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TO:

Commissioners

FROM:

Kevin R. McDonald

Chief, Certificate of Need

DATE:

March 15, 2018

SUBJECT:

Thomas Johnson Surgery Center, LLC.

Docket No. 17-10-2410

Enclosed is the staff report and recommendation on a Certificate of Need ("CON") application filed by Thomas Johnson Surgery Center, LLC ("TJSC").

Thomas Johnson Surgery Center ("TJSC") is a physician outpatient surgery center ("POSC") with one operating room ("OR") and one procedure room located at 197 Thomas Johnson Drive in Frederick, Maryland (Frederick County). It was established in 2008. The majority of ownership shares in this POSC are owned by SCA-Frederick, L.L.C. (65%) and the balance of ownership resides with a group of physicians who are surgical practitioners at the POSC (35%). SCA-Frederick, L.L.C. is a subsidiary of Surgical Care Affiliates, Inc., a wholly owned subsidiary of UnitedHealth Group Incorporated. Surgical Care Affiliates has an ownership interest in five surgery centers in Maryland, including TJSC.

TJSC proposes the establishment of an ambulatory surgical facility through the conversion of a non-sterile procedure room to a second sterile operating room. If the project is implemented, the facility will have two operating rooms and no procedure rooms. The estimated project cost is \$183,031.

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, and with other applicable CON review criteria in COMAR 10.24.01.08.

IN THE MATTER OF	*	BEFORE THE
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THOMAS JOHNSON	*	MARYLAND HEALTH
	*	
SURGERY CENTER, L.L.C.	*	CARE COMMISSION
	*	
Docket No. 17-10-2410	*	
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Staff Report and Recommendation

March 15, 2018

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I. INTRODUCTION

THE APPLICANT

Thomas Johnson Surgery Center ("TJSC") is a physician outpatient surgery center ("POSC") with one operating room ("OR") and one procedure room located at 197 Thomas Johnson Drive in Frederick, Maryland (Frederick County) that was established in 2008. The majority of ownership shares in this POSC are owned by SCA-Frederick, L.L.C. (65%) and the balance of ownership resides with a group of physicians who are surgical practitioners at the POSC (35%). SCA-Frederick, L.L.C. is a subsidiary of Surgical Care Affiliates, Inc., a wholly owned subsidiary of UnitedHealth Group Incorporated. Surgical Care Affiliates has an ownership interest in five surgery centers in Maryland, including TJSC. (DI #2, Exhibits 4 & 5).

THE PROJECT

TJSC proposes the establishment of an ambulatory surgical facility through the conversion of a non-sterile procedure room to a second sterile operating room. If the project is implemented, the facility will have two operating rooms and no procedure rooms.

The proposed project is estimated to cost \$183,031, including: \$107,582 for renovating 420 square feet of space; \$4,829 for a contingency allowance; \$5,620 for an inflation allowance; and \$65,000 for legal and other consultant fees.¹ The applicant anticipates providing \$25,000 in cash and plan to borrow \$158,031 to fund the project.

STAFF RECOMMENDATION

Staff recommends approval of the project based on its conclusion that Thomas Johnson Surgery Center's proposed project complies with the applicable standards in COMAR 10.24.11, the General Surgical Services chapter of the State Health Plan. The applicant has demonstrated that the project is needed. Its surgical case volume growth and its projected future growth are likely to require operating room hours consistent with operation of two operating rooms at optimal capacity use. The project is viable, and will be a cost-effective alternative for meeting the project objective of increasing the facility's surgical capacity. The project will have a positive impact on patient access to services offered by TJSC and on the cost to the health care delivery system. It will not have a negative impact on other providers.

II. PROCEDURAL HISTORY

A. Record of the Review

Please see Appendix 1, Record of the Review.

¹ Staff noted that the amount allotted for the cost of legal and consultant fees accounted for a higher percentage than ordinary for a CON project budget. TJSC acknowledged that and attributed it to planning for a "worst case" scenario and reported that it will likely not spend that amount for this project. (DI #12, p. 2).

B. Interested Parties

There are no interested parties in this review.

C. Local Government Review and Comment

No comments were received from any local governmental body.

D. Community Support

Six letters of support for the project were submitted with the applicant's CON application. The letters were from local business persons, surgeons who operate at TJSC, and patients who received care at TJSC. (DI #2, Exh. 14; DI #9, pp. 4-5).

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 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 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 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.

