Craig P. Tanio, M.D.
CHAIR

STATE OF MARYLAND

Ben Steffen
EXECUTIVE DIRECTOR

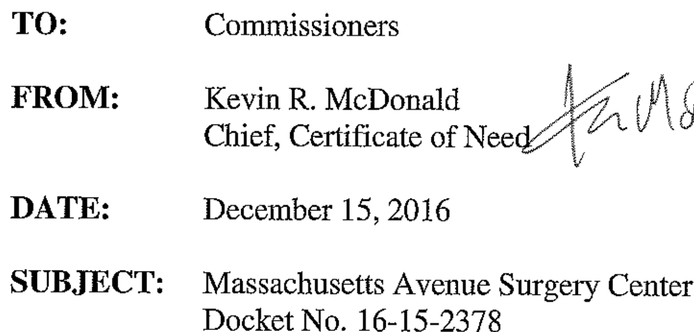
MARYLAND HEALTH CARE COMMISSION

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: December 15, 2016

SUBJECT: Massachusetts Avenue Surgery Center
Docket No. 16-15-2378

Enclosed is the staff report and recommendation for a Certificate of Need ("CON") application filed by Massachusetts Avenue Surgery Center, LLC ("MASC").

MASC is an ambulatory surgical center with three operating rooms ("OR") and one procedure room, located at 6400 Goldsboro Road, Suite 400, Bethesda, MD 20817. This project proposes to convert the existing non-sterile procedure room to a fourth OR. MASC has previously received two CON approvals -- in 2006 and 2012 -- to increase the number of ORs.

The total project cost is estimated to be $266,397, will be funded with cash and is anticipated to take five months to complete.

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 Commission, and the other applicable CON review criteria at COMAR 10.24.01.08.

TOLL FREE
1-877-245-1762

TDD FOR DISABLED
MARYLAND RELAY SERVICE
1-800-735-2258

IN THE MATTER OF	*	**BEFORE THE**
	*	
MASSACHUSETTS AVENUE SURGICAL CENTER, LLC	*	**MARYLAND HEALTH**
	*	
	*	**CARE COMMISSION**
Docket No. 16-15-2378	*	
	*	

* *

Staff Report and Recommendation

December 15, 2016

TABLE OF CONTENTS

PAGE

I. INTRODUCTION....1

A. The Applicant....1
B. The Project....1
C. Summary of Recommendation....1

II. PROCEDURAL HISTORY....2

A. Review of the Record....2
B. Interested Parties and Participating Entities in the Review....2
C. Local and Community Review and Comment....2
D. Community Support....2

III. STAFF REVIEW AND ANALYSIS....1

A. COMAR 10.24.01.08G(3)(a) — THE STATE HEALTH PLAN.... 1

.05A. General Standards....2

1. Information Regarding Charges....2
2. Charity Care Policy....3
3. Quality of Care....4
4. Transfer Agreements....4

.05B. Project Review Standards....4

1. Service Area....4
2. Need- - Minimum Utilization for Establishment of a New or Replacement Facility....6
3. Need – Minimum Utilization for Expansion of an Existing Facility....6
4. Design Requirements....8
5. Support Services....8
6. Patient Safety....8
7. Construction Costs....8
8. Financial Feasibility....10
9. Preference in Comparative Review....11

B. COMAR 10.24.01.08G(3)(b)—NEED....11

C. COMAR 10.24.01.08G(3)(c)--AVAILABILITY OF MORE COST-EFFECTIVE ALTERNATIVES....11

D. COMAR 10.24.01.08G(3)(d)—VIABILITY OF THE PROPOSAL....12

E. COMAR 10.24.01.08G(3)(e)—COMPLIANCE WITH CONDITIONS OF PREVIOUS CERTIFICATES OF NEED....12

F. COMAR 10.24.01.08G(3)(f)—IMPACT ON EXISTING PROVIDERS....13

IV. SUMMARY AND STAFF RECOMMENDED DECISION ....

FINAL ORDER ....

