TO: Shannon Magro, Physicians Surgery Center of Frederick
Christopher P. Dean, Esq., Counsel for Frederick Health Hospital, Inc.

FROM: Trupti Brahmbhatt, Ph.D., Commissioner/Reviewer

RE: Recommended Decision
Andochick Surgical Center, LLC d/b/a
Physicians Surgery Center of Frederick
Docket No. 21-10-2451

DATE: February 22, 2023

Enclosed is my Recommended Decision in the review of the Certificate of Need (CON) application submitted by Andochick Surgical Center, LLC d/b/a Physicians Surgery Center of Frederick (PSCF) for the addition of two sterile operating rooms and one non-sterile procedure room.

The relevant State Health Plan chapter considered in the review of this project is COMAR 10.24.11, State Health Plan for Facilities and Services: General Surgical Services[1]. I also considered the general CON review criteria at COMAR 10.24.01.08G(3)(a) through (f). I considered the comments of Frederick Health Hospital, Inc., an interested party, and the entire record in this review and recommend that the Maryland Health Care Commission **DENY** Physician Surgery Center of Frederick's application for a Certificate of Need. PSCF has failed to meet its burden of proof in demonstrating that the proposed project satisfies all applicable SHP standards and criteria for review. My attached Recommended Decision details my analysis and findings regarding applicable standards and criteria.

Project Description

PSCF proposes to add two operating rooms and one procedure room to an existing ambulatory surgery center. The proposed project would establish it as an "ambulatory surgical facility" (ASF) subject to CON regulation, [2] with four operating rooms and two procedure rooms. The applicant states the proposed project will add 10,955 square feet (SF) and also include renovation of 1,065 SF of existing space to the center located at 81 Thomas Johnson

[1] This application was reviewed under the previous iteration of the General Surgical Services Chapter, COMAR 10.24.11, with an effective date of January 15, 2018.
[2] An ambulatory surgical facility is a health care facility that has three or more operating rooms. Md. Code Ann., Health-Gen. § 19-114.

Court, Suite B in the City of Frederick (Frederick County). PSCF leases the space from Andochick Properties, LLC.

The total cost of the proposed project is estimated to be $5,657,000. The total cost for PSCF to fit out the additional space and complete the renovation component of the project is $2,805,300, with the landlord responsible for the cost of constructing the space for the new addition at $2,851,700.

Recommendation

I recommend that the Maryland Health Care Commission **DENY** Physician Surgery Center of Frederick's application for a Certificate of Need to add two operating rooms and one procedure room to an existing ambulatory surgery center.

Procedurally, the applicant did not provide adequate responses to questions I have posed and I do not find that the quality and reasonableness of some of the projections and assumptions made in project planning have been well documented. The applicant has made revisions throughout the review process, raising further doubts about the thoroughness of the project planning process and the reliability of the information undergirding the applicant's projections.

Specifically, I found that PSCF did not meet the State Health Plan standards addressing charity care, need, financial feasibility, and impact. In addition, PSCF did not satisfy review criteria requiring PSCF to demonstrate that the project is needed, is financially viable, and would have an acceptable impact on existing providers and the health care delivery system.

Further Proceedings

This matter will be placed on the agenda of a meeting of the Maryland Health Care Commission on March 16, 2023, which begins at 1:00 p.m. at 4160 Patterson Avenue in Baltimore. This meeting is expected to be a "hybrid" meeting at which Commissioners and persons with matters before the Commission may attend in person or attend virtually through a Zoom webinar format. However, I request that representatives who plan to speak on behalf of the applicant and interested party attend the meeting in person. Please let the Commission know as soon as possible if there are any concerns with my request to appear in person. The link to register to attend the meeting will be placed on the Commission's meeting page: https://mhcc.maryland.gov/mhcc/pages/home/meeting_schedule/meeting_schedule.aspx?id=0. After registering, each person will receive a confirmation email containing information

about joining the Commission meeting via the Internet. The Commission will issue a final decision based on the record of the proceeding.