TJSC stated that it provides information to the public concerning charges and the range and types of services provided, upon inquiry. Patients are provided estimates of actual charges

depending on the procedures required. (DI #2, p. 14) The applicant included TJSC's Facility Fee Schedule with a comprehensive list of CPT codes and charges. (DI #2, Exh. 7).

Staff concludes that TJSC satisfies this standard, based on its current provision of charges for the full range of services upon request and its commitment to provide each patient with charge information for required procedures.

(2) 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.
 - (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.

TJSC submitted a copy of its charity care policy with its CON application (DI #2, Exh. 8), The charity care policy states that TJSC will make a determination of probable eligibility for charity care within two business day of a request for charity care, application for medical assistance or both. The policy also provides that TJSC will publish notice of the availability of charity care in the *Frederick News Post* on an annual basis, post notice of the availability of charity care in its admissions office and business office, and provide to each person who seeks services at the time

of admission individual notice of the availability of charity care, the potential for Medicaid eligibility and the availability of assistance from other government funded programs. TJSC revised and augmented its charity care policy to add notification to the Frederick County Department of Social Services and the local homeless shelters such as Frederick Rescue Mission, and Advocates for Homeless Families. (DI #15).

TJSC's policy also states that the facility will assist patients with filing applications for Medical Assistance, and provides the rules on eligibility for charity and reduced charge care. (DI #2, Exh. 8; DI #9, p.1). TJSC will make written notices and policies available in both English and Spanish, as well as have interpreters for non-English speaking patients. (DI #9, p. 1).

(b) A hospital with a level of charity care ... that falls within the bottom quartile... shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

This standard is only applicable to existing hospitals seeking to add OR capacity. It does not apply to this project.

- (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.

Historically, this POSC has been a negligible provider of charity care; 0.03% of total operating expenses in CY 2015 and 0.01% in CY 2016. (See the following table.) For CY 2017, TJSC projected the provision of \$800 of charity care in CY 2017, projected to be equivalent to 0.03% of total operating expenses.

The Commission's survey of ambulatory surgical facility indicates that, in 2015, statewide, charity care provided by ambulatory surgery centers, as a proportion of total operating expenses, was 0.46%. The applicant states a commitment to equal this level of charity care provision beginning in CY 2018, as shown in Table III-1 below. (DI #2, pp. 15-16).

Table III-1: Thomas Johnson Surgery Center Charity Care as a Percentage of Total Operating Expenses, CY 2015 through CY 2020

The second secon		2015	20)16	2	017		2018		2019		2020
Charity Care	\$	687	\$	240	\$	800	\$	19,947	\$	20,918	\$	21,724
Total Operating												
Expense	\$ 2,	494,456	\$ 2,86	62,612	\$ 3,0	14,637	\$ 4	,336,262	\$ 4	,547,295	\$4	,722,577
% Charity Care		0.03%		0.01%		0.03%		0.46%		0.46%		0.46%

Source: DI #2, pp.32-33; Commission staff analysis of data presented by the Applicant

The applicant's plan for achieving the level of charitable care provision to which it is committed includes: notifying the public of the availability of charity care via annual notices in the *Frederick News Post*; posting the notice of charity care availability on its website, in Admissions and the Business Office; and providing notice of charity care availability to the Frederick County Department of Social Services, Advocates for Homeless Families and the local homeless shelters such as the Frederick Rescue Mission. Additionally, the applicant's Charity Care Compliance Plan also calls for it to:

- Annually remind referring physicians and surgeons that TJSC accepts patients who need charity care;
- Annually remind TJSC staff who interact with patients that charity care is available so that they may enable patients who request information about it or suggest it to patients who voice concerns about the ability to pay for services;
- Develop a monthly report comparing the Year-to-Date ratio of charity care rendered to the cumulative annual Total Operating Costs, and provide this report to the Board of Directors as well as making it a regular item on the agenda of TJSC's monthly management meetings;

The policy states that if the target is not being reached, "TJSC will take every action possible to meet its commitment," re-emphasizing the tactics described above. (DI #2, Exh. 9 and its revised version, DI #15).

As a POSC, TJSC had no charity care obligation and reports providing only nominal amounts of charity care. Because of this standard, it has been required to make a commitment to provide about \$20,000 in charity care per year during the first few years of operation, based on its projected expense levels.

