STATE OF MARYLAND

Craig P. Tanio, M.D.
CHAIR

Ben Steffen
EXECUTIVE DIRECTOR

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

MEMORANDUM

TO: Commissioners

FROM: Kevin R. McDonald
Chief, Certificate of Need

DATE: April 20, 2017

SUBJECT: Kaiser Permanente Gaithersburg Medical Center
Docket No. 17-15-2390

Enclosed is the staff report and recommendation regarding a Certificate of Need ("CON") application filed by Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.

The applicant proposes to expand its ambulatory surgery facility at the Kaiser Permanente Gaithersburg Medical Center ("GMC"), which is located at 655 Watkins Mill Road in Gaithersburg, to add a third operating room ("OR"). The surgical facilities at GMC received a Certificate of Need ("CON") in 2010 that included shell space for a third OR. GMC opened in April 2013. The estimated cost of $1,998,352 to finish the shell space will be paid for out of cash reserves.

Staff recommends that the Commission APPROVE the project based on staff's conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for General Surgical Services, and the CON review criteria at COMAR 10.24.01.08.

IN THE MATTER OF	*	**BEFORE THE**
	*	
KAISER PERMANENTE	*	**MARYLAND HEALTH**
GAITHERSBURG MEDICAL	*	
CENTER	*	**CARE COMMISSION**
	*	
DOCKET NO. 17-15-2390	*	
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STAFF REPORT AND RECOMMENDATION

April 20, 2017

TABLE OF CONTENTS

Page

I. INTRODUCTION

A. The Applicant

The applicant is Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. ("KPMAS"), a non-profit corporation that is part of an integrated delivery system that provides health care services nationally and locally under the name Kaiser Permanente ("KP" or "Kaiser"). KPMAS contracts with a Kaiser entity in the region, the Mid-Atlantic Permanente Medical Group ("KP Medical Group"), a multi-specialty group practice of more than 1,200 physicians, to meet the medical care needs of Kaiser Permanente members in Maryland, Virginia, and the District of Columbia.

Kaiser Permanente is a health maintenance organization ("HMO") with approximately 310,000 members in the Maryland and DC area. KPMAS owns and operates 17 outpatient medical office buildings in Maryland to provide care directly to Kaiser's members. It contracts with community practitioners and facilities to provide care that KPMAS and the KP Medical Group do not provide directly or that are needed to meet the geographic access needs of its KP members.

KPMAS currently operates five facilities offering ambulatory medical care in Montgomery County. (DI #2, p.9). It states that co-location of primary and specialty care with ancillary services at full-service medical centers is a key component of the Kaiser Permanente vision of comprehensive and affordable health care, allowing patients to have multiple services in the same visit and obtain better coordination of care. Consistent with this model, KPMAS stated that the driver of this project is its focus on creating an integrated care experience to promote cost-effectiveness, efficiency, quality of care, and member convenience and satisfaction.

B. The Project

The applicant's Gaithersburg Medical Center ("GMC" or "Center")) is a multi-specialty facility with an on-site ambulatory surgery facility ("ASF") located at 655 Watkins Mill Road in Gaithersburg, in Montgomery County. KPMAS proposes the addition of a third operating room ("OR") to its ASF that opened in 2013. The surgical facilities at the Center received Certificate of Need ("CON") approval in 2010 that included shell space for a third OR. In addition to outpatient surgery, the Center also provides diagnostic imaging, laboratory, therapy, and pharmacy services. It houses primary and specialty physician offices, an urgent care center, and observation beds. The estimated cost to finish the shelled OR space is $1,998,352 and will be funded with cash reserves. (DI #2, p.9).

C. Summary of Staff Recommendation

Staff recommends approval of the project based on its conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for General Surgical Services. The need for the project has been demonstrated and the cost effectiveness of adding additional needed OR capacity through the finishing of space already created for this eventuality is obvious. The project is viable and the applicant has complied with all terms and conditions of prior CONs. The project will have a positive impact on the ability of Kaiser members

to have ready access to outpatient surgery at the Center and will not have a negative impact on other health care providers.

II. PROCEDURAL HISTORY

A. Record of the Review

See Appendix A for the record of this project review.