APPENDICES:

Appendix 1: Review of Record

Appendix 2: Excerpted CON Standards for General Surgical Services from the State Health Plan Chapter 10.24.11

I. INTRODUCTION

A. The Applicant

Massachusetts Avenue Surgery Center, LLC ("MASC" or the "Center") is an existing ambulatory surgery center ("ASC"), located at 6400 Goldsboro Road, Suite 400, in Bethesda, (Montgomery County). It has three operating rooms ("ORs") and one non-sterile procedure rooms. The practice was established in 2004 by 14 physicians as a physician outpatient surgery center ("POSC"), the term used in the State Health Plan to describe an outpatient surgical facility with no more than one operating room. POSCs can be established without CON approval. MASC started operations with one operating room, and two non-sterile procedure rooms.[1] Since then, MASC has expanded by obtaining two CONs for two additional ORs. Over time, the number of physicians with privileges at the Center has grown from 14 to 54, representing the specialties of general surgery, gynecology, orthopedics, pain management, plastic surgery, podiatry, and urology.

MASC is owned by medical practitioners, mostly doctors of medicine. Eight practitioners have an ownership share of 5.9% and the remaining 52.48% of ownership is composed of members with less than 5% individual equity.

The Center's service area covers parts of Montgomery County and Prince George's County. The facility also draws patients from Washington, DC and Arlington, Virginia, reflecting the office locations of the physicians who staff the Center.

B. The Project

The proposed project will convert the existing non-sterile procedure room through renovation to create a fourth OR. The primary driver of the project is the introduction of total joint replacement cases ("TJR") which require significantly more OR time than the average case currently handled by MASC. This renovation project will include architectural modifications and mechanical, electrical, and plumbing (MEP) systems updates to support the additional OR.[2] The total estimated capital cost of the project is $266,397 and the applicant plans to fund the project with cash. The project is expected to take five months to complete.

C. Summary of Recommendation

Staff recommends approval of this project based on its conclusion that the proposed project complies with the applicable standards in COMAR 10.24.11, the State Health Plan for Facilities and Services: General Surgical Services. The need for the project has been demonstrated and converting a procedure room to an operating room to significantly enhance service capacity

---

[1] Non-sterile procedure rooms located outside of the restricted area of an outpatient surgical facility and not used for open surgical procedures are not regulated under Maryland's Certificate of Need program.

[2] Architectural modifications include removal of the sink, altering the millwork, modifying the ceiling for OR lighting and supports; MEP updates include new medical gases, emergency nursing/call devices, power receptacles, HVAC system modifications for the new air exchange.

appears to be cost effective. The modest investment is projected to enable a significant increase in revenue, improving the financial performance of a currently viable operation. Finally, the applicant has complied with all conditions of prior CONs.

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 regarding this project.

D. Community Support

There were no letters of support received for this project.

III. STAFF REVIEW AND ANALYSIS

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

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 ("Surgical Services Chapter")..

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) <u>Information Regarding Charges</u>
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 stated that MASC provides information regarding charges for the range and types of services it provides, upon request. A copy of MASC's Facility Fee Schedule was submitted with its CON application. (DI#2, Exh. 4). MASC complies with this standard.

<u>(2) Charity Care Policy</u>
(a) Each hospital and ASF shall have a written policy for the provision of charity care that ensures access to services regardless of an individual's ability to pay and shall provide ambulatory surgical services on a charitable basis to qualified indigent persons consistent with this policy. The policy shall have the following provisions:

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

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

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

MASC submitted a copy of its charity care policy (which includes guidelines to supplying the information to patients and their family), and a copy of its Financial Assistance Application. (DI#2, Exh. 5). MASC's Charity Care policy states that services will be rendered to indigent patients regardless of their ability to pay, and includes a provision that determination of probable eligibility for financial assistance will be made within two business days after the initial application for financial assistance is received. To demonstrate its compliance with the requirement to post notice of its charity care policy, MASC stated such notice is posted in the Center's admissions office, business office and patient waiting areas. MASC also provided a copy of the public notice

regarding charity care it publishes annually in a local newspaper serving Montgomery, Prince George's and Carroll County (the Gazette).

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

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

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

(iii) If an existing ASF has not met the expected level of charity care for the two most recent years reported to MHCC, the applicant shall demonstrate that the historic level of charity care was appropriate to the needs of the service area population.