TJSC's Charity Care Compliance Plan goes beyond the posted notices required in subpart (2)(a)(ii) to include outreach to agencies and organizations which serve or advocate for population groups likely to benefit from charity care. Other strengths of that compliance plan are provisions committing to give monthly feedback to Board members and management staff regarding charity care performance, and the steps to be taken if/when performance is lagging, e.g., reminding referring physicians and surgeons of charity care availability, additional outreach to service agencies, and reissuing its standard notices. The Charity Care Compliance Plan is included as Appendix 3. (DI#15).

MHCC staff concludes that the applicant has met this standard.

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

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

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

In responding to these standards, the applicant:

- Provided evidence that the applicant: is licensed, in good standing, with the Maryland Department of Health; is in compliance with the conditions of participation of the Medicare/Medicaid program; and is accredited by the Accreditation Association for Ambulatory Health Care, Inc. (DI #2, Exh. 10);
- Submitted a copy of its Transfer Agreement with Frederick Memorial Hospital ("FMH"), which specifies the responsibilities of TJSC and FMH for ensuring the appropriate and safe transfer of patients between the facilities; that it is TJSC's responsibility to provide for appropriate and safe transfer of the patient to the Hospital, to provide the Hospital's Emergency Department with as much advance notice of a transfer as reasonably possible, and to send pertinent medical information necessary to continue the patient's treatment without interruption and essential identifying information on referral forms with each patient. (DI #2, Exh. 11);
- Submitted a letter from its architect, The Burrell Group, P.C., stating that the construction is designed in compliance with the applicable codes, including Maryland Department of Health regulations at COMAR Title 10, the NFPA 101 Life Safety Code as required by Medicare, and the requirements of the FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014 edition. (DI #2, Exh. 12); and
- Stated that TJSC uses FMH for laboratory services. TJSC sends pathology specimens to FMH or uses Metamark Genetic to arrange other pathology services. TJSC performs radiology, as well as pregnancy and blood glucose testing, in-house. (DI #2, p. 25).

The text of these standards and the location of the applicant's 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.

TJSC's primary service area consists of ten Frederick County zip code areas. Its secondary service area includes ten more Frederick County zip code areas, as well as several zip code areas in Washington and Montgomery Counties, and in the state of West Virginia. (DI #2, pp. 21-23).

MHCC staff concludes that the applicant has identified TJSC'S service area and meets this 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.

To meet this standard, the applicant must demonstrate that its existing OR was utilized optimally over the past 12 months and that the expanded two-OR capacity is likely to be used at optimal capacity² or higher levels of use within three years of the completion of the project. TJSC provided historical and projected data on surgical volume to demonstrate its ability to meet this standard.

When TJSC opened in 2008, the center chose to limit itself to providing surgical services to Medicare patients. Since then it has negotiated contracts with CareFirst BlueCross, UnitedHealthcare, Cigna, and Aetna, and growth in privately insured patients has supported steady case volume growth. (DI #2, p. 30).

Utilization data presented by the applicant is summarized in Table III-2 below. TJSC reports that its surgical volume increased consistently between 2012 and 2017, with an exception in 2016 due to the departure of one surgeon and the six-week disability of another. (DI #9, p. 3). TJSC projects continued growth based on its "knowledge of the existing physicians' practices" as well as the recent addition of an orthopedist who has begun performing total joint replacements at the facility and the imminent addition of two more orthopedic surgeons. These additions are expected to boost case volume growth and operating room hours, as a resulting of increased average time per procedure. (DI #2, p. 5, 23). In response, TJSC expanded its routine hours of operation in 2017 and is considering opening one Saturday per month. (DI #9, pp. 3-4; DI #12, p. 1).

² "Optimal capacity" is defined in the General Surgical Services Chapter 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.

Table III-2: TJSC Historical and Projected Utilization, CY 2012-2020

			Operati Cleaning/Pre		ORs	
Ye	ar	OR Cases	Surgical Procedure Time	Turnaround Time (25 minutes per case)	Total OR Time	Needed @ Optimal Capacity
Historic	2012	474	406.4	197.5	603.9	0.4
	2013	866	726.2	360.8	1,087.0	0.7
	2014	1,308	963.5	545.0	1508.5	0.9
	2015	1,779	1,222.9	741.3	1,964.2	1.2
	2016	1,660	1,085.0	691.7	1,776.7	1.1
Projected	2017 *	1,827	1,231.6	761.3	1,992.9	1.2
	2018	2,445	1,918.2	1,018.8	2,937.0	1.8
	2019	2,542	2,012.7	1,059.2	3,071.9	1.9
	2020	2,666	2,133.6	1,110.8	3,244.4	2.0

* projected based on six months of data

Source: DI #12, p. 1; Additional analysis of applicant's data by Commission staff

As shown in the table, TJSC reportedly reached optimal capacity use of its single OR in 2014-15 and projects demand for operating room time in 2018 equivalent to 1.8 ORs operating at optimal capacity. It projects demand equivalent to optimal use of two rooms by 2020.