B. Local Government Review and Comment

No comments on this project were provided by the local health department or any other local government body

C. Community Support

No comments were received about the project.

D. Interested Parties

There are no interested parties in this review.

III. STAFF REVIEW AND ANALYSIS

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

A. The State Health Plan.

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

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

COMAR 10.24.11.05 STANDARDS

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

(1) Information Regarding Charges. ***Information regarding charges for surgical services shall be available to the public. A hospital or an ambulatory surgical facility shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.***

The applicant responded that, since the vast majority of the patients served are Kaiser members,[1] there are no charges to most patients other than Kaiser Permanente co-payments and deductibles, as the cost of patient care is covered by members' health plan premiums. Any bills for copays or deductibles come from KPMAS, and not from the Center. (DI #2, p.17).

Given the HMO model in which this facility operates and that almost exclusively serves Kaiser subscribers for which no surgical facility charge is generated, staff concludes that this standard is not applicable.

(2) Charity Care Policy.

Paragraphs (a) – (c) of this standard are not applicable for this CON application.

(d) A health maintenance organization, acting as both the insurer and provider of health care services for members, if applying for a Certificate of Need for a surgical facility project, shall commit to provide charitable services to indigent patients. Charitable services may be surgical or non-surgical and may include charitable programs that subsidize health plan coverage. At a minimum, the amount of charitable services provided as a percentage of total operating expenses for the health maintenance organization will be equivalent to the average amount of charity care provided statewide by ASFs, measured as a percentage of total ASF expenses, in the most recent year reported. The applicant shall demonstrate that:

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

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

(iii) If the health maintenance organization's track record is not consistent with the expected level for the population in the proposed service area, the applicant shall demonstrate that the historic level of charity care was appropriate to the needs of the population in the proposed service area.

Paragraph (d) of this standard applies to this application by KPMAS, an HMO. The applicant stated that it provides charitable care and coverage as part of its non-profit mission to improve health in the communities it serves. In this case, rather than providing a set amount of charity care for surgical services, it provides financial assistance to reduce barriers to care and health coverage. KPMAS also stated that it works with community organizations and local governments to enroll uninsured low income individuals and families that have no access to any

[1] There were no non-Kaiser subscribers treated at the ASC in 2016. (DI #13).

other public or private care and coverage available to them. Thus, individuals receiving charitable care from a KPMAS ambulatory surgical facility would primarily be existing participants in one of its charitable health programs, or members needing assistance with co-payments and cost shares, rather than non-members applying for financial assistance with surgical procedure costs. (DI #2, pp. 19-21).

In 2015, KPMAS's provision of charitable health care was 0.9% of total operating expenses, exceeding the statewide ASF average of 0.46%.[2] The following description of three of Kaiser's charitable health programs was provided.

Charitable Health Access Program (CHAP)	
Description	KP collaborates with local governments and community based not-for-profit organizations to provide health care and coverage for uninsured families in need. CHAP helps those who do not qualify for any public or private care and coverage plans, either commercially or through the ACA, and have incomes below 300% of the federal poverty line (FPL). CHAP members receive a 100% subsidized premium and a Medical Financial Assistance Award to help reduce the copays and cost-shares of the off-exchange Gold Medal Plan. The program offers up to 24 months of comprehensive coverage to qualified families. Once enrolled, members have access to primary, specialty, and preventive care, in-patient care, health education classes and all services provided within the KP integrated delivery system. After 24 months, recertification may be an option to remain in the program. In Maryland, KPMAS enrolls members through community partners in Anne Arundel County, Baltimore City, Baltimore County, Frederick County, Howard County, Montgomery County and Prince George's County. In 2015, KPMAS invested $23,938,952 in CHAP.
Medical Care for Children Partnership (MCCP) Programs	
Description	KP partners with local governments, hospitals and/or nonprofit community groups to identify uninsured children who are ineligible for public or private health care programs and are below 300% of the FPL. Once enrolled in the program, children receive free primary care and all services available within the KP integrated delivery system. Over 3,700 children in the Mid-Atlantic Region were able to rely upon KPMAS as their medical home as of August 2016. In 2015, KPMAS spent $4,768,380 in charitable care expenditures for this program in Maryland. It currently participates in partnerships in Montgomery County and Prince George's County in Maryland.
Medical Financial Assistance (MFA) Program	

[2] Kaiser reported that the total operating expenses for Kaiser Permanente Mid-Atlantic Region were $3,076,877,324; two of Kaiser's charitable programs (CHAP and MCCP) totaled $28,707,332 in 2014.

