




MARYLAND HEALTH CARE COMMISSION

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MEMORANDUM

TO: Commissioners

FROM: Kevin R. McDonald
Chief, Certificate of Need 

DATE: July 18, 2019

SUBJECT: Maryland Surgery Center for Women, LLC t/a Maryland Surgery Center
Docket No. 18-15-2434

Enclosed is the staff report and recommendation regarding a Certificate of Need (“CON”) application filed by Maryland Surgery Center for Women, LLC, d/b/a Maryland Surgery Center (“MSC”), an existing physician outpatient surgery center in Rockville in Montgomery County, Maryland.

MSC plans to convert one of its five procedure rooms to a sterile operating room (“OR”), resulting in a total of two sterile ORs, thereby establishing an ambulatory surgical facility (“ASF”).

The estimated capital cost for MSC to convert one of its procedure rooms to a second OR is approximately \$183,155. The estimated cost of the renovations is \$107,211. Capital equipment additions would be restricted to the cost of an anesthesia machine and related monitors totaling an estimated \$43,900. The remainder of the total capital costs are attributed to attorney fees of \$25,000 and an inflation allowance of \$7,044. The applicant intends to pay for these renovations using its own 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

MARYLAND SURGERY

CENTER FOR WOMEN, LLC

d/b/a MARYLAND SURGERY

CENTER

Docket No. 18-15-2434

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BEFORE THE

MARYLAND

HEALTH

CARE

COMMISSION

Staff Report and Recommendation

July 18, 2019

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I. INTRODUCTION

The Applicant

Maryland Surgery Center for Women, LLC doing business as (“d/b/a”) Maryland Surgery Center (“MSC”) is an existing physician outpatient surgery center (“POSC”)¹ with one operating room (“OR”) and five procedure room in the town of Rockville in Montgomery County. Sixty percent of MSC is owned by AmSurg Holdings, Inc. and the remaining interests are owned by 27 physicians, each of whom has less than a five percent ownership interest. (DI #2, p. 3). AmSurg Holdings is a part owner of over 260 outpatient surgery centers in 35 states and the District of Columbia.²

The Project

MSC proposes to convert one of its five procedure rooms to a sterile operating room, resulting in a total of two sterile ORs, thereby establishing an ambulatory surgical facility (“ASF”).³ The applicant states that, with changes to technology and the transition of some of the higher acuity cases to outpatient centers, it has had significant difficulty accommodating additional volume and has outgrown its single OR. The applicant also notes that the high acuity cases require lengthy OR time and extended recovery time, pushing cases into evening hours and requiring the Center to be open on Saturdays. (DI #2, p. 6).

The estimated capital cost for MSC to convert one of its procedure rooms to a second OR is approximately \$183,155. Renovations will include moving the entry door of one OR, closing off the existing door that opens to the recovery room, and replacing the existing single scrub sink with a double sink to accommodate both ORs. Minor changes related to the waste gas line installation for an anesthesia machine also will be required. The estimated cost of the renovations is \$107,211. Capital equipment additions would be restricted to the cost of an anesthesia machine and related monitors totaling an estimated \$43,900. (DI #2, p. 6). The remainder of the total capital costs are attributed to attorney fees of \$25,000 and an inflation allowance of \$7,044. (DI #2, Att. 4, Table E).

MSC expects to complete the renovation and achieve first use within three months of receiving its CON and to reach full utilization within 36 months of first use. The applicant states that renovation will commence one month after the CON is obtained and is expected to be completed within one month. It also states that the second OR will be operational after final

¹ A physician outpatient surgery center (POSC) is defined at COMAR 10.24.11.08B(25) as “any 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.”

² <https://www.amsurg.com/about-us/our-centers/>

³ If the Commission approves MSC’s CON application, its status as an ASF will be short-lived. Effective October 1, 2019, Maryland law enacted in the 2019 session of the General Assembly becomes effective and, as of that date, an ambulatory surgical facility will be defined in Maryland law as having three or more ORs.

inspections, which it expects will be completed within one month after the renovation is completed. (DI #2, pp. 7, 8).

Staff Recommendation

Staff concludes that MSC demonstrated that its projected surgical case volume and OR minutes for the proposed ASF will operate the two general purpose ORs at optimal capacity, as defined in the Surgical Services Chapter, COMAR 10.24.11, within 36 months of CON approval. MSC forecasts that the project will be financially viable and prove to be a cost-effective option for delivering outpatient surgical services for physicians and residents within its service area. Commission staff concludes that MSC's forecasts are credible, and believes that the project will have a positive impact on patient access and reduce the cost of outpatient surgery for most patients and payers, without having a significant negative impact on other providers of outpatient surgical services.