As provided in COMAR 10.24.01.09B, an applicant or interested party may submit written exceptions to the enclosed Recommended Decision. Written exceptions must identify specifically those findings or conclusions to which exception is taken, citing the portions of the record on which each exception is based. Copies of exceptions and responses to exceptions must be communicated to all parties, via regular mail or email, by the due date and time shown below. If the deadline is met via email, please assure that paper copies of the exceptions or response to exceptions are also mailed to the Commission the same day.

Oral argument during the exceptions hearing before the Commission will be limited to 10 minutes for the applicant, and 10 minutes for the interested party unless extended by the Chair. The schedule for the submission of exceptions and any response to exceptions is as follows:

Submission of exceptions:	Wednesday, March 1, 2023, no later than 4:00 pm.
Submission of responses:	Monday, March 6, 2023, no later than 4:00 p.m.
Exceptions hearing:	March 16, 2023, 1:00 p.m. Monthly Commission Meeting

cc: Scott E. Andochick, M.D.
James P. Sherwood, VP Business Dev. & Strategy, Frederick Health
Jennifer Coyne, Miles & Stockbridge, PC
Patricia Nay, M.D., Executive Director, Office of Health Care Quality, MDH
Alexa Bertinelli, Assistant Attorney General, MHCC
Caitlin Tepe, Assistant Attorney General, MHCC
Paul Parker, Director, Health Care Facilities Planning and Development, MHCC
Wynee Hawk, Chief, CON, MHCC
William Chan, Program Manager, MHCC
Barbara A. Brookmyer, M.D., Health Officer, Frederick County

IN THE MATTER OF	*	
	*	
ANDOCHICK SURGICAL	*	**BEFORE THE**
	*	
CENTER, LLC d/b/a	*	
	*	**MARYLAND HEALTH**
PHYSICIANS SURGERY	*	
	*	
CENTER OF FREDERICK	*	**CARE COMMISSION**
	*	
Docket No. 21-10-2451	*	
	*	

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Reviewer's Recommended Decision

March 16, 2023

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I. INTRODUCTION

A. The Applicant

Andochick Surgical Center, LLC d/b/a Physicians Surgery Center of Frederick (PSCF) is an "ambulatory surgery center" (ASC) as defined in COMAR 10.24.11, the Maryland Health Care Commission's State Health Plan regulations for general surgical services. It operates two operating rooms and one procedure room and is used in the performance of multiple surgical specialties. It is located at 81 Thomas Johnson Court, Suite B in the City of Frederick (Frederick County). PSCF is a limited liability company established in December 2007. PSCF leases the space from Andochick Properties, LLC. Scott E. Andochick, M.D., is the owner of Andochick Properties, LLC and is the president and medical director of PSCF. (DI #9, p. 6 and Exh. 2 and 3). Ownership of PCSF is divided between several surgeons associated with the center, with Dr. Anochick holding the largest interest. (DI# 40). See Appendix 2 for the PSCF organizational chart and ownership information.

B. The Project

PSCF proposes to add two operating rooms (ORs) and one procedure room. This would establish it as an "ambulatory surgical facility"[1] (ASF) subject to Certificate of Need (CON) regulation, with four operating rooms and two procedure rooms. Md. Code Ann., Health-Gen. §§ 19-114(d)(1) & 19-120(f). The applicant states the proposed project will add 10,955 square feet (SF) and include renovation of 1,065 SF of existing space in the center. The applicant states that the proposed project will include enlarging the current clean and dirty rooms for additional workspace; adding workspace for sterile processing and storage space for sterilized equipment and supplies; improvements to staff changing rooms and showers; and changes to the corridors for easy access and flow to and from the operating rooms and procedure rooms. PSCF estimates that the facility will be completed in April 2024. (DI #41, Exh. 2, p. 3). The ASC would continue to operate during construction of the new addition.