Staff concludes that the applicant's historical and projected surgical volume supports its need for a second OR, and that the proposed project is consistent with this standard.

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

An applicant proposing to expand the number of operating rooms proposed 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.

This standard is not applicable. The proposed project involves establishment of an ambulatory surgical facility through expansion of a POSC.

(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.

The applicant states that it has taken patient safety into account with the design of this project, citing the following design elements: maintaining clearances and space requirements as outlined in the FGI Guidelines; selecting proper finishes to maximize the ability to sanitize the space; adjusting the ventilation system to meet or exceed the required air changes in the operating rooms; and designing the second operating room to be similar to the existing OR, which will minimize training requirements and allow the staff to move from one OR to another with minimal chance of confusion, resulting in improved patient safety. (DI #2, pp. 25-26). Copies of the project drawings are included in Appendix 3.

The application demonstrates that TJSC has considered patient safety in its designs for the second operating room, and has met this standard.

(7) Construction Costs.

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. To make this comparison, a 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 adjusts for a variety of factors, including cost data: for the latest month; the location of the construction project; 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 also identifies costs that should not be included in the MVS calculations. These exclusions include costs: for buying or assembling land, for improvements to the land, related to land planning, for discounts or bonuses paid for financing, for yard improvements, for off-site work, for furnishings and fixtures, for marketing costs, and for general contingency reserves³.

TJSC proposes the renovation of 420 square feet ("SF") of existing building space, converting an existing procedure room back to an operating room. Among the renovations will be modifications to the HVAC and plumbing systems, as well as doorways and storage space. TJSC calculated the MVS benchmark to be \$472.66 per SF.⁴ The applicant's calculation of a benchmark included an assumption that adjusted the benchmark down by 50%, since this is a renovation project, and not new construction, for which the MVS Guide is more suited.⁵

The estimated cost for the components presented by the applicant that are accounted for in the MVS Guide (the building cost, architectural fees, and permits) is \$107,582 -- or \$256.15 per SF. Excluding demolition, the adjusted cost was estimated at \$242.72 per square foot, or 49% lower than the calculated MVS benchmark.. (DI #9, Exh. 2).

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

⁴ The applicant stated that the adjustments presented in the application were derived from the approach that Commission staff used in the matter of Massachusetts Avenue Surgery Center (Docket No. 16-15-2378). (DI #9, Exh. 2).

⁵ Staff notes that the revision of COMAR 10.24.11, the Surgical Services Chapter of the State Health Plan, which became effective after this application was submitted, subjects only new construction to this analysis, not renovation projects.

Staff validated and accepted the applicant's analysis that the construction cost is well below the MVS benchmark and that the project complies with this standard.

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

Utilization projections were based on historic utilization trends, the addition of three physicians, and population growth. TJSC based its estimates of revenue on the utilization projections and current charge levels, rates of reimbursement, contractual adjustments and discounts, and bad debt as experienced by the facility. The expense numbers are based on current staffing and overall expense projections that are consistent with the utilization projections and the current expenditure levels at TJSC. (DI #2, pp. 27, 32-33). The applicant has historically generated an excess of revenues over expenses, and projects continued profitable operation, as shown in Table III-3. (DI #2, p. 27).

Table III-3: Thomas Johnson Surgery Center Charity Care as a Percentage of Total Operating Expenses. CY 2015 through CY 2020

			<u>. </u>			
2012 100 PM	2015	2016	2017	2018	2019	2020
Cases	1,779	1,660	1,827	2,445	2,542	2,666
Net Revenue	\$3,927,150	\$4,026,462	\$4,133,563	\$6,896,427	\$7,377,206	\$7,872,387
Expenses	\$2,494,456	\$2,862,612	\$3,014,637	\$4,336,262	\$4,547,295	\$4,722,577
Net Income	\$1,432,694	\$1,163,850	\$1,118,926	\$2,560,165	\$2,829,911	\$3,149,810

Source: DI #2, pp. 29,32-33

Staff concludes that the applicant's utilization and financial projections are based on reasonable assumptions and comply with this standard.