MASC states that it has made a concerted effort to provide a level of charity care that meets the needs of its patient population. MASC reports provision of $61,739 of charity care in FY 2014 which was equivalent to 0.84% of the Center's operating budget, comparing favorably with that year's statewide average for ambulatory surgical facilities of 0.48%. In 2015 MASC reported providing charity care with a value of $$88,116, equivalent to 1.12% of expenses, more than doubling the statewide average. MASC has pledged to continue providing charity care to patients in need of financial assistance once this project is complete.

MASC's reporting complies with the charity care standard.

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

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 the following standards:

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

Staff has concluded that the proposed project meets the requirements of these standards. The applicant: is licensed, in good standing, by the Maryland Department of Health and Mental Hygiene, is in compliance with the conditions of participation of the Medicare/Medicaid program, and is accredited by the Accreditation Association for Ambulatory Health Care. It has a written transfer agreement with Sibley Hospital. The facility is reportedly designed in compliance with Section 3.7 of the 2014 Facilities Guideline Institute's Guidelines for Design and Construction of

Healthcare Facilities. The text of these standards and the locations within the application where compliance is documented are attached as Appendix 2.

(3) <u>Quality of Care (See Appendix 2)</u>

(4) <u>Transfer and Referral Agreements (See Appendix 2)</u>

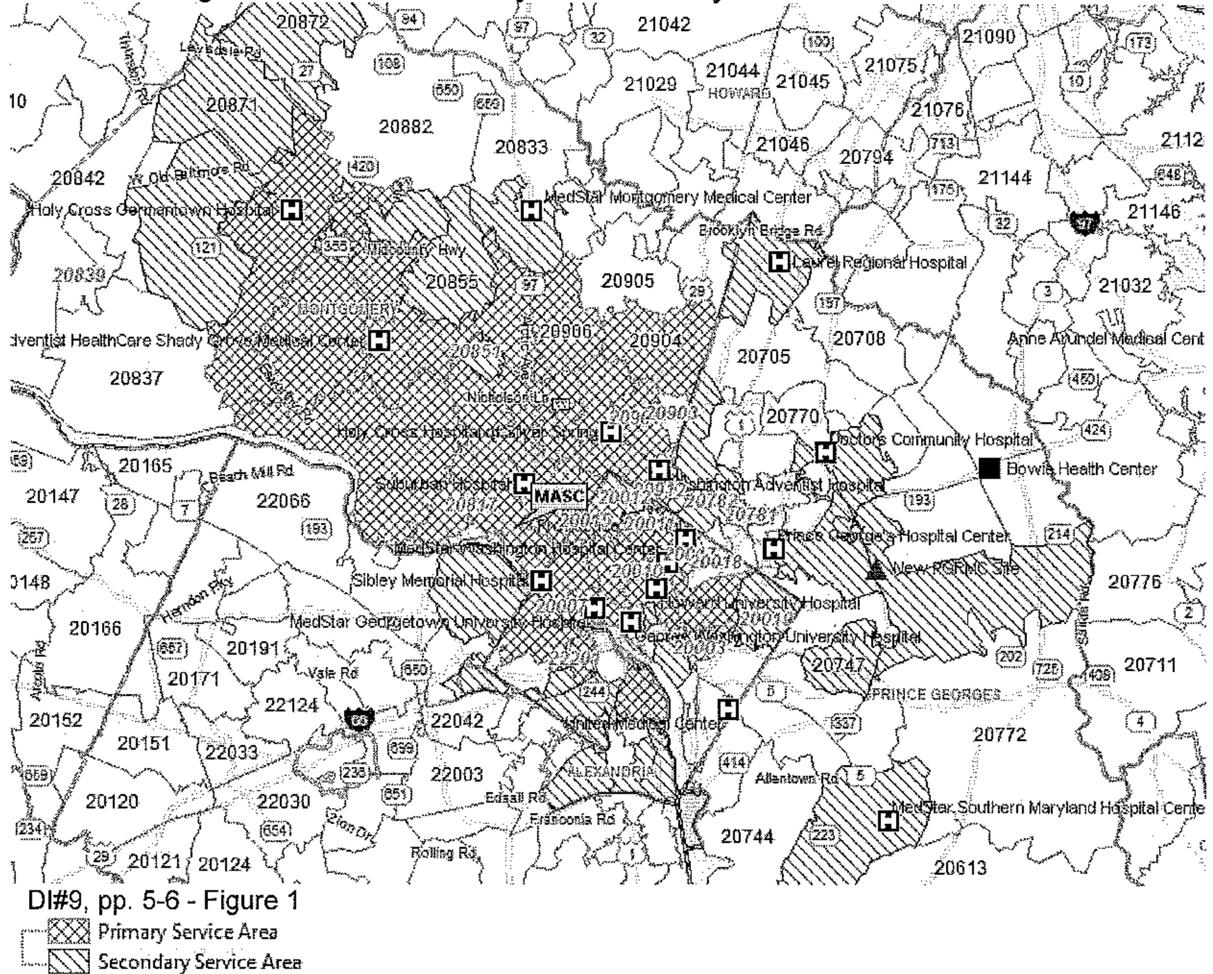
B. PROJECT REVIEW STANDARDS. The standards in this section govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate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