The applicant states that surgical case volume is growing. (DI #2, p. 6). The ASC has ten surgical practitioners on staff. The applicant indicates that three additional orthopedic surgeons have requested staff privileges at PSCF as the facility seeks to develop a total joint replacement program. The applicant also states it expects to recruit an ophthalmologist in 2022. (DI #2, p. 6)

PSCF indicates that the existing facility space and capacity has become inadequate to support the increased need for surgical time. To accommodate surgical time demands, the applicant states that surgical staff are working later hours and on weekends. With the lack of space for staff, equipment, and supplies, PSCF has had to lease additional space in an adjacent office. (DI #2, p. 6).

The applicant states that increasing operating room capacity and physical space will better accommodate PSCF's surgeons and patients, allowing for more privacy through increasing waiting room capacity and providing more recovery space. (DI #2, pp. 7-8).

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[1] Section 19-114(b) of the Health-General Article and COMAR 10.24.11.B(3) define an ambulatory surgical facility as a health care facility that has three or more operating rooms.

The total cost of the proposed project is estimated to be $5,657,000. (DI #41, Exh. 1, Table E). The proposed project costs are estimated to be split, on a near even basis, between the applicant and the landlord. Both entities will share in the cost of the new building addition, with the landlord contributing 52% of the estimated $4.4M cost of new construction. PSCF, which leases the ASC space and will lease the larger ASF space, will fit out the additional space and complete the renovation component of the project. PSCF anticipates funding its share of the cost with commercial loan debt ($2.197M), $550,000 in cash, and $58,000 in interest income from bond proceeds. (DI #11, Exh. 11). Appendix 5 provides the project budget estimate detail.

C. Background – Surgical Facilities in Frederick County

There are 17 licensed providers of outpatient surgical services located in Frederick County.[2] This includes Frederick Hospital, an independent hospital which reports an inventory of 11 mixed use/general purpose[3] operating rooms and 15 licensed ASCs and 1 ASFs that operate a total of 10 ORs. The single ASF that falls within the definition of a regulated "health care facility" is Frederick Surgical Center, a multi-specialty facility with four operating rooms. The other four ASCs with sterile operating rooms include the applicant, PSCF, a multi-specialty center with two ORs and Thomas Johnson Surgery Center, also a two-OR center with multiple specialties. One of the two ASCs with a single operating room reports more than one surgical specialty. The other specializes in eye surgery.

The 11 Frederick County ASCs that report operations limited to clean procedure rooms (i.e., they have no sterile operating rooms) are primarily single specialty centers. These include three gastrointestinal (GI) endoscopy centers, two pain management centers, and five centers specializing in, respectively, vascular surgery, obstetric and gynecological procedures, plastic surgery, urology, and podiatry. One center with only procedure rooms reports both orthopedic surgery and pain management as specialties.

D. Reviewer's Recommendation

I recommend denial of the requested CON. This recommendation is based on my finding and conclusion that the applicant has not complied with all applicable State Health Plan (SHP) standards in COMAR 10.24.11. These include the standards for Charity Care Policy, Need–Minimum Utilization for Establishment of a New or Replacement Facility, Financial Feasibility, and Impact. I also find that the proposed project has not demonstrated that is viable, under the review criterion of Viability at COMAR 10.24.01.08G(3)(d).

I find that the applicant has not met its burden of proof in demonstrating the need for the proposed project, that the project is viable, and that the likely impact of this project on the local health care delivery system for outpatient surgery is acceptable, as is required by COMAR

[2] Physicians may provide surgical services in their offices without obtaining an ASF license. A license is required if the surgical setting bills third-party payors for the facility's services.

[3] This category of OR is predominant in the general hospital setting. These ORs are used for a mixture of both inpatient and outpatient surgical procedures and are non-specialized with respect to the specialty categories of surgical cases for which they are used.

10.24.01.08G. The project will have an impact on other providers of this service that I cannot ignore.

Procedurally, the applicant did not provide adequate responses to questions I have posed and I do not find that the quality and reasonableness of some of the projections and assumptions made in project planning have been well documented. The applicant has made revisions throughout the review process, raising further doubts about the thoroughness of the project planning process and the reliability of the information undergirding the applicant's projection of project feasibility.

