI#2, page 50).

Staff Analysis

Commission staff agrees that the proposed project will not negatively affect geographic and demographic access to services. The case volume to be shifted away from Holy Cross Hospital is about 30 percent of the total outpatient surgical volume for Holy Cross Hospital. For CY2008, HSCRC data indicates that a total of 4,352 outpatient surgical cases were performed at Holy Cross and 1,326 of these cases were performed on Kaiser members from the primary service area for KPLSC. The 1,326 cases to be shifted represent use of less than one of the 14 mixed-use operating rooms at Holy Cross Hospital, assuming optimal utilization of the operating rooms (97,920 minutes per room) and that the average case time for outpatient cases is similar to the case time estimated by Kaiser for KPLSC (59.5 minutes per case) (DI#2, page 33).

Kaiser's plans to shift surgical case volume away from its existing facility in Kensington to KPLSC significantly reduces the need for surgical capacity at Kaiser's Kensington facility. Although Kaiser only explicitly states its intentions to close operating rooms at its Kensington facility in its CON request for a Kaiser facility in Gaithersburg, KPLSC also significantly affects the utilization of operating rooms at Kaiser's Kensington facility. As Kaiser noted, approximately 60 percent of the cases performed at Kaiser's Kensington facility were from the service area for KPLSC. However, Commission staff is not concerned about KPLSC negatively affecting Kaiser's Kensington facility because the Kensington facility is owned by Kaiser and the operating room capacity will be adjusted to optimize use of the remaining operating rooms.

Commission staff agrees that Kaiser members will benefit from a shorter drive time. Many Kaiser members who would be expected to utilize KPLSC are currently directed to Holy Cross Hospital for surgeries or Kaiser's Kensington facility. For Kaiser members living in the Southern part of Prince George's County, those locations are considerably further away.

No objections have been raised to the proposed project. In addition, although surgical case volume is expected to be pulled away from other locations, it does not appear any one facility will be significantly impacted. Lastly, three local elected officials wrote letters of support for the proposed facility (DI#2, Exhibit 7).

With regard to costs for consumers, the proposed project is unlikely to alter pricing power or price positions because the competitive landscape for surgical services because many of the cases for the proposed facility are ones that would otherwise be performed at one of several other locations. The cases represent only a small proportion of surgical cases at these other locations. Therefore, the market for surgical services in those locations will not likely be altered. 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. Kaiser also reported that ambulatory surgery is a small part of its total health care expenditures on members, so it does not expect that premiums will be significantly affected by moving surgical cases from non-Kaiser locations to KPGSC (DI#17, page 15).

Commission staff concludes that the proposed project will not have an undue 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.

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, Staff recommends approval of the project.

- KPLSC has demonstrated that establishing six operating rooms at a new location is reasonable because it will be able to use more than five operating rooms at optimal capacity within two years of opening the new facility, based on estimates of the surgery rate per 1,000 Kaiser members and Kaiser membership projections.

- KPLSC has demonstrated that the proposed new facility is a more cost-effective approach to expanding surgical capacity and access of Kaiser members than building an addition to Kaiser's Kensington location or continuing to use existing facilities. In addition, the proposed project will increase the availability and accessibility of surgical services for Kaiser members in the primary service area of KPLSC.

- 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 be minimal. Cases will also be shifted away from an existing Kaiser facility located in Kensington, and two operating rooms at Kensington will be taken out of service to eliminate excess operating room capacity.

IN THE MATTER OF	*	**BEFORE THE**
	*	
KAISER PERMANENTE	*	**MARYLAND HEALTH**
	*	
LARGO SURGICAL CENTER	*	**CARE COMMISSION**
	*	
DOCKET NO. 09-16-2304	*	
	*	

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FINAL ORDER

Based on the analysis and findings contained in the Staff Report and Recommendation, it is this 20th day of May, 2010, by a majority of the Maryland Health Care Commission, **ORDERED:**