(1) <u>Service Area</u>

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 applicant defined its service area as the zip code areas from which the first 75% of the MASC's discharges originated. That area includes 63 zip code areas in the District of Columbia, Montgomery County, Prince George's County and northern Virginia. The areas identified in the map below depict MASC's primary service area (the zip code areas from which the first 60% of cases were generated) and a secondary service area (the next 15% of cases).

Figure III-1: MASC's Primary and Secondary Service Area



The largest number of cases come from Montgomery County, followed closely by the District of Columbia (see Table III-1). These two jurisdictions account for approximately 65% of MASC's case volume. The applicant stated that this project is not anticipated to t change the MASCs service area.

Table III-1: MASC Patient Origin, CY2010

Patient Residence	# of Cases	% of Total
District of Columbia	1,001	26.7%
Montgomery County	1,426	38.1%
Prince George's County	147	3.9%
Virginia	270	7.2%
All Others (285 other zip codes)	902	24.1%
Total	**3,746**	**100%**

Source: MHCC Freestanding Ambulatory Surgery Survey, 2010

This standard has been met.

(2) <u>Need – Minimum Utilization for Establishment of a New or Replacement Facility</u>

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

(3) <u>Need - Minimum Utilization for the Expansion of Existing Facilities</u>

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 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. 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 category; and

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

To meet this standard, the applicant must demonstrate that: the proposed OR will be utilized at optimal capacity[3], that the existing three OR's were utilized optimally over the past 12 months, and that (with the renovation of the procedure room to a fourth OR) all four ORs will likely be utilized at full capacity or at higher levels within three years of the project's completion.

MASC presented data showing mostly healthy year-over-year growth from its inception in 2005 through 2015. The Center opened with 844 cases in 2005 and within two years served 1,400 cases. Between 2007 and 2010 the Center saw an average of 1,486 cases annually. In 2011, the number of cases exceeded 2,000, and grew to 3,061 by 2015.

MASC attributes its growth to several factors:

- By 2016 the number of surgeons utilizing MASC had grown to 48; three more surgeons are expected to be added in the next few months, including a spine surgeon. (DI#2, p.4)

- MASC surgeons began performing Total Joint Replacements (TJR) on an outpatient basis rather than the hospital setting in 2015, adding a projected 75 such cases in the current year (2016). (DI#2, p.7)

---

[3] Optimal capacity is defined in the General Surgical Services Chapter of the State Health Plan as 80% of "full capacity use." "Full capacity 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 of operation.

- Both the service area population and the practices of the physicians on staff have grown. (DI#, p.26) Using population data from Nielsen, the applicant states that the Center's primary service area population grew 9.5% between 2010 and 2016, and is projected to increase another 6.6% by 2021.