II. PROCEDURAL HISTORY

A. Record of the Review

See Appendix 1, Record of the Review.

B. Interested Party in the Review

On December 30, 2021, Frederick Health Hospital, Inc. (Frederick Hospital) submitted comments in opposition to PSCF's CON application and requested to be recognized as an interested party (IP) in this review. (DI #22). This facility is the only general hospital operating in Frederick County and is located approximately 2.6 miles from the applicant's location. As stated above, Frederick Hospital reports an inventory of 11 mixed use/general purpose operating rooms. Frederick Hospital states that a majority of the surgery time in its operating rooms is used for general surgery and orthopedic surgery. (DI #22, p. 3.)

Frederick Hospital asserts that the proposed project is not consistent with five standards in the SHP's General Surgical Services chapter of regulation: the two general standards on procedure volume and charity care and the project review standards for need, financial feasibility, and impact. Turning to the general review criteria and covering some of the same ground, the hospital also comments that the applicant has failed to establish a need for the project and failed to demonstrate that the project is the most cost effective among alternatives. Finally, Frederick Hospital argues that the project has not demonstrated that it is viable or that the project has an acceptable impact. Regarding impact, the hospital claims that the applicant has not addressed the proportion of case volume expected to shift from other providers of outpatient surgery, such as Frederick Hospital, and that the project will have a negative impact on the case mix of surgical patients at the hospital, removing "less complex" and "more reimbursable" cases from the hospital. It also claims that the project will have a negative impact on staffing, citing a current "crisis" in health care facility staffing. Citing the lack of a credible plan by the applicant to recruit the additional staff it will need, the hospital states its belief that the applicant will turn to recruiting the hospital's existing staff, leaving the hospital with more severe staffing challenges while simultaneously creating a higher average acuity level among the surgical patients using the hospital, with the potential for negatively affecting patient safety.

I was appointed Reviewer in this application and on March 15, 2022, I recognized Frederick Hospital as an interested party in this review within the meaning of COMAR

10.24.01.01B(20) because it provides the same services as the applicant in the same planning region. (DI #29). The IP comments will be addressed in my review and analysis of the standards and criteria specifically cited by the IP.

C. Local Government Review and Comment

No comments were received from any local governmental body.

III. REVIEW AND ANALYSIS

Commission regulations at COMAR 10.24.01.08G(3)(a) through (f) identify six criteria for use in the review of proposed projects seeking CON approval. The first is evaluation of the relevant SHP standards, policies, and criteria.

A. The State Health Plan

COMAR 10.24.01.08G(3)(a) 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 (SHP) chapter to be considered in the review of this project is COMAR 10.24.11, State Health Plan for Facilities and Services: General Surgical Services. This application was submitted prior to the revision to this SHP chapter, that became effective October 18, 2021. This review is based on the standards of the former chapter. COMAR 10.24.11.04C.

COMAR 10.24.11.05A — General Standards. The following general standards encompass Commission expectations for the delivery of surgical services by all health care facilities in Maryland, as defined in Health General §19-114(d). Each applicant that seeks a Certificate of Need for a project or an exemption from Certificate of Need review for a project covered by this Chapter shall address and document its compliance with each of the following general standards as part of its application.

(1) Information Regarding Charges

Information regarding charges for surgical services shall be available to the public.

(a) A physician outpatient surgery center[4], ambulatory surgical facility, or a general hospital shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

[4] "Physician outpatient surgery center" or "POSC" is a term used in the previous iteration of the general surgical services component of the SHP, which, as previously noted, is applicable in the review of this project, to denote ASFs falling below the threshold of CON regulation. In the current SHP, updated in 2021, this term has been replaced with the term "ambulatory surgery center" or "ASC."

PSCF states that "(A)ll patients are provided information regarding estimates of charges and patients responsibility as contracted with their insurance company based upon the procedure they are scheduled for." (DI #2, p. 18-19). The applicant indicates that it will encourage patients to make inquiries as needed and the business office will assist/educate by phone, email, text, letter or other method preferred by the patient.