(9) Preference in Comparative Reviews.

This is not a comparative review, so this standard is not applicable.

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.

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

Staff concludes that TJSC has addressed the need for a second operating room based on reasonable volume projections indicating that two ORs are likely to be used at or close to optimal capacity within three years of the addition of the second OR.

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.

TJSC has adjusted its operations to accommodate increased demand. These initiatives included:

- Moving appropriate or eligible cases to the procedure room to open time in the one operating room;
- Expanding routine hours into the later evening, and occasionally, into the weekend. Current typical Monday through Friday hours are from 6:00 a.m. to 6:30 p.m. (or as late as necessary until discharge of the final patients); and
- Considering opening one Saturday per month. (DI #2, p. 30; DI #9, pp. 3-4).

TJSC's assessed that extending hours is not the best solution to addressing increased demand since it requires patients to fast all day before surgery or to arrive at unreasonably early hours, and attempts at Saturday hours were not well received by patients who prefer surgical procedures scheduled during the week.

Other efforts to address the need for additional operating room space included:

- Meeting with the property manager annually about acquiring an adjacent suite. However, adjacent spaces are under lease.
- Relocating TJSC to another site. However, the costs of replicating the existing facility and paying rent on two sites during the renovation were deemed too high. (DI #2, p. 30).

Although the applicant did not provide estimated costs for each of the alternatives listed, staff concludes that the choice of converting the existing procedure room into a second operating room is a cost-effective choice for meeting TJSC's goals, compared to the alternatives. The applicant has made efforts to maximize the time available in its one operating room and extended the facility's hours of operation. Additionally, TJSC was unable to obtain additional space within the existing property and determined the cost of relocating to another location is substantially higher. Therefore, staff recommends that the Commission find that the addition of an OR, through repurposing an existing procedure room, is the most cost-effective alternative for increasing OR capacity.

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.

Availability of Resources to Implement the Proposed Project

The estimated total project budget to complete the project is \$183,031, which the applicant will fund with \$25,000 cash and a five-year loan for \$158,031, as shown in Table III-4.

Table III-4: Thomas Johnson Surgery Center

Project Budget

1 Toject Buaget	WASTED TO SECU	
Use of Funds		Total
Renovations		
Building	\$	96,582
Fixed Equipment		0
Architect/Engineering Fees		9,000
Permits (Building, Utilities, etc.)		2,000
Subtotal	\$	107,582
Other Capital Costs		
Movable Equipment	\$	0
Contingency Allowance		4,829
Gross Interest during Construction		0
Other		0
Subtotal		4,829
Total Current Capital Costs	\$	112,411
Inflation Allowance		5,620
Total Capital Costs	\$	118,031
Legal Fees*		40,000
Non-Legal Consultant Fees		25,000
Subtotal*	\$	65,000
Total Uses of Funds	\$	183,031
Sources of Funds		
Cash	\$	25,000
Working capital loans		158,031
Total Sources of Funds	\$	183,031

Source: DI #2, Exhibit 1, Table E * See footnote 1, page 1, supra.

TJSC provided a letter from Physicians Capital, a division of Evolve Bank & Trust, stating its commitment to finance the project. (DI #2, Exh. 13). To support its plan to use cash to fund a portion of the project, TJSC submitted a letter from the independent Certified Public Accounting firm of Albright Crumbaker Moul & Itell,⁶ which concluded that TJSC generates sufficient cash flow from continuing operations and current available funds to provide contributions of \$112,411 towards the project. (DI #9, Exh. 4).

The applicant has demonstrated it has sufficient resources to finance the project.

⁶ The independent accounting firm states that it is independent with respect to Thomas Johnson Surgery Center, LLC and any of its officers, directors, and LLC members, and has no financial interest in the Maryland Health Care Commission's review of TJSC's CON application. (DI #9, Exh. 4).

Availability of Resources to Sustain the Proposed Project

TJSC's projected operating results are shown in Table III-5 below. Because projected volume growth is most significant in the first year of operation, based on doubling the operating room space at the facility, the applicant projects that net income will more than double within the first two years of full operation. Likewise, salary, contractual, and supply expenses are projected to increase as a result of the increased patient volume. Additional project expenses include interest on project debt and project depreciation beginning in 2018, but any expenses associated with converting the existing procedure room to an OR should not impact the facility's ability to remain profitable at any point.