For these reasons, as explained more fully in this Staff Report, Commission staff recommends that the Commission issue a CON for the proposed ambulatory surgical facility based on staff's conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the General Surgical Services chapter of the State Health Plan, and with the Certificate of Need review criteria at COMAR 10.24.01.08G(3)(a)-(f).

II. PROCEDURAL HISTORY

A. Record of the Review

Please see Appendix 1, Record of the Review.

B. Interested Parties

There are no interested parties in this review.

C. Local Government Review and Comment

No comments were received from a local governmental body.

D. Community Support

Maryland Surgery Center submitted letters supporting the establishment of the proposed ambulatory surgical facility. (DI #2, Att. 18). Letters of support for the project were received from a number of physicians who will use the facility:

- Holy Cross Anesthesiology Associates, PA, Silver Spring, Maryland
- Uri Prikoupenko, MD, Surgical and Office Gynecology, LLC, Rockville, Maryland
- Brad Norman, MD, Capital Women's Care, Silver Spring, Maryland
- Richard Margolis, MD of Capital Women's Care, Silver Spring, Maryland

- Craig Dickman, MD, Capital Women's Care, Silver Spring, Maryland
- George Resta, MD, Capital Women's Care, Silver Spring, Maryland
- Eric Ashkin, MD, Capital Women's Care, Silver Spring, Maryland
- Robert Levit, MD, Capital Women's Care, Silver Spring, Maryland

III. STAFF REVIEW AND ANALYSIS

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

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 chapter in this review is the General Surgical Services chapter, COMAR 10.24.11 ("Surgical Services Chapter").

.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) A physician outpatient surgery center, ambulatory surgical facility, or a general hospital 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.*
- (b) The Commission shall consider complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration when evaluating an applicant's compliance with this standard in addition to evaluating other sources of information.*
- (c) Making this information available shall be a condition of any CON issued by the Commission.*

MSC states that it “will 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.” MSC notes that information will be communicated via its website. Staff concludes that MSC meets this standard, and recommends that if the Commission chooses to award a CON it should include the following condition:

Maryland Surgery Center for Women, LLC d/b/a Maryland Surgery Center 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 also states that it is unaware of any complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration concerning its providing information regarding charges to the general public. (DI #2, p. 13). Staff review did not find any complaints recorded for MSC.

Staff concludes that MSC meets this standard.

(2) Information Regarding Procedure Volume.

A hospital, physician outpatient surgery center, or ASF shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the location where an individual has inquired. A hospital, POSC, or ASF shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.

MSC stated that, upon inquiry, it will provide information on surgical procedure volume for the most recent 12 months available and will update this information at least annually. (DI #2, p 13).

Staff concludes that MSC complies with this standard.

(3) Charity Care Policy.

- (a) *Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care that ensures access to services regardless of an individual’s ability to pay and shall provide ambulatory surgical services on a charitable basis to qualified indigent persons consistent with this policy. The policy shall have the following provisions:*

- (i) *Determination of Eligibility for Charity Care. Within two business days following a patient’s request for charity care services, application for medical assistance, or both, the facility shall make a determination of probable eligibility.*

The applicant’s charity care policy states that it will make and communicate a decision regarding a patient’s eligibility within two days of receiving a request for charity care, and will

base its decision on the patient's statement of annual income and number of family members. (DI #9, Att. 22).

(ii) Notice of Charity Care Policy. Public notice and information regarding the facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population and in a format understandable by the service area population. Notices regarding the facility's charity care policy shall be posted in the registration area and business office of the facility. Prior to a patient's arrival for surgery, the facility shall address any financial concerns of the patient, and individual notice regarding the facility's charity care policy shall be provided.

The applicant's charity care policy states that various referral sources, including community health centers, free clinics, and Holy Cross Hospital, receive a notice regarding availability of charity care annually. This notice is also published annually in the *Montgomery Herald*. (DI #9, Att. 22).

The applicant states that notices regarding its charity care policy are posted in its registration area and business office. (DI #2, p. 15). The applicant's charity care policy provides that it will address any financial concerns of the patient and provide its charity care policy prior to patient's arrival for surgery. (DI #9, Att. 22).

(iii) Criteria for Eligibility. A hospital shall comply with applicable State statutes and Health Services Cost Review Commission ("HSCRC") regulations regarding financial assistance policies and charity care eligibility. An ASF, at a minimum, shall include the following eligibility criteria in its charity care policies. Persons with family income below 100 percent of the current federal poverty guideline who have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services free of charge. At a minimum, persons with family income above 100 percent of the federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands. A health maintenance organization, acting as both the insurer and provider of health care services for members, shall have a financial assistance policy for its members that is consistent with the minimum eligibility criteria for charity care required of ASFs described in these regulations.