Description	The Medical Financial Assistance Program is an income-eligibility-based financial assistance program to provide a defined amount of financial assistance to be used for health care services within Kaiser medical offices. Patients who cannot afford out-of-pocket costs of health care services may apply to this financial assistance program for free or reduced medical care services at Kaiser clinics, based on financial eligibility criteria. The MFA Program is open to Kaiser members who need assistance with co-payments for services, as well as to non-members seeking care from Kaiser medical offices. Kaiser posts information about its MFA Program on its website, kp.org, and the application for MFA appears on Kaiser's website. In addition, Kaiser displays posters and brochures in its medical offices regarding the availability of the MFA Program. Determination of probable eligibility is made within two business days.

Source: DI #2, pp. 20-21.

The applicant complies with the HMO requirements of the Charity Care standard.

Standards .05A(3), Quality of Care; .05A(4), Transfer Agreements; .05B(4), Design Requirements; and .05B(5), Support Services.

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

.05A(3), Quality of Care;
.05A(4), Transfer Agreements;
.05B(4), Design Requirements; and
.05B(5), Support Services.

The applicant is in compliance with the conditions of participation of the Medicare and Medicaid programs and is accredited by the Accreditation Association for Ambulatory Health Care. It has a written transfer agreement with Shady Grove Adventist Hospital. The facility is designed in compliance with Section 3.7 of the 2014 Facilities Guideline Institute Guidelines. Finally, the required support services (laboratory, radiology, and pathology) are provided at the Center. The text of these standards and the locations within the application where compliance is documented are attached as Appendix B.

(3) Quality of Care. See Appendix B.

(4) Transfer Agreements. See Appendix B.

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

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

KPMAS stated that it generally defines the service area for its larger specialty care centers as that area within a 30-mile radius of the facility, sometimes adjusted for the existence or lack of other Kaiser facilities in the area. The applicant considers this facility's service area to include parts of Frederick and Montgomery Counties, and provided a comprehensive list of the included zip code areas. (DI #2, pp. 23-24).

The applicant meets this standard.

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

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

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

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

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

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

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

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

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

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

KPMAS presented the surgical volume and room utilization statistics shown in Table III-1, below. These numbers show that case volume supported the need for a third OR in 2014

(although marginally), and by 2015 easily surpassed the volumes required to justify three rooms. GMC accommodated this case volume in its two ORs by operating longer hours than it – and the State Health Plan's guidance - identify as optimal.

Table III-1: Historical and Projected Utilization at GMC, CY 2014-2019

Year	OR Cases	Operating Room and OR Cleaning/Prep. Minutes			Number of ORs	ORs Needed
		Surgical procedure time (mins.)	Turnover Time (mins.)	Total Time (Hours)		
2014	1,845	158,301	46,125	3,407	2	**2.09**
2015	2,228	191,162	55,700	4,114	2	**2.52**
2016	2,459	193,790	61,475	4,254	2	**2.61**
2017 projected	2,567	211,007	64,175	4,486	3	**2.81**
2018 projected	2,707	222,515	67,675	4,837	3	**2.96**
2019 projected	2,808	230,818	70,200	5,017	3	**3.07**

Source: DI #2, p.26.

The projected volume growth for 2017-2019 shown in both Tables III-1 and III-2 are based on growth projections in the number of Kaiser subscribers in Montgomery and Frederick Counties and shows the actual and projected relationship between Kaiser subscribers and surgical cases. KPMAS projects growth in surgical cases that parallels the growth in the subscriber base.