PSCF provided its Setting Up Payor Contracts Policy, which states that the "Current insurance participation list will be posted in the business office and copies made available to the public upon request." (DI # 11, Exh 1). A representative list of the health carrier networks in which PSCF currently participates is also included on its website at: https://physicianssurgctr.com/billing/.[5] Also, the applicant provided a representative list of the names of the health carrier networks in which each surgeon and other health care practitioner that provides services at PSCF currently participates. (DI # 11, Exh 5).

(b) The Commission shall consider complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration when evaluating an applicant's compliance with this standard in addition to evaluating other sources of information.

The applicant states that it is unaware of any complaints to the Consumer Protection Division in the Office of the Attorney General or to the Maryland Insurance Administration since its formation in November 2007. (DI # 9, p. 11).

(c) Making this information available shall be a condition of any CON issued by the Commission.

PSCF submitted a copy of its Insurance Verification/Pre-authorizations Policy that provides its procedures for calculating patient-responsible charges for both self-pay and patients with insurance coverage. (DI # 11, Exh 5-6, pp. 2-4). The policy also provides the procedures that the business office staff will use to contact patients once the expected patient balance has been calculated. (DI # 11, Exh 5, pp. 4-6).

Reviewer's Analysis and Findings

Based on my review of the policies submitted by PSCF, I conclude that the applicant satisfies this standard. While I recommend that this application be denied, should the Commission choose to approve this project, I note that COMAR 10.24.11.05A(1)(c) requires that a CON for surgical services include a condition requiring the CON holder to provide to the public upon inquiry information concerning charges for the full range of surgical services it provides and maintain compliance with applicable laws and regulations regarding the posting of charges.

(2) Information Regarding Procedure Volume.

A hospital, physician outpatient surgery center, or ASF shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the

[5] The Reviewer observed seeing PSCF's list of participating network providers on December 21, 2022.

location where an individual has inquired. A hospital, POSC, or ASF shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.

PSCF affirmed that it will provide information regarding the volume of specific surgical procedures performed at the facility for the most recent 12 months to the public upon request. (DI # 2, p. 20). The applicant states this information will be updated on a regular basis.

Interested Party Comments – Frederick Hospital

Frederick Hospital pointed out that PSCF failed to provide information regarding procedure volume, Attachment F, in its CON application submission. (DI #22, p. 4).

Applicant's Response to Comments

PSCF responded that a list of the surgical procedures by specialty performed at PSCF was submitted in its CON application, along with CPT procedure description and charges (DI #2, Att. E, F, and G) and reiterated that in its response to comments from Frederick Hospital (DI #27, Exh. 1).

Reviewer's Analysis and Findings

PSCF provided exhibits showing procedure volume with the paper copy of its application and in response to Frederick Hospital's comments. PSCF has affirmed in its application that it will provide the information to the public upon request. I find that PSCF complies with this standard.

(3) Charity Care Policy.

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

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

PSCF submitted a copy of its Charity Care Policy and the written procedure states "Every patient requesting charity care write-offs must complete a Financial Assistance Form … and attach any and all applicable documentation. Upon receipt of information needed a probable eligibility determination will be made within two business days, and the patient notified." (DI #9, Exh. 8, p. 1). Subsequently, the applicant responded to a request for more detail on the charity care standard and attached an Application for Charity Care Assistance. Section I of the application requested citizenship status and proof of residency. (DI#41, Exh. 8).

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

PSCF's submitted a copy of the revised public notice that is posted in the facility lobby (DI #9, Exh. 9) and states copies of this notice (available both in English and Spanish) will be made available upon request and on its website at: https://physicianssurgctr.com/wp-content/uploads/2021/10/CharityCarePolicy1.pdf.

The applicant states that the notice of charity care is published annually and submitted documentation that the *Frederick News-Post* published notification that PSCF will provide "surgical care services on a charity basis for all who qualify without regard to age, race, creed, color, sexual orientation, or national origin. Qualifications include those that are determined to be financially or medically indigent." (DI #41, Exh. 9). The public notice also states "Upon receipt of your eligibility request/documents, you will be provided with probable eligibility notification within two days. (DI#41, Exh. 9).