MSC's policy is to provide services free of charge to persons with family income below 100 percent of the current federal poverty guidelines, no health insurance, and who are not eligible for any public program coverage for medical expenses. The policy also states that persons with family income above 100 percent of the current federal poverty guidelines but below 200 percent of the current federal poverty guidelines will be eligible for services at a discounted rate based on a sliding scale of discounts. (DI #9, Att. 22).

- (b) *A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent HSCRC Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.*

This standard is not applicable, as this is not a hospital application.

- (c) *A proposal to establish or expand an ASF for which third party reimbursement is available, shall commit to provide charitable surgical services to indigent patients that are equivalent to at least the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses.⁴ 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*

MSC states that it has a history of providing charity care as detailed in Table III-1 below. The applicant has provided a level of charity care that well exceeds the percentage of charity care provided by all ASFs in Maryland in FYs 2016 and 2017. Staff notes that as a POSC, which does not require a CON to be established, the applicant had no obligation to provide charity care.

Table III-1: Charity Care, Maryland Surgery Center, 2017

| | Value of Charity Care | Total MSC Operating Expenses | Level of Charity Care Provided As Percentage of Total Operating Expenses | |
|-------------|-----------------------|------------------------------|--|-------------------|
| | | | MSC | All Maryland ASFs |
| 2016 | \$88,167 | \$2,874,548 | 3.1% | 0.46% |
| 2017 | \$111,116 | \$2,985,535 | 3.7% | 0.42% |

Source: DI #9, p. 6 and MHCC's FYs 2016 and 2017 Freestanding Ambulatory Surgery Facility Survey

Table III-2: Track Record and Projected Charity Care, Maryland Surgery Center

| Indicate CY or FY | Two Most Recent Years (Actual) | | Current Year Projected | Projected Years | | |
|-------------------|--------------------------------|---------|------------------------|-----------------|------|------|
| | CY 2016 | CY 2017 | CY 2018 | 2019 | 2020 | 2021 |

⁴ In MHCC's latest Freestanding Ambulatory Surgery Facility Survey (2017), the 38 reporting Maryland ASFs reported providing, on average, a level of charity care valued at 0.42% of total expenses.

| | | | | | | |
|---|--------------------|--------------------|---------------------|---------------------|---------------------|---------------------|
| Charity Care Value Dollar Amount | \$ 88,167 | \$ 11,116 | \$ 111,116 | \$ 115,539 | \$ 120,413 | \$ 125,325 |
| TOTAL OPERATING EXPENSES | \$2,874,548 | \$2,985,535 | \$ 3,235,566 | \$ 3,607,113 | \$ 3,671,840 | \$ 3,736,734 |
| Charity Care as a % of Op Expenses | 3.1% | 3.7% | 3.4% | 3.2% | 3.3% | 3.4% |

Source: DI #9, p. 6

Its track record over the two most recent calendar years and its projected levels of charity care further support the applicant's commitment to providing charity care, as reported in Table III-2, above. Staff concludes that the applicant's track record demonstrates its commitment to providing charity care.

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

MSC states that it has built relationships with physicians that disseminate information to patients about MSC's charity care offerings and refer patients to receive charity care services at MSC. These referring physicians practice at Community Health Centers in Montgomery and Prince George's County, free clinics such as Community Clinic, Inc. and others, and Holy Cross Hospital. (DI #2, p. 16). The applicant notes that, per its charity care policy, charity care levels will be tracked internally and reported to management on a monthly basis. (DI #9, p. 6).

As noted above, the proposed facility's projected charity care provision is well in excess of the State average, and the applicant describes a solid plan for achieving that level of charity care. Staff concludes that the applicant has met the requirements of all components 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 reviewed the CON application and confirmed that the applicant provided information and affirmations that demonstrate full compliance with these standards:

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

In responding to these standards, the applicant:

- Provided evidence to show that it currently is licensed by the State of Maryland.

- Submitted a transfer and referral agreement that complies with Department of Health regulations and have procedures for emergency transfer of patients from the ASF to a hospital.
- Submitted a letter from its principal architect stating that the facility is designed to comply with FGI Guidelines.
- Stated that while MSC does not directly provide laboratory, radiology, and pathology services, it does have established contractual agreements with outside providers of these services.

The text of these standards and location of the documentation of compliance are attached as Appendix 2.

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.

The primary service area for the applicant includes zip code areas located in Montgomery and Prince George's Counties. (DI #2, Att. 15).

MSC identified the projected service area of its Montgomery County facility, consistent with the standard.