Table III-2: Historical and Projected Utilization at GMC, 2014-2019

Calendar Year	Subscribers	Year to Year Change	Cases	Year to Year Change	Cases per 100 subscribers
2014 actual *	62,074	-- --	1,845	-- --	2.97
2015 actual	71,235	14.8%	2,228	20.8%	3.13
2016 actual	81,165	13.9%	2,459	10.4%	2.93
2017 projected	*87,614*	*7.9%*	*2,567*	*7.9%*	*2.93*
2018 projected	*92,403*	*5.5%*	*2,707*	*5.5%*	*2.93*
2019 projected	*95,863*	*3.7%*	*2,808*	*3.7%*	*2.93*

Source: DI #2, p.35

Staff notes that the projected 2017-2019 surgical volumes are not a critical factor in this review, as the Center's actual results in 2015 and 2016 justified a third OR based on the State Health Plan's optimum capacity use assumptions. Thus, even without any further increase in demand for surgery at this center, the project would still be consistent with this standard.

(4) <u>Design Requirements.</u> See Appendix B.

(5) Support Services. See Appendix B.

(6) Patient Safety.

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

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

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

KPMAS stated that user input is being actively included in the design process through review of plans and input on equipment and design features of the ORs. The applicant listed factors that it believes will allow expansion of OR capacity to improve the safety of its operations:

- An additional OR will allow the Center to minimize the number of procedures performed in the late afternoons and evenings, times of day that industry studies show have a higher incidence of medical errors;

- The new OR will be designed and equipped to closely match the two existing ORs, standardization that will allow staff to move from one room to another with minimal chance of confusion;

- Patient safety features are already incorporated in the design guidelines of the Facilities Guidelines Institute Guidelines for Design and Construction of Healthcare Facilities, which KPMAS will follow in this project. Adherence to these guidelines, specified in the Surgical Services Chapter, at .05B(4)[3] primarily addresses circulation patterns in the facility, space requirements, room finishes, and air handling and filtration systems for maintenance of a sterile operating environment and the air quality levels needed to minimize the risk of surgical-related infections; and

- Specific consideration is being given by KPMAS to the lighting in each room to identify any opportunities to minimize staff and surgeon fatigue from that source while still maintaining the illumination levels necessary to conduct the procedures.

KPMAS also cited its investment in an electronic healthcare record system ("EHR") to support the delivery of care to its members and to enhance communications among its medical professionals. The system includes physician order entry for laboratory and radiology tests, as well as electronic prescribing capability connected with the Kaiser Pharmacy systems. The EHR allows physicians to send test orders and receive test results electronically, leading to rapid availability of test results to all Kaiser treating physicians with EHR access, prevention of duplicate testing and enhancement of patient safety. The EHR performs other patient-safety functions as well, such as automated clinical decision support for adverse drug event prevention, drug-allergy checking, alerts when preventive health screenings are due, and medication adherence monitoring.

[3] See Appendix B for the text of the standard.

The applicant states that this system has increased efficiency, reduced errors, and improved patient care and patient safety.

The project complies with this standard.

(7) Construction Costs.

The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

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

(b) Ambulatory Surgical Facilities.

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

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

Paragraph (b) of this standard requires a comparison of the project's estimated construction cost with an index cost derived from the Marshall Valuation Service ("MVS") guide. For comparison, an MVS benchmark cost is typically developed for new construction based on the relevant construction characteristics of the proposed project. The MVS cost data include the base cost-per-square-foot for new construction by type and quality of construction for a wide variety of building uses including outpatient surgical centers. The MVS guide also includes a variety of adjustment factors, including adjustments of the base costs to the costs for the latest month, the locality of the construction project, as well as factors for the number of building stories, the height per story, the shape of the building (such as the relationship of floor area to perimeter), and departmental use of space. The MVS guide identifies costs that should not be included in the MVS calculations. These exclusions include costs for buying or assembling land, making improvements to the land, costs related to land planning, discounts or bonuses paid for through financing, yard improvements, costs for off-site work, furnishings and fixtures, marketing costs, and funds set aside for general contingency reserves.[4]

[4] Marshall Valuation Service Guidelines, Section 1, p. 3 (January 2016).

Both KPMAS and MHCC staff found that the estimated cost per square foot for this project, which is a very small scale project (finishing 520 square feet of existing building space) to be substantially higher than the index cost derivable for such a project using the MVS guidelines. Staff calculated an MVS index construction cost of $810 per square foot because the project involves development of expensive operating room space in a shell. The estimated cost per square foot for the project, based on the estimate of $769,556 for the actual building cost, architectural and engineering fees, and permits, is $1,480 per square foot, 82% higher than the benchmark. Using different adjustments, the applicant calculated a larger spread, 91%, between an MVS benchmark cost and the estimated project cost.