- The applicant also estimated that a number of new patient visits will result from insurance companies inclusion of ASC's as "in-network" providers for outpatient services outside of hospitals. Since deductibles are lower for treatment sought in non-hospital settings, subscribers will benefit from lower deductibles. Seeking treatment at an outpatient facility will also decrease the risk of cross contamination with sick patients seeking treatment at a hospital. (DI#2, p.26).

Table III-2 below presents MASC's recent and projected surgical volume and room utilization statistics.

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

Year	OR Cases	Operating Room and OR Cleaning/Prep. Minutes			Utilization as %		Number of ORs	ORs Needed
		Surgical procedure time (mins.)	Turnover Time (mins.)	Total Time (Hours)	...of Full Capacity	...of Optimal Capacity		
2014	2,808	191,520	70,200	4,362	71%	89%	3	**2.67**
2015	3,061	222,480	76,525	4,983	81%	102%	3	**3.06**
2016 projected from YTD	3,131	230,344	78,275	5,144	84%	105%	3	**3.15**
2017 projected	4,105	257,209	102,635	5,997	73%	92%	4	**3.68**
2018 projected	4,241	267,160	106,022	6,220	76%	95%	4	**3.80**
2019 projected	4,381	277,102	109,521	6,444	79%	99%	4	**3.96**

Source: DI #2, p.34.

Note: In the above table the applicant did not include cases performed in the procedure room in 2014 - 2016 period as OR cases. However, they are included in the 2017- 2019 projection of cases as they will be performed in the additional OR. Most of these are pain management cases. Those cases totaled 587 in 2014, 669 in 2015, and 860 (estimated from YTD) in 2016. (DI #2, p.32).

In projecting future volumes and OR time, it is important to take into account that the recently-added TJR cases, projected to grow to 175 by 2019, require much longer procedure times (an average of 128.4 minutes compared to an average 72.2 minutes for non-TJR cases). MASC states that this increase in case times is forcing MASC surgeons to redirect many of their urologic and gynecological cases requiring general anesthesia back to a more expensive and less efficient acute care setting. (DI#2, p.7) The introduction of these cases is the primary basis requiring the expansion of OR capacity.

The data provided by the applicant shows that MASC reached optimal capacity for its 3 ORs in 2015.

MASC projects strong growth in demand between 2016 and 2017. As noted, MASC is not planning to replace the case volume currently performed in the non-sterile procedure room and these cases will continue to account for a substantial proportion of the time in the converted procedure room, which will, as intended, be available for open surgery employing general anesthesia after the project is completed. .Limiting the projection to cases requiring a sterile operating, MASC projects a need for 3.5 ORs by 2019, based on the SHP's capacity assumptions.

The project complies with this standard.

(4) <u>Design Requirements (See Appendix 2)</u>

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

The applicant provides these services and will continue using its current vendors for radiation dosimetry services (Landauer), laboratory services (LabCorp), and pathology services (Dianon). This standard is met.

(6) <u>Patient Safety</u>
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*;**

The applicant stated that the room design will maintain the recommended clearances and space requirements as outlined in the FGI Guidelines, and will include finish selections that maximize the ability to sanitize the space. The capacity of the heating, ventilation, and air conditioning system will be expanded to provide required humidity control, air changes and air filtration to the fourth OR. Finally, the new OR will have a design similar to the existing ORs, thus minimizing training requirements and allowing staff to move from one room to another with minimal chance of confusion, thus improving patient safety.

The applicant has provided a summary of design features that document that the planning of the project took patient safety into account. Staff concludes that the applicant has met the requirements of this standard.

(7) <u>Construction Costs</u>
The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

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

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of an ambulatory surgical facility construction or renovation project shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality,
and other listed factors.
(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost by 15% or more, then the applicant's project shall not be approved unless the applicant demonstrates the reasonableness of the construction costs. Additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility may be provided to support an applicant's analysis of the reasonableness of the construction costs.

This standard requires a comparison of the project's estimated construction cost with an index cost derived from 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 includes the base cost per square foot for new construction by type and quality of construction for a wide variety of building uses including outpatient surgical centers. The MVS guide also includes a variety of adjustment factors, including adjustments of the base costs to the costs for the latest month, the locality of the construction project, as well as factors for the number of building stories, the height per story, the shape of the building (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].