Table III-5: Thomas Johnson Surgical Center Revenue & Expense Statement, CY 2015 - CY 2020

Calendar Year	Two Most R	Most Recent Years Current Year I			Projected Year			
	2015	2016	2017	2018	2019	2020		
(100 min 100 m	- ALCANDAN							
Gross Revenues	\$26,835,894	\$27,406,290	\$27,614,830	\$46,297,329	\$49,522,101	\$52,842,177		
Allowance for Bad								
Debt		60,246	7,862	28,226	30,192	32,216		
Contractual								
Allowance	22,908,057	23,319,342	23,472,606	39,352,729	42,093,786	44,915,851		
Charity Care	687	240	800	19,947	20,918	21,724		
Net Operating								
Revenue	\$3,927,150	\$4,026,462	<i>\$4,133,563</i>	\$6,896,427	\$7,377,206	\$7,872,387		
		E	xpenses			The second secon		
Salaries & Wages	\$713,513	\$756,476	\$855,080	\$977,531	\$1,001,094	\$1,026,407		
Contractual Services	113,389	157,876	197,710	303,538	318,311	330,580		
Interest on Current		·						
Debt	-	(1,136)	(442)	(442)	(442)	(442)		
Interest on Project	-	-	-					
Debt				4,285	3,411	2,499		
Current Depreciation	_	95,913	137,956	148,385	148,385	148,385		
Project Depreciation	-	-	-	10,758	10,758	10,758		
Current Amortization	-	40,444	49,111	49,111	49,111	49,111		
Supplies	808,881	963,830	1,011,707	1,988,074	2,145,294	2,264,018		
Other Expenses*	858,673	849,208	763,513	855,022	871,373	891,261		
Total Operating								
Expenses	\$2,494,456	\$2,862,612	\$3,014,637	\$4,336,262	\$4,547,295	\$4,722,577		
Net Income	\$1,432,694	\$1,163,850	\$1,118,926	\$2,560,165	\$2,829,911	\$3,149,810		

*Includes rent, equipment rental, credit card processing, management fees, real estate taxes, travel, uniforms, linens

Source: DI #2, pp. 32-33.

The facility expects to hire an additional 0.8 FTE surgical technician and 1.6 FTE registered nurses. TJSC states that its recruiters have been its physician members, but if needed, it will advertise in local newspapers and professional journals, and use employment agencies. (DI #2, p. 36).

Staff concludes that the proposed 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.

This criterion is not applicable. This is the first time that Thomas Johnson Surgery Center has submitted a CON application for review.

F. Impact on Existing Providers

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

Impact on Other Providers

The Surgical Services Chapter includes guidance for assessing the impact of a new ambulatory surgery center on a hospital. This guidance dictates that if the 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% of the operating room capacity at a hospital, then the applicant shall include, as part of the 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.

TJSC expects three surgeons who currently operate at Frederick Memorial Hospital to begin providing or adding services at TJSC. TJSC projected that the caseload redirected to TJSC may be as high as 560 cases in 2018, 578 in 2019, and 602 in 2020. TJSC presented the impact analysis shown in Table III-6 below. For its analysis, TJSC used an assumption that FMH had 9 general purpose ORs with a full capacity of 2,375 hours, or 142,500 minutes, per room. Thus, TJSC estimated that the redirected cases to TJSC account for 4.3% of FMH's operating room capacity. In this analysis, TJSC used the minutes per case for the additional physicians, which is longer than the average OR case for other physicians at the practice (projected at 73 minutes compared to 39 minutes for all other physicians currently at TJSC, respectively, for 2018). (DI#2, pp. 24, 35-36).

Table III-6: Applicant's Estimated Impact of Proposed Project on Surgical Volume at Frederick Memorial Hospital in 2018

Number of Operating Rooms at FMH	9
Full OR capacity at FMH	142,500
Total Capacity	1,282,500
Number of redirected cases projected for 2018	560
Potential Minutes Impact	54,800
Estimated Impact on FMH Cases	4.3%

Source: DI #2, pp. 24 & 35

Using a similar approach, MHCC staff calculated a slightly different estimate of the potential impact of TJSC on FMH's surgical services by incorporating several different assumptions regarding operating room capacity at the hospital, shown in Table III-7. According to the Commission's *Annual Report on Selected Maryland Acute Care and Special Hospital Services, FY 2017*, FMH has 11 general purpose mixed-use operating rooms. To estimate surgical capacity, staff used the *optimal* capacity of these rooms at 80% of full capacity, or 114,000 minutes per year, and calculated the potential minutes of impact to be 54,880 using 73 minutes of average OR time, plus 25 minutes turnaround time, per case.