As noted, the unusually high cost for a project of this type, when expressed in terms of cost per square foot, is related to the small scale of the project, but there are also higher costs related to the specific conditions confronted in a project of this type. Because this is a busy surgical facility, KPMAS wants to maintain operations while the project is implemented. To assure safe operation and minimize any project-related disruption, all work will have to be performed at night and on weekends, and weeknight work shifts will have to be short (six hours) because work cannot start till the post-anesthesia unit is cleared and must end early enough so that a terminal cleaning regime for the entire OR suite and central processing can be completed. This cleaning regime is a recommendation that emerged from KPMAS's pre-construction risk assessment.

In 2016, Kaiser initiated a very similar project at the KPMAS South Baltimore County Medical Center, located in Halethorpe, which ultimately came in at a cost estimate well above the MVS index or benchmark cost for similar reasons. That project, which involved the fitting out of 491 square feet of shell space to add a third operating room, ultimately involved an estimated cost of $2,253,239, with $697,099 of that total representing the building, architectural and engineering, and permitting costs relevant to this standard. Thus, that project's construction cost was $1,420 per square foot, about four percent less than the estimated construction cost of the GMC fit-out.

Because KPMAS can demonstrate that the cost of recently constructed surgical facilities similar to the proposed facility support the reasonableness of the construction cost estimate for the GMC project, staff recommends that the Commission find that the GMC project is consistent with this standard. While not directly related to this standard, the application notes that these high costs, relative to the MVS benchmark, will not have an effect on charges, because this facility serves HMO patients who are not billed on a charge per service basis. This expenditure will represent a relatively small, incremental addition to KPMAS's capital budget (e.g., straight-line depreciation of the total $2 million dollar project cost over a 10 to 15 year period, is approximately $130,000 to $200,000) which would have no appreciable impact on member premiums.

(8) <u>Financial Feasibility.</u>

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

(a) An applicant shall document that:

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

With regard to subparagraph (a)(i), the applicant referred to utilization and population projections provided in Standard .05B(3) that demonstrates an increase in subscriber population and case volume. Commission staff notes that actual usage supported the need for a third OR by 2015 or earlier. (DI #2, p.33).

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

As previously noted, the Center will not charge patients for the services they obtain at the facility. As a facility operated by a staff model HMO, payments for subscriber services are covered by subscriber premiums, not fees paid for specific services. Similarly, any copayments and deductibles are charged by and accrued to KPMAS and not to the Gaithersburg Medical Center. (DI #2, p.33).

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

KPMAS stated that its staffing and expense projections are based on its utilization projections and current staffing and expense levels. Although projected staffing shows growth that appears somewhat disproportionate to its current staff-to-caseload ratio, the resulting staffing ratios are much like those in the very similar recently approved KPMAS ambulatory surgical facility in Baltimore County (Docket # 16-03-2372). (DI #2, Exh. 11, Table L.; Table 3, p.45; Figure 5, p.35).

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

The applicant stated that the expenses at the Center are entirely subsidized by Kaiser Foundation Health Plan of the Mid-Atlantic States. As noted in 8(a)(ii), above, revenue accrues at that level as well.

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

See responses to (8)(a)(ii) and (iv), immediately above.

The applicant has demonstrated the project's financial feasibility.

(9) Preference in Comparative Reviews.

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

This standard is not applicable.

C. Need

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

This criterion directs the Commission to consider the "applicable need analysis in the State Health Plan," which, in this instance, is found in the Surgical Services Chapter at COMAR 10.24.11.05B(3), Need – Minimum Utilization for Expansion of an Existing Facility. As previously outlined and supported by the data provided in Tables III-1 and III-2, the proposed project is consistent with the Chapter's need standard for OR additions.

D. Availability of More Cost-Effective Alternatives

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

The only alternative discussed by the applicant was to forego the project and continue to operate with two ORs. This option would require GMC to continue operating at extended hours (10 hours/day from 7:30 AM to 5:30 PM) and continue referring patients (approximately 527 in 2016) to alternative Kaiser ASF's. This option was rejected as inconvenient to both patients and staff.