For this project MASC is proposing the renovation of 497 square feet ("SF") of existing building space. A special procedure room of approximately 270 SF will be converted into a new operating room. Among the renovations will be modification to the mechanical, electrical, and plumbing systems as well as new lighting. Outside the actual room renovations affecting 230 SF will be required to extend the restricted corridor.

The Center developed an MVS benchmark cost using the most recent MVS base cost for an outpatient surgery center (November 2015) for a Class A/B, outpatient surgical center construction ($ 369.05 per SF) and adjusting it for the shape of the area affected, the ceiling height, and the location, updated to the month of CON application preparation. The result was a

[4] Marshall Valuation Service guidelines, Section1, p.3 (January 2016).

benchmark cost of $571.42 per SF for the construction of comparable new space. Recognizing that the proposed project involves the renovation of existing space not the construction of new space, MASC multiplied the benchmark by 68.39% to arrive at a benchmark for the renovation of $390.78 per SF Thus, the estimated renovation cost of the proposed project at $354.63 per SF. is 9.3% less than the benchmark developed by the applicant.

Commission staff notes that the adjustment of the MVS benchmark for new construction to arrive at the benchmark for renovations was based on the development of the benchmark for the Green Spring Station Surgery Center[5] that involved the finishing of shell space in a medical office building. Because the proposed project involves renovation of space in an existing surgery center not a medical office, MHCC staff calculated an alternative MVS benchmark based on the assumption that the proposed project is more like the finishing of shell space in a surgical center than finishing space in a medical office building. Staff developed a benchmark for new surgical center construction adjusted for the mix of space that will be affected, operating room and corridor space.[6] Then staff adjusted this revised base of $479 per SF. for the shape of the area affected, the ceiling height, and the Bethesda location, and the current month (November 2016). The result is a MVS benchmark of $742 per SF. for new construction of comparable space. To account for the fact that the project is limited to the renovation of existing outpatient surgical space, staff applied the hospital differential cost factor[7] for unassigned space (0.5) to the adjusted MVS benchmark for comparable new construction. The result is an MVS benchmark for the proposed project of $371.20 per SF. MASC's estimated renovation costs of $354.63 per SF is 4.5% under this MVS benchmark.

The table below summarizes comparison of the project cost estimate with both the MVS benchmark developed by MASC and the benchmark developed by Commission staff.

[5] Green Spring Station Surgery Center, Docket Number 15-03-2369

[6] The MVS hospital Departmental Cost Differential Factor for OR space is 1.89 and for internal circulation it is 0.6

[7] MVS does not include departmental differential cost factors for outpatient surgical centers

Table III-x: Comparison of MASC's Renovation Budget to Marshall Valuation Service Benchmark Developed by The Applicant and MHCC Staff

Project Budget Item	Project Budget
Renovations	
Building	150,000
Fixed Equipment	0
Normal Site Preparation	0
Architect/Engineering	11,250
Permits	15,000
Capitalized Construction Interest	0
Financing Fees	0
Total Project Costs	$176,250
Project Costs for MVS Comparison	$176,250
Square Feet ("SF")	497
Adjusted Project Cost per SF	**$354.63**
Applicant Benchmark	
Applicant's MVS Benchmark Cost/SF	**$390.78**
(Under)	**($36.15)**
Percent Under Benchmark	**(9.3%)**
MHCC Staff Benchmark	
MHCC Staff MVS Benchmark Cost/SF	**$371.20**
(Under)	**(16.57)**
Percent Under Benchmark	**(4.5%)**

Source: DI#2, pp.36-38 and Marshall Valuation Service

The standard requires that an ambulatory surgery center whose projected cost per square foot exceeds the MVS benchmark cost for a good quality, Class A construction estimate by 15% or more demonstrate that the construction costs are reasonable. Because the project's construction costs is below the MVS benchmark, no such determination is required. Therefore, the applicant has demonstrated consistency with this standard.

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

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(s) by the likely service area population of the facility;

MASC based its projected utilization on its historic trends and population growth.

(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;

Revenue estimates are based on the utilization projections and current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, as experienced by MASC. Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels at MASC.