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

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

- (a) An applicant proposing the establishment or replacement of a hospital shall submit a needs assessment that includes the following....***

- (i) *Historic trends in the use of surgical facilities for inpatient and outpatient surgical procedures by the new or replacement hospital's likely service area population;*
 - (ii) *The operating room time required for surgical cases projected at the proposed new or replacement hospital by surgical specialty or operating room category; and*
 - (iii) *In the case of a replacement hospital project involving relocation to a new site, an analysis of how surgical case volume is likely to change as a result of changes in the surgical practitioners using the hospital.*
- (b) *An applicant proposing the establishment of a new ambulatory surgical facility shall submit a needs assessment that includes the following:*
- (i) *Historic trends in the use of surgical facilities for outpatient surgical procedures by the proposed facility's likely service area population;*
 - (ii) *The operating room time required for surgical cases projected at the proposed facility by surgical specialty or, if approved by Commission staff, another set of categories; and*
 - (iii) *Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.*

Trends and Projections

MSC provided comprehensive data showing its historical (2015-2018) and projected OR utilization and documentation of the current surgical caseloads of physicians who perform surgery at the facility. (DI #16, p. 1).

Table III-3, below, shows the actual surgery volumes at MSC for 2015-2018, and projections for 2019 through 2021. Optimal capacity for dedicated outpatient general ORs, according to Regulation .07 of the Surgical Services Chapter, is 1,632 hours per year.⁵ MSC has demonstrated that its existing single OR was utilized optimally over the past 12 months. The applicant shows a need for two ORs within three years of completion of project. The total surgical case minutes at MSC increased 16% between 2015 and 2018, even total cases have declined slightly. The applicant attributes increase in minutes to an increase in higher acuity cases during this time period.

**Table III-3: Surgical Cases and Operating Room Minutes, Maryland Surgery Center
Actual 2015 – 2018 and Projected 2019 through 2021**

| | Actual | Projected | |
|--|--------|-----------|--|
|--|--------|-----------|--|

⁵ "Optimal capacity" is defined in the General Surgical Services Chapter, COMAR 10.24.11.07A(1)(b)(iii), as 80% of "full capacity use." "Full capacity" (for a general purpose outpatient OR) is defined as operating for a minimum of 255 days per year, eight hours per day, which results in an available full capacity of 2,040 hours per year. Thus, optimal capacity is 1,632 hours per year.

| | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 | Change, 2018- 2021 |
|---|---------|---------|---------|---------|---------|---------|---------|--------------------------|
| Total Cases | 1,373 | 1,251 | 1,284 | 1,261 | 1,636 | 1,767 | 2,050 | 63% |
| Total Minutes (includes turnaround time) | 101,516 | 103,402 | 115,309 | 118,130 | 152,802 | 165,027 | 192,043 | 63% |
| Total Hours (minutes/60) | 1,691.9 | 1,723.4 | 1,921.8 | 1,968.8 | 2,546.7 | 2,750.5 | 3,200.7 | 63% |
| OR Need (based on Optimal Capacity) | 1.0 | 1.1 | 1.2 | 1.2 | 1.6 | 1.7 | 2.0 | N/A |

Source: DI #16, Tables 1, 2, pp. 1, 2

Notes: Turnaround is 25 minutes, as defined by Maryland Surgery Center; OR Need = Total Hours/1,632

MSC states that its single OR has been operating extended hours into the evening and on weekends in order to accommodate the increasing number of cases and increasing level of case acuity. Over the last two years, the applicant added urology and pain management specialties, as many hospitals are no longer performing these procedures due to increasing costs of performing such procedure in a hospital setting. As a result, the applicant states that it is finding it increasingly difficult to accommodate this surge in demand. It cites difficulty in scheduling due to lack of available OR time and uncertain scheduled start times. MSC opened as a single specialty center in 2001 and now provides services for four different specialties including OB/Gynecology, Urology, and Colorectal and General Surgery. (DI #2, p. 31).

Staff concludes that MSC's projected utilization growth can support a two-OR ASF and meets the minimal capacity use standard for this project while continuing to make efficient use of its overall surgical capacity.

(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 .07 of this 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, consistent with Regulation .07 of this chapter. The needs assessment shall include the following:***

- (i) Historic and projected trends in the demand for specific types of surgery among the population in the proposed service area;*
- (ii) Operating room time required for surgical cases historically provided at the facility by surgical specialty or operating room category; and*
- (iii) Projected cases to be performed in each proposed additional operating room.*

This standard is not applicable, as this applicant is not a new or hospital or ASF.