Given that the initial CON for GMC (Docket No. # 10-03-2303) approved shell space for an additional OR in anticipation of member growth and demand for surgical services, choosing the option to execute this expansion is eminently logical. It would quickly address GMC's current levels of demand for OR capacity. (DI#2, p.40-42).

Staff concludes that the applicant's selection of this option is the most cost-effective alternative to address the need for an additional operating room.

E. Viability

The Commission shall consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frames set

forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

KPMAS submitted audited financial statements covering 2014 and 2015. The statements demonstrate that the applicant has adequate funds for this modest project. (DI #2, Exh. 8). However, these statements, combined with the applicant's audited statement for 2013 received in review of the applicant's 2016 project, show cumulative losses of $36 million between 2013 and 2015. When asked to address this performance in that review (Kaiser Permanente Baltimore Surgical Center review, Docket No. 16-03-2372), KPMAS submitted a projected profit and loss statement for its operations for the next ten years, which was based on its long-term strategic plan. This projection showed that the organization anticipated reversing the losses by increasing revenue through membership growth (KPMAS projects growing its membership from 634,000 in 2016 to 1.12 million in 2024) while reducing its rate of expense growth over time. In Montgomery and Frederick Counties KPMAS membership grew from 62,000 in 2014 to 81,000 in 2016, a 31% increase.

Indeed, the 2013-2015 losses declined, from $19 million in 2013 to $12 million in 2014, and $5 million in 2015. , as

Staff recommends that the Commission find this project to be viable.

F. Compliance with Conditions of Previous Certificates of Need

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

The applicant stated that KPMAS received three CONs in 2010 to establish three separate ambulatory surgical facilities in: Largo (Docket No. 09-16-2304); Gaithersburg (Docket No. 09-15-2303); and Baltimore (Docket No. 10-03-2306). Each of these projects was approved with the condition that it:

(1) Provide the Commission with documentation of obtaining 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; and,

(2) Execute 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.

KPMAS met both conditions for all three projects approved in 2010 and the projects received first use approval from MHCC staff. By completing each approved project on time and in accordance with the approved budget, each project also met the terms of its CON.

KPMAS also received a CON in 2016 to add an OR to its existing facility in Baltimore County (Docket No. 16-03-2372) that project required approval of a change in its approved cost in November 2016. This project was also completed on time and in accordance with the modified budget.

The applicant has demonstrated compliance with all terms and conditions of previous CONs.

G. Impact on Existing Providers

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

The applicant responded that this project does not have an impact on other facilities, as it is intended to improve the ability of the Center to handle the case volume it is already experiencing. It is not a surgical center that directly completes for surgeons or patients with other surgical centers. Similarly, it will have no impact on payer mix, as it is used nearly exclusively by KP subscribers, who will have better availability and access to surgical care as a result of this project. KPMAS also states that it will have no impact on costs to the health care system, as it has no impact on Kaiser Permanente premiums and is intended to serve subscribers already using the Center.

Staff concludes that the impact of this project is positive for Kaiser members and that there will be no negative impact on existing providers.

IV. SUMMARY AND STAFF RECOMMENDATION

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

Accordingly, Staff recommends that the Commission **APPROVE** the application of the Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. for a Certificate of Need authorizing the addition of a third operating room through the finishing of existing space at its Gaithersburg Medical Center.

IN THE MATTER OF	*	**BEFORE THE**
	*	
KAISER PERMANENTE	*	**MARYLAND HEALTH**
GAITHERSBURG AMBULATORY	*	
SURGERY CENTER	*	**CARE COMMISSION**
	*	
DOCKET NO. 17-15-2390	*	
	*	

*** ***

FINAL ORDER

Based on the analysis and conclusions in the Staff Report and Recommendation, it is this 20th day of April, 2017, by the Maryland Health Care Commission, **ORDERED:**

That the application by Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc. for a Certificate of Need to add an operating room through the finishing of existing shelled space at the Kaiser Permanente Gaithersburg Medical Center at a cost of $1,998,352 be, and hereby is, **APPROVED**.

