

**IN THE MATTER OF**

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**BEFORE THE**

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**SUMMIT AMBULATORY**

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**MARYLAND**

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**SURGICAL CENTER, L.L.C.**

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**HEALTH CARE**

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**Docket No. 18-02-EX009**

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**COMMISSION**

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**STAFF REPORT & RECOMMENDATION**

**EXEMPTION FROM CERTIFICATE OF NEED TO ESTABLISH  
AN AMBULATORY SURGICAL FACILITY**

**December 20, 2018**

## **I. INTRODUCTION**

### **A. Background**

Changes to COMAR 10.24.11, the Surgical Services Chapter of the State Health Plan for Facilities and Services (“SHP”) that became effective in early 2018 created a limited alternative pathway for establishing an ambulatory surgical facility (“ASF”) with two operating rooms through an exemption from Certificate of Need (“CON”) review rather than through review and approval of a CON application. An "ambulatory surgical facility" is defined in the Surgical Services Chapter, at COMAR 10.24.11.08B(2),<sup>1</sup> as

a health care facility that:

- (a) Has two or more operating rooms;
- (b) Operates exclusively for the purpose of providing surgical services to patients requiring postoperative observation but who do not require hospitalization and in which the expected duration of services would not exceed 24 hours following admission;
- (c) Seeks reimbursement from payors as an ambulatory surgical facility, as defined in Health-General Article §19-3B-01, Annotated Code of Maryland; and
- (d) Is physically separate from any hospital.”

The amendments to the Surgical Services Chapter that went into effect earlier this year allow the Maryland Health Care Commission (“MHCC” or “Commission”) to issue an exemption from CON review to permit the establishment of an ambulatory surgical facility with two sterile operating rooms when such facility establishment is requested by the office of one or more health care practitioners or a group practice, as defined in §1-301 of the Health Occupations Article, provided that MHCC determines that all applicable general and project review standards are met.

### **B. The Applicant**

Summit Ambulatory Surgical Center, L.L.C. (Summit”), located at 7580 Buckingham Boulevard, Suite 100, in Hanover (Anne Arundel County) is, for purposes of CON regulation, classified as a “physician outpatient surgical center” or “POSC.” A POSC is a “center, service, office, facility, or office of one or more health care practitioners that has no more than one sterile operating room, that operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization, and that seeks reimbursement from payors for the provision of ambulatory surgical services.” These centers are licensed in Maryland as “freestanding ambulatory surgical facilities” and certified by Medicare as “ambulatory surgical centers” (“ASCs”) in the same way that larger outpatient surgical facilities with two or more operating rooms are licensed and certified. However, establishment of a POSC does not require CON approval because a POSC is not defined as a health care facility in the Commission’s statute

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<sup>1</sup> The MHCC’s definition and its basis for exemptions is based on the definition of “ambulatory surgical facility” in Maryland Code Ann., Health General (“Health-Gen.”) §19-114(b).

and regulations. A POSC can be established through issuance of a determination of coverage by MHCC staff, which determines that it falls below the two-operating room threshold requiring issuance of a CON. Most outpatient surgical facilities in Maryland are POSCs.

Summit is a specialty urological POSC owned by Chesapeake Urology Associates, L.L.C. (“CUA”), which is owned by 44 physicians who specialize in urology and urological surgery. CUA has 18 outpatient surgical centers in eight jurisdictions. Six physicians, four of which are physician owners of CUA, are identified as practitioners who use or will use the Hanover center proposing to expand its operating room capacity. The POSC that is the subject of this exemption request currently has a single sterile operating room and three non-sterile procedure rooms.

### **C. The Project**

Summit proposes to convert an existing non-sterile procedure room to a second sterile OR. It does not propose replacement of the non-sterile procedure room. This conversion to a two-OR ambulatory surgical facility is estimated to cost \$25,000. The applicant notes that the facility was designed in anticipation of this expansion of OR capacity, which is why the conversion of one of the three procedure rooms to a second OR is relatively inexpensive.

### **D. Staff Recommendation**

MHCC staff recommends that the Commission approve Summit’s request for an exemption from CON review to establish itself as a two-operating room ambulatory surgical facility that will also operate two non-sterile procedure rooms. A review of the basis for this recommendation follows.

## **II. PROCEDURAL HISTORY**

Summit filed a request for an exemption from CON review on September 14, 2018. This initial filing was incomplete and a request addressing the applicable criteria and standards was filed on November 6, 2018.