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

PSCF's Charity Care Policy states "Persons with a family income below 100% of current federal poverty guidelines who have no health insurance coverage and are not eligible for any public program to cover medical expenses are eligible for services free of charge. Those above 100 % but below 300% will be eligible for discounts on a sliding fee scale for families." (DI #9, Exh. 8, pp. 1-2).

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

This standard is not applicable, given that the applicant is not a hospital.

(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.

PSCF states that it "will provide charity care as a core principle of its mission to provide the best services to all in our community." (DI #2, pp. 22-23). PSCF attached documentation showing that the average amount of charity care provided by ASFs in the years 2017-2019 was 0.59% of net revenue (DI #2, Exh. S) and set a charity care goal of 0.68% of expenses by the end of 2025. To meet this goal, the applicant plans to make its policy available to the public, physicians' offices, health departments, and local agencies. PSCF notes that the COVID-19 pandemic impacted its surgical practice in 2020, resulting in temporary closure for 60 days. PSCF states that its business office will post notice of its charity care policy and that staff will educate patients and perform outreach with individuals to increase awareness about this policy. (DI #2, p. 23).

PSCF states the level of charity care it provides has increased annually with the exception of 2020 due to the COVID-19 pandemic and the temporary closure of the ASC. (DI #2, p. 23). PSCF states that it will offer assistance to individuals who experience immediate and/or temporary financial hardship to ensure that all persons seeking surgical care are able to receive it at PSCF.

Interested Party Comments – Frederick Hospital

Frederick Hospital states that while PSCF indicates a charity care goal level of providing charity care equivalent to 0.68% of its operating expenses, PSCF has never previously met this goal and projects it will not be met for several more years. (DI #22, p. 4). Frederick Hospital further states that, with the exception of the pandemic year of 2020, PSCF "does not explain why its charity care historically has not satisfied expectations or that it was appropriate to the needs of the community." (DI #22, p. 4).

The IP states that PSCF's failure to meet the standard for charity care will have an adverse impact on Frederick Hospital. (DI#22, p. 5). By attracting self-pay or insured patients from Frederick Hospital and other surgical facilities, the IP states that its surgical services will bear an ever-increasing proportion of the community's non-reimbursable procedures for all patients, regardless of their ability to pay. (DI #22, p. 5). Frederick Hospital states that PSCF should be required to provide more than a verbal commitment to provide charity care and should specifically explain why it failed to meet its charity goals for 2018 and 2019. (DI#22, p. 5). Frederick Hospital

points out that PSCF's lack of specificity about the expansion of its charity care policy provision demonstrates a lack of commitment to provide charitable surgical services to indigent patients and to meet its stated charitable care threshold. (DI #22, p. 4).

The IP states its belief that the applicant's project will pull hundreds of reimbursable orthopedic surgery cases from Frederick Hospital, which would increase the proportion of non-reimbursable procedures that the hospital would have to bear, regardless of the patient's ability to pay. The IP states that PSCF's proposed project will "disproportionately remove those reimbursable services from the health care facility that it needs the most to provide the same care to the medically indigent." (DI #22, p. 5).

Applicant's Response to Interested Party Comments

PSCF states that its facility met and exceeded its charity care commitment goal of 0.68% for the years 2020 and 2021. The applicant states it "takes pride in and remains committed to the continuance of providing service to the underserved in the Frederick Community regardless of their ability to pay." (DI #27, p. 3 and Exh. 2). PSCF states it has met and exceeded its charity care commitment goal and that it "remains committed to the continuance of this method of providing service to the underserved in the Frederick Community regardless of their ability to pay…." . (DI #27, p. 3). It provided a document representing the charity care provided in 2020 and 2021. (DI #27, Exh. 2) It states that it has an outreach plan to continue offering charity care to persons in need. (DI #27, p. 17).