(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 application includes a small increase in staffing which is commensurate with the projected volume increase and at rates consistent with current salary levels.

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

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

MASC reports net income of $1.5 million in 2014 and $2.3 million in 2015. It projects that net income will grow at an annual average of 6.7% in the first three years following implementation of the project. (DI#2, Exhibit 1, Table G)

Table III-4: MASC Uninflated Financial Projections, CY2016-2019

	2016	2017	2018	2019
Cases	3,131	4,099	4,243	4,381
Revenue	$11,326,840	$11,884,581	$12,522,307	$13,194,254
Expenses	$8,378,303	$8,742,010	$9,227,684	$9,615,587
Net Income	***$2,948,538***	***$3,142,570***	***$3,294,623***	***$3,578,667***

Source: DI#2, Exhibit 1, Table G.

(9) <u>Preference in Comparative Review</u>

This is not a comparative review, so this standard does not apply.

B. Need

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

The need for the renovation of the current procedure room for a fourth OR has been addressed previously in this report under COMAR 10.24.11.06B(3), Need – Minimum Utilization for Expansion of an Existing Facility. Staff h as conclud ed that the applicant has provided documentation that its volume projections are obtainable, and that four operating rooms are likely to be used at optimal capacity within three years of commencing operation of the fourth OR. While, the applicant has noted that case volume that does not require a sterile operating room will constitute a portion of this use, given that it is losing it only non-sterile procedure room through this project, it has reasonably demonstrated that it will have demand for OR cases that exceeds optimal capacity for three ORs. Staff recommends that the Commission find the proposed project in compliance with the applicable State Health Plan need analysis, which is structured as OR service capacity assumptions.

C. Availability of More Cost-Effective Alternatives

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

The applicant identified one alternative for meeting the proposed projects objective, the leasing of additional space to expand OR capacity. Not undertaking the renovation or this alternative will require shifting current case volumes elsewhere. This would reduce the efficiency of surgeon time and increase the charges incurred for cases that might relocate to the hospital setting.

MASC considered attempting to expand by leasing more space in its current location, but with no space adjacent, that would require a relocation and renovation of the Center's entire footprint, at an estimated cost of $6.5 million (16,250 sq. ft. at $400/sq. ft.) In addition, the renovation was estimated to take six months to complete, a period during which MASC would be paying rent on both the space it was occupying and the space it was renovating. The applicant rejected this option due to the cost. (DI#9, p.9)

Staff concludes that the applicant's selection of this option is a cost effective alternative to the need for additional operating room time. The capital cost is modest and the project preserves the ability of the MASC practitioners to maintain the range of cases performed at this single location as the demand for sterile OR time increases. Staff recommends that the Commission find the project to be cost effective.

D. Viability of the Proposal

COMAR 10.24.01.08G(3)(d) requires the Commission to consider the availability of financial and nonfinancial resources, including community support, necessary to implement the project within the time frame set forth in the Commission's performance requirements, as well as the availability of resources necessary to sustain the project.

MASC submitted unaudited financial statements for 2014 and 2015. Those statements show ample cash available to cover the project's cost. Current assets ($724,824) far exceed current liabilities ($57,974). Since MASC was not submitting audited statements (which it does not have), MASC submitted a letter from its accountant attesting that the Center has ample funds to support the project's capital investment. (DI#2, Exhibit 11). MASC generated net income of $1.5 million in 2014 and $2.3 million in 2015. (DI#2, Exhibit 1, Table L).

Funds for the renovation are readily available, and both historic and projected operating results are healthy. Staff recommends that the Commission find that this project is viable.

E. Compliance with Conditions of Previous Certificates of Need

COMAR 10.24.01.08G(3)(e) requires the Commission to consider the applicant's performance with respect to all conditions applied to previous Certificates of Need granted to the applicant.

MASC has received two CONs, one in 2006 (Docket No. 06-15-2181) to increase the number of ORs from one to two, and a second in 2012 (Docket No. 12-15-2328) to increase the number of OR's to three. The first CON was approved with the condition that MASC obtain accreditation from the Joint Commission on Accreditation of Healthcare Organizations (now called the "Joint Commission") or the Accreditation Association for Ambulatory Health Care and become a participating Maryland Medicaid provider within 18 months of CON approval.