(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.*

MSC states it has taken patient safety into consideration with the design of this Project, working closely with the architect and engineers to ensure compliance with all standards and FGI Guidelines. The facility is already equipped with proper ventilation, air exchange and finishes. The applicant will install a waste gas line for the addition of the anesthesia machine to eliminate the potential of anesthetic gases escaping into room air. The applicant mentioned that the facility has been designed to enhance infection control and standardize OR layout lessening the need for additional staff training and adjustment. (DI #2, p. 24). Staff concludes that the applicant considered patient safety in its design of the proposed ASF, and meets 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 new construction 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. This*

standard does not apply to the costs of renovation or the fitting out of shell space.

- (ii) If the projected cost per square foot of new construction 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) does not apply because the project does not include any new construction.

(8) Financial Feasibility.

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

(a) An applicant shall document that:

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

The applicant based its projections on its historical utilization trends, its transition from single to multi-specialty, and an increase in certain higher acuity level cases moving from hospital ORs to ambulatory surgery centers. The applicant based its revenue estimates on the utilization projections and current charges and rates of reimbursement and based its expenses on current staffing and other overall expenses. MSC has historically generated an excess of revenues over expenses and projects a continued profitable operation after the addition of a second OR. (DI #2, p. 25).

- (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;***

MSC bases its estimates of revenue on its utilization projections and current charges and rates of reimbursement. (DI #9, p. 10).

- (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***

The applicant bases its projected staffing levels that will result from this project on its current experience with OR staffing. (DI #9, p. 10). MSC expects to hire 2.5 direct care FTEs to accommodate the increase in volume that will result from this project. (DI #2, Table H).

(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 projects an excess of revenues over expenses by FY 2021, the first full year of operation, as shown in Table III-6 below.

Table III-6: Maryland Surgery Center Revenue and Expense Projections, FY 2021-FY 2023

| | FY 2019 | FY 2020 | FY2021 |
|---------------------------------|----------------|----------------|---------------|
| Operating Room Cases | 1,636 | 1,767 | 2,050 |
| Net Operating Revenue | \$6,876,246 | \$7,166,300 | \$7,458,687 |
| Total Operating Expenses | \$3,607,113 | \$3,671,840 | \$3,736,734 |
| Net Income(Loss) | \$3,269,133 | \$3,494,460 | \$3,721,953 |

DI #2, Table 1, Statistical Projections – Entire Facility and DI #2, Table 3, Revenues and Expenses – Entire Facility.

The applicant projected a reasonable utilization for its facility, basing its projections on its historical utilization trends, its transition from single to multi-specialty, and the migration of certain higher acuity level cases from hospital ORs to ASFs. Its revenue and expense projections were based on utilization projections and current charges and rates of reimbursement. MSC also based its projected staffing levels on its current experience. Thus, staff concludes that the proposed project satisfies the financial feasibility standard.

(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.

This paragraph of the standard is not applicable as this project is projected to generate excess revenue over total expenses.

(9) Impact.

(a) An application to establish a new ambulatory surgical facility shall present the following data as part of its impact assessment, in addition to addressing COMAR 10.24.01.08G(3)(f):

(i) The number of surgical cases projected for the facility and for each physician and practitioner;

(ii) A minimum of two years of historic surgical case volume data for each physician or practitioner, identifying each facility at which cases were performed and the average operating room time per case. Calendar year or fiscal year data may be provided as long as the time period is identified and is consistent for all physicians; and

(iii) The proportion of case volume expected to shift from each existing facility to the proposed facility.

MSC submitted data that identifies the physician and the historic number of surgical cases and surgical minutes (FY 2017 and FY 2018) as well as the projected number of cases and surgical minutes for each physician who may perform surgery at the proposed ASF. The applicant claims that the only case shift from existing facilities that will occur is a result of the payor-driven migration of certain higher acuity level cases from hospital ORs to ASFs. (DI #16).

(b) An application shall assess the impact of the proposed project on surgical case volume at general hospitals;

(i) If the applicant's needs assessment includes surgical cases performed by one or more physicians who currently perform cases at a hospital within the defined service area of the proposed ambulatory surgical facility that, in the aggregate, account for 18 percent or more of the operating room time in use at a hospital, then the applicant shall include, as part of its impact assessment, a projection of the levels of use at the affected hospital for at least three years following the anticipated opening of the proposed ambulatory surgical facility.

(ii) The operating room capacity assumptions in Regulation .07A of this chapter and the operating room inventory rules in Regulation .07C of this chapter shall be used in the impact assessment.

The applicant anticipates that certain procedures will continue to move to outpatient settings because payors are requiring that these procedures be performed in an outpatient setting. This is a natural volume shift prompted by payors. The applicant only anticipates this natural impact on surgical case volume of hospitals in the service area. (DI #2, pp. 25-26).