## **III. PROJECT CONSISTENCY WITH REVIEW CRITERIA**

### ***.06 Exemption from Certificate of Need Review for the Establishment of an Ambulatory Surgical Facility.***

#### ***A. Applicability.***

***The Commission may issue an exemption from Certificate of Need review to permit the establishment of an ambulatory surgical facility with two sterile operating rooms in the following circumstances, provided that the Commission determines that all applicable general and project review standards are met.:***

***(1) The office of one or more health care practitioners or a group practice, as defined in §1-301 of the Health Occupations Article, seeks to establish an ambulatory surgical facility with two operating rooms;***

*(2) A general hospital with two or more operating rooms seeks to establish an ambulatory surgical facility with two operating rooms in conjunction with conversion of the hospital to a freestanding medical facility on the same campus as the freestanding medical facility or immediately adjacent to the freestanding medical facility, if it seeks such an exemption:*

*(a) In conjunction with an exemption to convert to a freestanding medical facility; or*

*(b) After the issuance of an exemption to convert a general hospital to a freestanding medical facility and prior to the closure of the general hospital.*

*(3) A general hospital seeks to establish an ambulatory surgical facility with two operating rooms in conjunction with the closure of two dedicated outpatient or mixed-use operating rooms.*

Summit is the office of one or more health care practitioners. As such, it qualifies to establish itself as an ASF under the current statute and the SHP regulations established by MHCC.

## **B. General and Project Review Standards**

*(1) General Standards. An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall meet the applicable standards in Regulation .05A(1)-(4) of this chapter.*

The applicant states that it makes information on its usual and customary charges and the volume of surgical procedures performed available to patients or, in the case of procedure volume, the public, upon request or inquiry.

The applicant provided a charity care policy. This policy states that self-pay non-covered charges will be considered for a 100% charity care discount for persons with gross family income at or below 100% of the current federal poverty level established in the Federal Register and discounted charges will be considered for persons with household income between 101 and 300% of the federal poverty level. The policy notes that procedures that are discretionary in nature or cost intensive due to the cost of required supplies, disposables, or implants are not eligible for financial assistance. The policy, as submitted, indicated that probable eligibility determinations for financial assistance would be communicated to patients within two business days once the application and required documentation was received. The applicant supplemented its request, after discussion with staff, to bring this element of its policy in full alignment with the standard, that requires a determination of probable eligibility within two business days of a patient's request for financial assistance. The applicant reports that Summit provided actual charity care in the first seven months of 2018 equivalent to 2.3% of operating expenses, a level that exceeds the most recently reported overall average level of charity care provided by all ambulatory surgical facilities (0.56%), consistent with MHCC's general charity care policy standard.

Summit is licensed in good standing by the Maryland Department of Health, Medicare-certified, accredited by the Accreditation Association for Ambulatory Health Care, Inc., and enrolled in the Ambulatory Surgery Center Quality Reporting Program.

Staff recommends that the request for an exemption from CON review be found to comply with the applicable general standards for a project of this type.

**(2) Need. An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall:**

**(a) Demonstrate the need for two sterile operating rooms at the proposed ambulatory surgical facility utilizing the operating room capacity assumptions and other guidance included in Regulation .07 of this chapter; and**

**(b) Demonstrate that optimal capacity, as defined in Regulation .07 of this chapter will be reached for both operating rooms within three years of establishing the proposed ASF.**

Summit reports that, in the twelve months ending on September 30, 2018, the five physicians performing surgery at Summit during that period performed 1,029 cases in the center's OR, totaling 1,935 hours of OR time, based on the OR capacity assumptions established in the Surgical Services Chapter, equivalent to 119% of "optimal capacity," based on those same assumptions.

Summit reports that two additional physicians began performing surgery at the Hanover center in September 2018 and will use this center as their primary venue for outpatient surgery. Additionally, another CUA physician anticipates initiation of certain specialized cases at the facility in December 2018 and an additional physician is expected to begin using the center in March 2019. With this growth in practicing staff, Summit projects OR hours in Hanover for the proposed two ORs to grow to 3,672 hours by the fiscal year ending on September 30, 2021, 90% of full capacity and 113% of optimal capacity, based on the SHP's OR capacity assumptions.

Staff concludes that the exemption request complies with this standard.