MARYLAND HEALTH CARE COMMISSION

April 20, 2017

Appendix A:

Record of the Review

APPENDIX A: Record of the Review

Docket Item #	Description	Date
1	Commission staff acknowledged receipt of the Letter of Intent.	12/9/16
2	The applicant filed its Certificate of Need Application.	1/6/17
3	Commission staff acknowledged receipt of application for completeness review.	1/9/17
4	Commission staff requested the Washington Times publish notice of receipt of application.	1/9/17
5	Commission staff requested the Maryland Register publish notice of receipt of the application.	1/9/17
6	Notice of receipt of application was published in the Washington Times.	1/18/17
7	Following completeness review, Commission staff requested additional information.	1/30/17
8	Commission staff received responses to additional information request with large plans.	2/8/17
9	Commission staff notified applicant of formal start of review of the application.	2/16/17
10	Commission staff requested that the Washington Times publish notice of the formal start of the review.	2/16/17
11	Commission staff requested that the Maryland Register publish notice of the formal start of the review.	2/16/17
12	Request made for Local Planning Department comments from Local Health Planning.	2/16/17
13	Commission staff received email from applicant with updated data for 2016.	3/31/17

APPENDIX B

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

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

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

STANDARD	**APPLICATION REFERENCE (Docket Item #)**
A. (3) Quality of Care. A facility providing surgical services shall provide high quality care. … (c) An existing ambulatory surgical facility shall document that it is: (i) In compliance with the conditions of participation of the Medicare and Medicaid programs; and (ii) Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation agency recognized by the Centers for Medicare and Medicaid as acceptable for obtaining Medicare certification. (d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will: (i) Meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment. (ii) Obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility.	DI# 2, p.22 DI# 2, Exhibit 5
A.(4) Transfer Agreements. (a) Each ASF and hospital **shall have written transfer and referral agreements** with hospitals capable of managing cases that exceed the capabilities of the ASF or hospital.	DI# 2, p. 22

(b) Written transfer agreements between hospitals shall comply with the Department of Health and Mental Hygiene regulations implementing the requirements of Health-General Article §19-308.2.	DI# 2, Exhibit 6
B. (4) <u>Design Requirements</u>. Floor plans submitted by an applicant **must be consistent with the current FGI Guidelines.** (a) A hospital shall meet the requirements in Section 2.2 of the FGI Guidelines. (c) Design features of a hospital or ASF that are at variance with the current FGI Guidelines shall be justified. The Commission may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.	DI #2, p. 26-27 and DI# 8, p.2 and Exhibit 3
B.(5) <u>Support Services</u>. Each applicant **shall agree to provide as needed, either directly or through contractual agreements, laboratory, radiology, and pathology services**.	DI #2, p. 27

Appendix C

Project Budget

Kaiser Permanente Gaithersburg Medical Center	
A. Use of Funds	
1. Capital Costs	
c. Renovation	
(1) Building	$600,000
(2) Fixed Equipment(not included in construction	Incl Above
(3) Land Purchase	
(4) Site Preparation	-
(5) Architect/Engineering Fees	120,000
(6) Permits	49,556
SUBTOTAL	**$769,556**
c. Other Capital Costs	
(1) Major Movable Equipment	617,349
(3) Contingencies	163,501
(4) Other (PM recharge, IT, Terminal Cleaning)	390,006
Subtotal Other Capital Costs	**$1,170,856**
Capitalized Construction Interest	-
Total Current Capital Cost	**1,940,412**
Future Inflation	57,940
TOTAL PROPOSED CAPITAL COSTS	**$1,998,352**
Financing Cost and Other Cash Requirements	
a. Loan Placement Fees	-
d. Non-Legal Consulting Fees	
f. Debt Reserve Fund	-
SUBTOTAL	**-**
3. Working Capital Startup Costs	-
Subtotal Working Capital	
TOTAL USES OF FUNDS	**$1,998,352**
B. Sources of Funds For Project	
1. Cash	$1,998,352
3. Gifts, bequests	-
4. Interest Income	-
5. Authorized Bonds	-
TOTAL SOURCES OF FUNDS	**$1,998,352**