Staff concludes that the applicant complies with this standard.

(10) Preference in Comparative Reviews.

Since this review is not part of a comparative review, this standard is not applicable.

B. 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.” In this recommendation that discussion can be found in the Surgical Services Chapter at COMAR 10.24.11.05B(2), Need – Minimum Utilization for Establishment of a New...Facility.

In its analysis of the need standard, COMAR 10.24.11.05B(2), *supra*, pp. 9-11, staff concluded that its projected utilization growth is reasonable, can support a two-OR ASF, and meets the minimal capacity use standard for this project.

Staff concludes that implementing this proposal would provide physicians, surgeons, and consumers with greater access to lower cost alternatives for necessary surgeries and accommodate payors’ increasing demand for certain procedures to be performed in an outpatient setting. Staff recommends that the Commission find that the project is needed.

C. Availability of More Cost-Effective Alternatives

COMAR 10.24.01.08G(3)(c) The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or alternative facilities which have submitted a competitive application as part of a comparative review.

MSC considered the alternative of continuing to operate the facility at its current one-OR status, and continuing with the adjustments it has made to accommodate the increased demand, and not pursuing a CON. It determined that this is not a sustainable option because the adjustments that have been made to operate the facility at its current level have a negative impact on its ability to serve its patients, and puts additional stress the staff.

Adjustments it is currently operating under include:

- moving all eligible cases to the procedure room to open up time in the operating room;
- expanding routine hours into the evening and night (“normal” hours are considered to be 0700-1530, but it is not unknown for the facility to begin cases at 0600 and extend beyond 2100) and opening on Saturdays;
- offering premium pay to fulltime staff to encourage them to volunteer for the late or weekend hours that are above and beyond their fulltime work week;
- and hiring additional PRN staff to supplement the fulltime staff to prevent overtime burnout.

The applicant notes that these adjustments are costly. Despite the growth in the number of specialized cases being experienced, these adjustments make it difficult to accommodate the increase in demand. The addition of high acuity cases has resulted in decreased patient and physician satisfaction as the OR time scheduled differs greatly from the OR time needed. This scheduling issue affects patients and physicians costing time and negatively impacting their schedules.

The applicant states that this project is the most cost-effective alternative to alleviating the strain caused by the adjustments under which the facility has been operating. The applicant states that the goals of the project are to: reduce overtime and unnecessary additional overhead; prevent staff burnout; increase patient satisfaction; increase efficiency; reduce frustrations associated with lack of time to schedule larger cases; increase volume to meet demand; accommodate cases that are being forced out of hospital setting due to payer restrictions; and create open OR time to accommodate internal and external growth.

As the alternative to this project has a negative impact on the facility, its patients, and its employees, and there are no other facilities that have submitted competitive applications, staff recommends that the Commission find that MSC has given appropriate consideration to the alternative and selected the most cost-effective option. (DI #2, pp. 30, 31).

D. Viability of the Proposal

COMAR 10.24.01.08G(3)(d) 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.

Availability of Resources to Implement the Proposed Project

The estimated cost of this project is \$183,155⁶ with MSC providing all of the necessary funds in cash. (DI #9, Att. 19).

Availability of Resources to Sustain the Proposed Project

The applicant is projected to require 2.5 full-time equivalent (“FTE”) employees, including one OR nurse, 1 registered nurses, and 0.5 surgical technologist. (DI #2, Att. 16, Table H). MSC expects that the existing staff will be able to support most of the volume increases expected from the addition of one OR.

MSC’s projected operating results for the surgical center were shown earlier, in the Financial Feasibility standard in Table III-6, *supra*, pp 14, 15. It shows that MSC projects positive revenues in excess of \$3.2 million in the first year of operation, ramping up to over \$3.7 million by 2021. (DI #2, Tables 1, 3, pp. 28, 33).

Availability of Community Support

MSC submitted several letters from physician groups and individual physicians supporting this project. (DI #2, Att. 18).

Staff recommends that the Commission find that the proposed project is viable.

E. Compliance with Conditions of Previous Certificates of Need

⁶ The project budget is attached as App. 3.

COMAR 10.24.01.08G(3)(e) 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 Commission has not issued a Certificate of Need to Maryland Surgery Center for Women, LLC or its affiliates or subsidiaries over the prior 15 years.

F. Impact

COMAR 10.24.01.08G(3)(f) Impact on Existing Providers and the Health Care Delivery System. 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.

Impact on Other Providers

As described in the Impact standard earlier in this report, *supra*, pp. 14, 15 the applicant anticipates that there will be some surgical cases that it will be moving away from hospitals in the service area prompted by payors' requirements that certain procedures be performed in an outpatient setting. (DI #2, pp. 25-26).