Table III-7: Commission Staff's Estimated Impact of Proposed Project on Surgical Volume at Frederick Memorial Hospital in 2018

Number of Operating Rooms at FMH	11
Optimal OR capacity at FMH	114,000
Total Optimal Capacity	1,254,000
Number of redirected cases projected for 2018	560
Potential Minutes Impact	54,880
Estimated Impact of FMH Caseload	4.4%

In either scenario, the estimated number of cases that may likely be redirected to TJSC from FMH account for less than 5% of FMH's total surgical capacity.

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

The applicant states that its conversion of an existing procedure room to a second operating room will increase access to surgical services and enable more scheduling flexibility. TJSC states that the project is likely to reduce costs to the health care system because ambulatory surgery center charges are typically lower than hospital charges and the project is expected to shift some cases from the hospital setting to the ASF setting. (DI #2, p. 36).

Staff concludes that the applicant's analysis about the impact of the proposed project are reasonable. FMH will lose volume as a result of the project and the loss of case volume that may have otherwise been performed by three surgeons at the hospital. However, based on the data available, the impact is below a level that requires more detailed analysis by the applicant. The project is likely to have a positive impact on system costs in that cases will be redirected from the hospital setting to an ASF. TJSC will be more available and accessible at desirable times of the day for patients and physicians as a result of this project. Staff concludes that the impact of this project, as defined in this criterion, will primarily be positive.

IV. SUMMARY AND STAFF RECOMMENDATION

Based on its review of the proposed project's compliance with the Certificate of Need review criteria, COMAR 10.24.01.08G(3)(a)-(f), and with the applicable standards in COMAR 10.24.11, the General Surgical Services Chapter of the State Health Plan, Commission staff recommends that the Commission award a Certificate of Need for the project. Staff concludes that the proposed project complies with the applicable State Health Plan standards, is needed, is a cost-effective approach to meeting the project objectives, is viable, and 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.

Accordingly, Staff recommends that the Commission APPROVE Thomas Johnson Surgical Center's application for a Certificate of Need authorizing the addition of a second operating room by converting an existing procedure room to a sterile operating room.

FINAL ORDER

Based on the analysis and conclusions contained in the Staff Report and Recommendation, it is this 15th day of March, 2018, by a majority of the Maryland Health Care Commission, **ORDERED**:

That the application by Thomas Johnson Surgery Center, L.L.C., an existing physician outpatient surgery center, for a Certificate of Need to establish an ambulatory surgical facility through the addition of a second operating room at 197 Thomas Johnson Drive, in Frederick, at an estimated cost of \$183,031, is hereby **APPROVED**.

MARYLAND HEALTH CARE COMMISSION

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1: Record of the Review

Docket Item #	Description	Date
1	John J. Eller submitted on behalf of Thomas Johnson Surgery Center, LLC ("TJSC"), a notice of the intent by TJSC to apply for a CON for the conversion of one procedure room to a second operating room ("OR"), resulting in a total capacity after project completion of two ORs. Established in 2008, TJSC is located at 197 Thomas Johnson Drive in Frederick, Maryland, 21702. Commission staff acknowledged receipt of this Letter of Intent on August 8, 2017.	8/8/2017
2	John J. Eller submitted a Certificate of Need application on behalf of TJSC, proposing the conversion of one procedure room to a second operating room, resulting in a total capacity of two ORs (Matter No. 17-10-2410) located in Frederick, Maryland.	10/6/2017
3	Commission acknowledged receipt of CON application in a letter to TJSC.	10/13/2017
4	Commission requested publication of notification of receipt of the TJSC proposal in the <i>Frederick Post</i> .	10/13/2017
5	Commission requested publication of notification of receipt of the TJSC proposal in the <i>Maryland Register</i> .	10/13/2017
6	John J. Eller submitted tables to be incorporated as Exhibit 1 in the CON application.	10/20/17
7	The <i>Frederick Post</i> provided certification that the notice of receipt of application was published on October 21, 2017.	10/21/2017
8	Following completeness review, Commission staff found the application incomplete, and requested additional information.	11/20/2017
9	Commission received responses to the November 20, 2017 request for additional information.	11/30/2017
10	Following review of TJSC's responses, Commission staff requested additional information.	1/5/2018
11	Commission requested publication of notification of formal start of review for the TJSC proposal in the <i>Maryland Register</i> .	1/5/2018
12	Commission received responses to the January 5, 2018 request for additional information.	1/9/2018
13	Commission notified TJSC that its application is docketed for formal review on January 19, 2018 with a notice in the <i>Maryland Register</i> .	1/10/2018
14	Commission requested publication of the docketing notice in the next edition of the <i>Frederick Post</i> .	1/10/2018
13	Commission sent copy of the application to the Frederick County Health Department for review and comment.	1/10/2017
14	The <i>Frederick Post</i> provided certification that the notice of formal start of review of application was published on January 17, 2018.	1/17/18
15	Applicant submitted a revised Charity Care Policy as well as a revised Charity Care Compliance Plan via email to Kevin McDonald	3/7/18