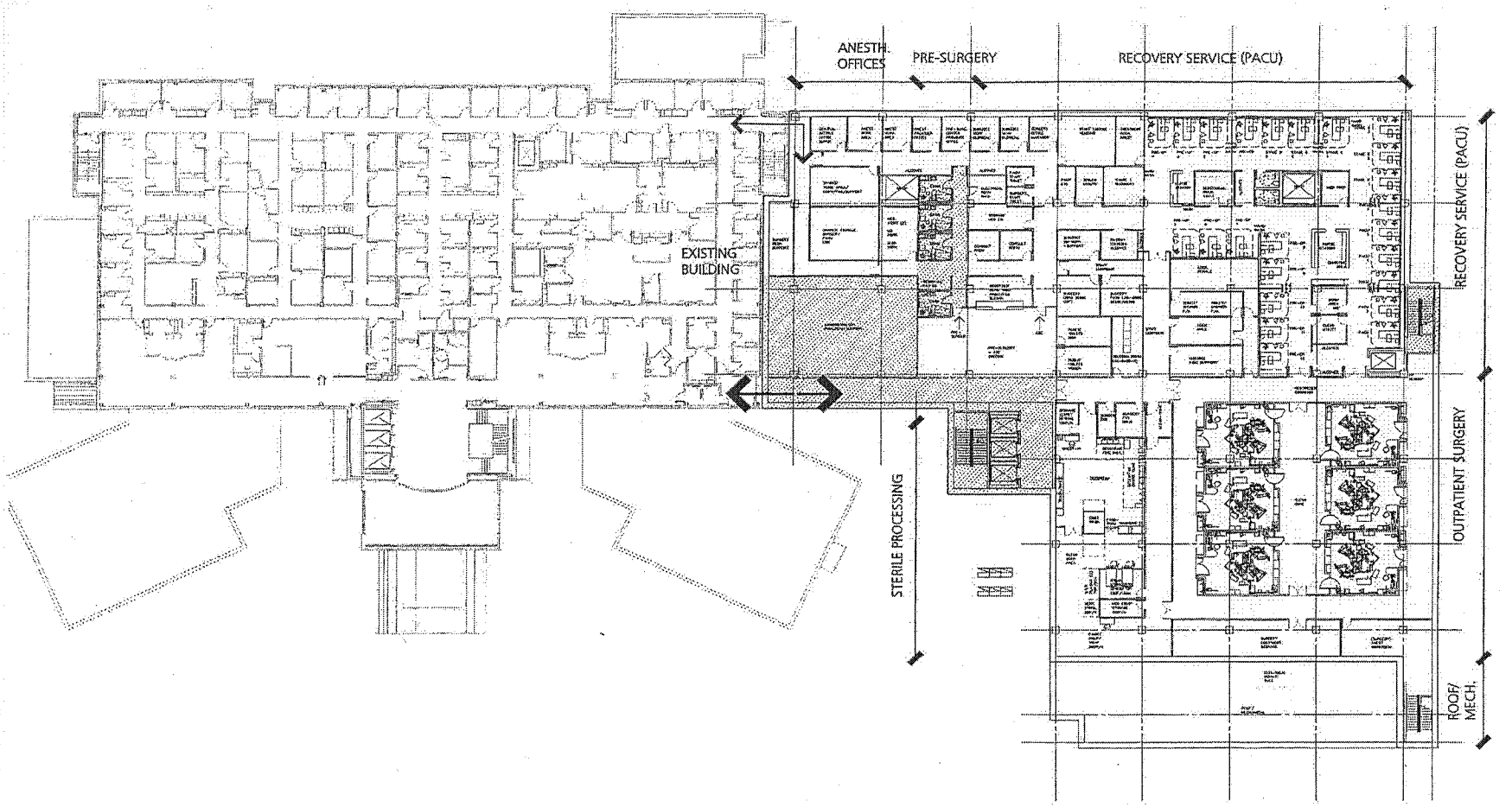
That the application of Kaiser Permanente for a Certificate of Need to establish a freestanding ambulatory surgery facility, Kaiser Permanente Largo Surgical Center with six operating rooms at 1221 Mercantile Lane, Largo, Maryland, at a cost of $16,961,103 is **APPROVED**, with the following conditions:

1. KPLSC 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, 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

APPENDIX A



SECOND FLOOR

NOVEMBER 20, 2009

SCALE: 1"=1/16"

KAISER PERMANENTE

KAISER PERMANENTE Full Service MOB - Largo

0' 5' 10' 20' 50'

TRUE NORTH

PLAN NORTH

ELLERBE BECKET

APPENDIX B

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