Applicant's Response to Reviewer's Request for Additional Information

The applicant was asked specifically to demonstrate "[W]hether PSCF's historic level of charity care was appropriate to the needs of PSCF's service area and to document how PSCF will provide charitable surgical services to indigent patients that are equivalent to at least the average amount of charity care provided by ambulatory surgical facilities annually." (DI #34, p. 2, Question #3).

In response, the applicant noted that the average statewide level of charity care it used in preparing its application (charity care equivalent to 0.63% of total operating expenses) was provided by Commission staff for the year 2019. (DI #36, Tab #3, Exh. 8). PSCF also provided a copy of its Public Notice defining financial or medical indigency for purposes of eligibility determination for either no obligation or a discounted obligation to pay for services based on income and family size. (DI #36, Tab #3, Exh. 11).

PSCF listed the following methods of assuring compliance regarding this standard:

a. The Board of Directors will review and update/revise the Charity Care Policy on an ongoing basis;
b. The Business Office Manager will submit monthly reports to the Performance Improvement Committee to evaluate progress in meeting the charity care level;
c. PSCF will promote notification of public information regarding access to charity care at PSCF on the PSCF website, publish the policy in the *Frederick News Post*, include the

policy in the PSCF patient brochure, include notification on the facility's simple admit patient on-line pre-screening program, and send information to the Frederick County Health Department and to local religious and outreach organizations;

d. PSCR will train business office staff to offer patients an application for charity care if they believe the patient may be in a position of need; and
e. The applicant states it will set aside an operating room one-half day per month for the purpose of charity care.

(DI #36, Tab #3, Exh. 12, p. 3).

In Table III-1 PSCF reported the following levels of charity care provision from 2013 through 2021. (DI #36, Tab 3, Exh. 5).

Table III-1: Physicians Surgery Center of Frederick – Historical Charity Care (2013 – 2021)

	2013	2014	2015	2016	2017	2018	2019	2020*	2021
Value of Charity Care	$963.87	$0.00	$930.11	$4,128.00	$1,620.00	$0.00	$8,314.00	$1,663.00	$78,385.00
Total Operating Expenses	$2,991,611	$3,329,291	$2,509,949	$3,192,182	$3,299,538	$3,783,992	$3,805,414	$4,068,407	$5,687,630
Ratio – Charity Care/Total Operating Expenses	0.03%	0.00%	0.04%	0.13%	0.05%	0.00%	0.22%	0.04%	1.38%

Source: DI#36, Tab 3, Ex. 5.

*PSCF was closed for 60 days of operation in 2020 because of the COVID-19 pandemic.

The applicant states that its 2019 increase in charity care was a result of expanded outreach to local organizations, charitable organizations, and urgent care facilities. However, in 2020, the applicant states that patients delayed surgical procedures during the pandemic emergency, contributing to lower levels of charity care. (DI #41, Tab 4, p. 5). In late 2020 and 2021, the applicant indicates that it expanded and promoted its charity care policy, resulting in the facility exceeding its goal level of charity care in 2021.

The applicant notes that Frederick County is a growing and wealthy community with a percentage of households in Frederick County making less than $25,000 per year that is lower than the State average of 12.8% and a percentage of households making over $200,000 per year that is higher than the State average. (DI #41, Tab 4, p. 6). PSCF states that these income levels have increased the challenge in reaching the underserved, though the applicant indicates it is committed and will work to achieve its charity care level goal of providing charity care valued at 0.68% of total operating expenses, at a minimum.

Interested Party Response to the Applicant's Response to Reviewer's Additional Questions

Frederick Hospital states that the applicant has not stated how it will satisfy future charity care requirements and that it has yet to provide a cogent argument as to why its historic level of charity care provision was appropriate to the needs of the community. (DI #38, p. 6). If the applicant does not demonstrate that it meets its charitable obligations, Frederick Hospital states that "a risk occurs that lucrative surgical cases will be performed in a for-profit entity that has failed to ensure access for those patients who are economically vulnerable." (DI #38, p. 7). Frederick Hospital argues that if a specialized outpatient facility only performs lucrative cases for those who can afford them, existing health outcome disparities for those economically vulnerable

will be maintained or widened. Frederick Hospital states that a sharp revenue decrease attributed to the departure of reimbursable procedures that could be performed at the hospital would have an adverse effect on its long-term sustainability.