MASC obtained AAAHC accreditation and became a Medicaid provider within 18 months of the CON approval, meeting the condition. MASC's second CON was approved without conditions.

Staff recommends that the Commission find that the applicant has complied with the conditions of previous CONs.

F. Impact on Existing Providers

COMAR 10.24.01.08G(3)(f) requires the Commission to consider information and analysis with respect to the impact of the proposed project on existing health care providers in the service area, including the impact on geographic and demographic access to services, on occupancy when there is a risk that this will increase costs to the health care delivery system, and on costs and charges of other providers.

MASC asserted that this project will not affect other existing providers, as the volume growth it projects is based on its existing volume levels adjusted for population growth. MASC states that the population will benefit from expanding this lower cost surgery setting. (DI#9, p.10-12) The addition of the fourth OR will allow more flexibility in scheduling patients. This project

requires a modest staffing increase (two Registered Nurses, one Surgical Technician and one additional janitor), which MASC is confident will not be a problem to secure and retain.

Commission staff recommends that the Commission find that the proposed project will not have an unacceptable impact on existing providers and will not increase costs to the health care delivery system.

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 approve the project. It complies with the applicable State Health Plan standards, is needed, is a cost-effective approach to meeting the project 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 the Center's ability to provide outpatient surgery without adversely affecting costs and charges or other providers of surgical care.

Accordingly, Staff recommends that the Commission **APPROVE** the application of the Massachusetts Avenue Surgery Center, LLC's for a Certificate of Need authorizing the addition of a fourth operating room through the renovation of currently leased space, converting an existing non-sterile procedure room to a small sterile operating room.

IN THE MATTER OF	*	BEFORE THE
	*	
MASSACHUSETTS AVENUE	*	MARYLAND HEALTH
SURGICAL CENTER, LLC	*	
	*	CARE COMMISSION
Docket No. 16-15-2378	*	
	*	

* *

FINAL ORDER

Based on the analysis and findings contained in the Staff Report and Recommendation, it is this 15th day of December, 2016, by a majority of the Maryland Health Care Commission, **ORDERED:**

That the application for a Certificate of Need to renovate a procedure room and convert it to a fourth operating room at the Massachusetts Avenue Surgical Center LLC, an existing freestanding ambulatory surgery facility, in leased space at 6400 Goldsboro Road, Suite 400, Bethesda, Maryland, at a cost of $266,397 is **APPROVED.**

Maryland Health Care Commission

APPENDIX 1

Record of the Review

Item #	Description	Date
1	Commission staff acknowledge receipt of Letter of Intent	5/10/16
2	The applicant filed their Certificate of Need application	7/8/16
3	Commission staff acknowledged receipt of application for completeness review	7/12/16
4	Commission staff requested that the *Washington Times* publish notice of receipt of application	7/12/16
5	Commission staff requested that the *Maryland Register* publish notice of receipt of application	7/12/15
6	Notice of receipt of application was published in the Washington Times	7/27/16
7	Following completeness review, Commission staff requested additional information	7/27/16
8	Commission staff received request for extension to file completeness information until 8/17/16 from applicant's counsel	8/3/16
9	Commission staff received responses to additional information request	8/11/16
10	Commission staff notified the applicant of formal start of review of application effective 9/16/16	9/1/16
11	Commission staff requested that the *Washington Times* publish notice of formal start of review	9/1/16
12	Commission staff requested that the *Maryland Register* publish notice of formal start of review	9/1/16
13	Request made for comments from the Local Health Planning Department on the CON application	9/1/16
14	Notice of formal start of review of application was published in the *Washington Times*	9/8/16

APPENDIX 2

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. … (a) An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health and Mental Hygiene. (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, and 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.21 DI#2, Exhibit 7
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. (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, p. 22

B.(4) Design Requirements. Floor plans submitted by an applicant **must be consistent with the current FGI Guidelines.** (a) A hospital shall meet the requirements in Section 2.2 of the FGI Guidelines. (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. 34 Exhibit 9