**(3) Design Requirements. An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall meet the following design requirements:**

**(a) The proposed expanded or new facility must be designed in conformance with the requirements for outpatient surgical facilities included in the current FGI Guidelines. An operating room shall be located in a restricted area. A non-sterile procedure room shall not be located in a restricted area. The clean and soiled work areas shall be physically separated; and**

**(b) Design or equipment features of a proposed expanded or new facility at variance with the current FGI Guidelines must be justified. Commission staff may consider the opinion of staff at the Facility Guidelines Institute, which publishes the Guidelines, in determining whether the proposed variance is acceptable.**

Summit states that the facility's design is compliant with this standard and this is consistent with staff's review of the floor plan drawings submitted. Staff concludes that the design standard has been satisfied by the applicant. A floor plan drawing of the facility is appended to this report.

**(4) Location.**

**(a) An applicant seeking to establish an ASF with two operating rooms must identify a specific location for the proposed ASF and may not locate or operate the proposed ASF in a way that effectively results in the establishment of an ASF with three or more operating rooms.**

*(b) An applicant seeking to establish an ASF with two operating rooms through relocation of operating rooms from a hospital shall locate the proposed ASF within the service area of the hospital.*

*(c) A general hospital seeking an exemption to convert to a freestanding medical facility that is also seeking to establish an ambulatory surgical facility in conjunction with this exemption process shall locate the proposed ambulatory surgical facility on the campus of the freestanding medical facility or an immediately adjacent location.*

This standard is not applicable to this project. Summit is an existing POSC adding a second OR. It is not relocating and, if authorized to add an OR, will not be located or configured in a way that effectively results in the establishment of an ASF with three or more ORs. No relocation of hospital ORs is part of this project.

**(5) Efficiency.**

*(a) An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under this regulation shall demonstrate how its project will result in the more efficient and effective delivery of surgical services by presenting an analysis that compares the level of efficiency and effectiveness of establishing a POSC instead of the proposed ASF.*

*(b) A hospital proposing to establish an ASF in conjunction with closure of two operating rooms shall demonstrate that the proposed ASF will result in an adjusted global budget that accounts for the lower surgical capacity of the hospital and is budget neutral or results in cost savings for Medicare and other payers, with respect to the global budget of the hospital, as determined by HSCRC.*

Summit cites its recent OR utilization, which slightly exceeds optimal capacity use as defined in the Surgical Services Chapter, and states that a second OR “is necessary to promote the efficiency, safety, and quality of the surgical services” it offers. It believes that a second OR will

increase efficiency and flexibility in scheduling and resource utilization, [noting that] nurse staffing . . . can be better leveraged with multiple rooms in use simultaneously. A second room also provides a measure of backup capability in the event that equipment in a given room requires maintenance or goes down leaving the room unusable.

The comparative analysis called for in this standard is more relevant to a proposal by a physician or group practice to develop a new two-OR ASF rather than a proposal such as that presented by Summit, in which an established POSC is establishing an ASF through renovations to add a second OR. These latter types of proposals are inherently more efficient alternatives from the standpoint of capital costs and staffing and have the important characteristic of placing additional capacity at the established center location.

Staff recommends that the request for exemption from CON review be found to comply with this standard.

**(6) Construction Costs.** *The estimated construction cost per square foot of the new construction required to establish an ambulatory surgical facility through an exemption from*

*Certificate of Need under this regulation shall be reasonable and consistent with current industry cost experience.*

*(a) The projected cost per square foot of new construction shall be compared to the benchmark cost of good quality Class A construction for outpatient surgical centers given in the Marshall Valuation Service® guide. This standard does not apply to the costs of renovation or the fitting out of shell space.*

*(b) 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 necessity and reasonableness of the construction costs. An applicant may provide additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility to support the applicant's analysis of the reasonableness of the construction costs.*

This standard is not applicable. The project will not involve new building construction. It will be limited to renovation of existing space. The renovations will be limited to fitting out an existing procedure room, originally designed and placed within the center's floor plan so that it could be easily retrofitted to a second operating room when case volume warranted this change.

### **C. Transferability and Procedural Requirements.**

This regulation notes, among other things, that an exemption from Certificate of Need may be issued with conditions if the Commission determines that approval with conditions is appropriate. In this case, staff does not believe that a conditional approval is necessary.

### **STAFF RECOMMENDATION**

Based on the information considered in this review, MHCC staff concludes that Summit Ambulatory Surgical Center, L.L.C. meets the requirements for an exemption from Certificate of Need review in accordance with COMAR 10.24.11.06. MHCC staff recommends that the Commission approve an exemption from Certificate of Need Review, authorizing Summit to renovate the existing surgery center to create a second operating room at an estimated cost of \$25,000.