The applicant does not expect to have any significant effect on other ambulatory surgical facilities in the jurisdiction, as MSC currently operates very extended hours based on its current utilization. The opening of a second OR will allow the facility to operate on a normal schedule as well as accommodate the level of volume growth in its projected future. (DI #2, p. 36).

Impact on access to health care services, system costs, and costs and charges of other providers

The applicant expects that opening a second OR will improve patients' access to outpatient surgical services in this service area. By operating for extended hours the facility has absorbed some of the demand for outpatient capacity being driven by the shifting of cases from a hospital to an outpatient setting, but it will not accommodate the level of volume growth the applicant projects, thereby limiting access. MSC expects that opening a second OR will allow the facility to accommodate surgeries that are being moved from hospitals to outpatient settings, as payors are increasingly requiring. This shift in setting should have a positive impact on the cost of the health care delivery system. (DI #2, p. 36).

Staff concludes that the impact of this project is positive for MSC and that it will not have an undue negative impact on existing providers and may positively affect costs to the health care delivery system. Staff recommends that the Commission find that the impact of the project will be positive.

IV. SUMMARY AND STAFF RECOMMENDATION

Based on the review of the proposed project's consistency with the Certificate of Need review criteria (COMAR 10.24.01.08G(3)(a)-(f)) and with the applicable standards in the General Surgical Services Chapter of the State Health Plan (COMAR 10.24.11), Commission staff recommends that the Commission issue a Certificate of Need to Maryland Surgery Center for Women, LLC to convert a procedure room into a second operating room. Staff concludes that the applicant demonstrated that the project complies with the applicable standards in the Surgical Services Chapter, is needed, is a cost-effective approach to meeting the project objectives, is viable, will have a positive impact on the applicant's ability to provide outpatient surgery without adversely affecting costs and charges or other providers of surgical care, and will benefit service area residents who will not travel as far to receive ambulatory surgery services.

Accordingly, Staff recommends that the Commission **APPROVE** Maryland Surgery Center's application for a Certificate of Need authorizing addition of one operating room to its existing facility located at 114000 Rockville Pike in Montgomery County, with the following condition:

Maryland Surgery Center for Women, LLC d/b/a Maryland Surgery Center 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.

| | | |
|------------------------|---|------------|
| IN THE MATTER OF | * | BEFORE THE |
| | * | |
| MARYLAND SURGERY | * | MARYLAND |
| | * | |
| CENTER FOR WOMEN, LLC | * | HEALTH |
| | * | |
| d/b/a MARYLAND SURGERY | * | CARE |
| | * | |
| CENTER | * | COMMISSION |
| | * | |
| Docket No. 18-15-2434 | * | |

FINAL ORDER

Based on the analysis and conclusions contained in the Staff Report and Recommendation, it, this 18th day of July, 2019, by a majority of the Maryland Health Care Commission, **ORDERED:**

That the application by Maryland Surgery Center for Women, LLC trading as Maryland Surgery Center for a Certificate of Need to renovate its existing physician outpatient surgery center to have two operating rooms and four procedure rooms at 11400 Rockville Pike in Rockville (Montgomery County), at an estimated cost of \$183,155, is hereby **APPROVED**, with the following condition:

Maryland Surgery Center for Women, LLC d/b/a Maryland Surgery Center 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.

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1:

Record of the Review

IN THE MATTER OF

Maryland Surgery Center for Women, LLC
d/b/a Maryland Surgery Center
Docket No. 18-15-2434

| Docket Item # | Description | Date |
|---------------|--|----------|
| 1 | MHCC staff acknowledges receipt of Maryland Surgery Center's Letter of Intent. | 8/6/18 |
| 2 | Commission acknowledges receipt of CON application. | 10/5/18 |
| 3 | MHCC staff acknowledge receipt of CON application. | 10/10/18 |
| 4 | MHCC staff requests publication of notification of receipt of Maryland Surgery Center's proposal in the <i>Washington Times</i> . | 10/10/18 |
| 5 | MHCC staff requests publication of notification of receipt of Maryland Surgery Center's proposal in the <i>Maryland Register</i> . | 10/10/18 |
| 6 | Notice of receipt of application as published in the <i>Washington Times</i> . | 10/18/18 |
| 7 | Following completeness review, MHCC staff found the application incomplete, and requested additional information. | 3/6/19 |
| 8 | MHCC staff provided update to request completeness and additional information. | 3/15/19 |
| 9 | MHCC staff received responses to the request for additional information. | 3/28/19 |
| 10 | Maryland Surgery Center submits additional information. | 4/2/19 |
| 11 | MHCC staff notified Maryland Surgery Center that its application will be docketed for formal review on May 24, 2019. | 5/9/19 |
| 12 | MHCC staff requests publication of notice of formal start of review for Maryland Surgery Center in the <i>Washington Times</i> . | 5/9/19 |
| 13 | MHCC staff requests publication of the notice of formal start of review in the <i>Maryland Register</i> . | 5/9/19 |
| 14 | MHCC staff sent copy of the application to the Worcester Health Department for review and comment. | 5/9/19 |
| 15 | Maryland Surgery Center submits additional information. | 6/27/19 |
| 16 | Maryland Surgery Center submits additional information. | 7/1/19 |