MARYLAND HEALTH CARE COMMISSION

APPENDIX 2:

Excerpted CON Standards for General Surgical ServicesFrom 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. Also included are references to where in the application or completeness correspondence the documentation can be found.

STANDARD	APPLICATION REFERENCE (Docket Item #)
.05A(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.	(Docket Item #) DI #2, Exhibit 10
(d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will: (i) Meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment. (ii) Obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility.	
.05A(4) Transfer Agreements.	DI #2, Exhibit 11

(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.	
(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.	
.05B(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.	DI #2, Exhibit 12
(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.	
.05B(5) Support Services.	DI #2 n 25
Each applicant shall agree to provide as needed, either directly or through	DI #2, p. 25
contractual agreements, laboratory, radiology, and pathology services.	

MARYLAND HEALTH CARE COMMISSION

APPENDIX 3:

Thomas Johnson Surgery Center Charity Care Compliance Plan

THOMAS JOHNSON SURGERY CENTER, LLC.

MANUAL: Policy & Procedure SECTION: General Administrative

POLICY: Charity Care Compliance Plan

Effective Date: Reviewed Date: Revised Date:

PURPOSE: TJSC has a history of providing charity care. As part of its Certificate of Need application to obtain a second operating room, TJSC committed to providing, at a minimum, annual charity care that is equivalent to 0.046% of its annual Total Operating Revenue. This policy is intended to assure that Thomas Johnson Surgery Center (TJSC) meets its commitment to providing charity care.

POLICY: TJSC will monitor the amount of charity care it provides on an ongoing basis. In addition to advertising in the media and posting notices about the availability of charity care, TJSC will annually remind referring physicians, surgeons, and TJSC staff about the availability of charity care.

PROCEDURE:

- 1. When scheduling patients for surgery, TJSC will not use ability to pay a consideration.
- 2. Consistent with TJSC's Charity Care Policy, TJSC will publish annual notice of the availability of charity care in the Frederick News Post and post notice of it on its website. We will also notify the local Social Service Department and Homeless Shelters. Individual notice of the availability of charity care, the potential for Medicaid eligibility and the availability of assistance from other government funded programs shall be provided to each person who seeks services in TJSC at the time of admission.
- 3. TJSC will annually remind referring physicians and surgeons that TJSC accepts patients who need charity care.
- 4. TJSC will annually remind TJSC staff who interact with patients that charity care is available so that they may enable patients who request information about it or suggest it to patients who voice concerns about the ability to pay for services.
- 5. TJSC Chief Executive Officer will develop a monthly report that will show the Year-to-Date cumulative number of charity care patients and their equivalent charges as well as the cumulative annual Total Operating Costs. S/he will provide this report to the Board of Directors. This report will be a regular item on the agenda of TJSC's monthly management meetings.
- 6. Should this report show that TJSC's charity care equivalent charges are not consistent with its commitment, TJSC will take every action possible to meet its commitment, including:
- a. Notifying all referring physicians and surgeons, reminding them of the availability of charity care.
 - b. Reminding staff who interact with patients that charity care is available.
 - c. Posting additional notices in the Frederick News Post
- d. Notifying local homeless shelters such as MD Coalition for Frederick MD, Frederick Rescue Mission, and Advocates for Homeless Families as well as the Frederick County Department of Social Services.

MARYLAND HEALTH CARE COMMISSION

APPENDIX 4:

Project Floor Plans