MARYLAND HEALTH CARE COMMISSION

APPENDIX 2:

Excerpted CON Standards for General Surgical Services

COMAR 10.24.11

Excerpted CON Standards for General Surgical Services

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. Also included are references to where in the application or completeness correspondence the documentation can be found.

| <u>STANDARD</u> | <u>APPLICATION REFERENCE (Docket Item #)</u> |
|--|---|
| <p><u>.05A(4) Quality of Care</u> A facility providing surgical services shall provide high quality care.</p> <ul style="list-style-type: none"> (a) An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health. (b) A hospital shall document that it is accredited by the Joint Commission. (c) An existing ambulatory surgical facility or POSC shall document that it is: <ul style="list-style-type: none"> (i) In compliance with the conditions of participation of the Medicare and Medicaid programs; (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. (iii) A provider of quality services, as demonstrated by its performance on publicly reported performance measures, including quality measures adopted by the Centers for Medicare and Medicaid Services. The applicant shall explain how its ambulatory surgical facility or each POSC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland. (d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will: <ul style="list-style-type: none"> (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; and | <p>DI #2, Atts. 9, 10, 11, 12</p> |

| | |
|--|----------------------------|
| <p>(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.</p> <p>(e) An applicant or a related entity that currently or previously has operated or owned a POSC or ambulatory surgical facility, in Maryland or outside of Maryland, in the five years prior to the applicant's filing of a request for exemption request to establish an ASF, shall address the quality of care at each location through the provision of information on licensure, accreditation, performance metrics, and other relevant information.</p> | |
| <p>.05A(5) <u>Transfer Agreements.</u></p> <p>(a) Each ASF shall have written transfer and referral agreements with hospitals capable of managing cases that exceed the capabilities of the ASF.</p> <p>(b) Written transfer agreements between hospitals shall comply with the Department of Health regulations implementing the requirements of Health-General Article, 19-308.2.</p> <p>(c) Each ASF shall have procedures for emergency transfer to a hospital that meet or exceed the minimum requirements in COMAR 10.05.05.09.</p> | <p>DI #2, Atts. 13, 14</p> |
| <p>.05B(4) <u>Design Requirements.</u></p> <p>Floor plans submitted by an applicant must be consistent with the current Facility Guidelines for Design and Construction of Health Care Facilities (FGI Guidelines):</p> <p>(a) A hospital shall meet the requirements in current Section 2.2 of the FGI Guidelines.</p> <p>(b) An ASF shall meet the requirements in current Section 3.7 of the FGI Guidelines.</p> <p>(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.</p> | <p>DI #9, Att. 24</p> |
| <p>.05B(5) <u>Support Services.</u></p> <p>Each applicant shall agree to provide laboratory, radiology, and pathology services as needed, either directly or through contractual agreements. .</p> | <p>DI #2, p. 23</p> |

MARYLAND HEALTH CARE COMMISSION

APPENDIX 3:

Maryland Surgery Center's Project Budget

Maryland Surgery Center's Project Budget

| Use of Funds | |
|--|-------------------|
| Renovations | |
| Building | \$66,711 |
| Fixed Equipment (not included in construction) | 0 |
| Architect/Engineering Fees | 33,000 |
| Permits | 7,500 |
| Subtotal | \$107,211 |
| Other Capital costs | |
| Moveable Equipment | \$43,900 |
| Contingency Allowance-equipment | 0 |
| Gross interest during construction period | 0 |
| Other (Attorney Fees) | 25,000 |
| Subtotal | \$68,900 |
| Total Current Capital Costs | \$176,111 |
| Inflation Allowance | 7,044 |
| Total Capital Costs | \$ 183,155 |
| Financing Cost and Other Cash Requirements | \$0 |
| Total Uses of Funds | \$ 183,155 |
| Source of Funds | |
| Cash | 183,155 |
| Total Source of Funds | \$ 183,155 |

DI #2, Attachment 3, Table E; DI #9, Attachment 29, Table E (revised)