Reviewer's Analysis and Findings

I cannot find that PSCF's track record in the provision of charitable health care facility services supports the credibility of its commitment to provide the level of charity care to which it has committed. I also find that it has not articulated a specific plan for achieving the level of charitable care provision to which it is committed.

The applicant reported no provision of charity care or only negligible charity care values between 2013 and 2019. The applicant has not provided a sufficient explanation of this poor track record.

The applicant correctly notes that Frederick County is not among the state's most impoverished jurisdictions. It does not provide a convincing picture of how it will reach out to lower income or medically indigent residents in the jurisdiction. In addition, while PSCF states that Frederick County is the main county it serves, it identified "Maryland, Pennsylvania and West Virginia" as part of its service area (DI # 2, p. 28). PSCF provides no explanation how it will serve lower income or medically indigent residents in the jurisdictions surrounding Frederick County, which PSCF includes as part of its service area. This lack of more specific planned actions does not give me confidence that it will maintain the level of charity care provision to which it has committed.

Frederick Hospital has expressed concerns that PSCF will pull self-pay and insured patients away from the hospital, leaving the hospital to bear the greatest burden among the jurisdiction's providers of ambulatory surgery in serving low income and indigent residents. I agree with Frederick Hospital's concern. While Maryland's hospital payment model mitigates the worst-case scenarios possible when the burden of serving the indigent population increases for the state's general hospitals, this puts upward pressure on the hospital charges that all payors must bear to support uncompensated and undercompensated care provision.

PSCF has the burden of demonstrating that its project meets all applicable criteria for review, including each of the SHP standards. COMAR 10.24.01.08G(1). PSCF was given multiple opportunities to provide more specificity with respect to how the historic level of charity care it has provided was appropriate to the needs of its service area population and how it will assure an appropriate level of charity care provision in the future. In my view, it failed to make an acceptable case.

Secondarily, I note that some elements of PSCF's charity care policy are questionable. It will rely on an application form requiring the patient to provide information regarding residency status and citizenship (DI#41, Exh. 8, p. 3,4) as well as detailed financial information prior to a determination of probable eligibility for financial assistance within two days of the request. With respect to charity care, health care facilities should not discriminate on the basis of citizenship status. Such policies can have a chilling effect on undocumented patients and are likely to result

in fewer opportunities for persons in need to obtain services and fewer opportunities to provide care to the indigent or uninsured, further shifting the burden to the hospitals.

For these reasons, I find that PSCF does not comply with this charity care policy standard.

(4) 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.

The applicant submitted a copy of its license dated July 1, 2018 from the Maryland Department of Health. (DI # 2, Att T).

(b) A hospital shall document that it is accredited by the Joint Commission.

The applicant is not a hospital.

(c) An existing ambulatory surgical facility or POSC shall document that it is:

(i) In compliance with the conditions of participation of the Medicare and Medicaid programs;

(ii) Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation agency recognized by the Centers for Medicare and Medicaid as acceptable for obtaining Medicare certification; and

(iii) A provider of quality services, as demonstrated by its performance on publicly reported performance measures, including quality measures adopted by the Centers for Medicare and Medicaid Services. The applicant shall explain how its ambulatory surgical facility or each POSC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland.

To demonstrate compliance with Medicare and Medicaid conditions of participation, the applicant provided letters from: the Office of Health Care Quality of the Maryland Department of Health (MDH) dated August 19, 2019 indicating it was in compliance with Federal participation requirements for an ambulatory surgery center participating in the Medicare and/or Medicaid programs (DI # 2, Att. V); Novitas Solutions, a CMS contractor, notifying PSCF of enrollment to participate in the Medicare program (DI #9, Exh. 12); and the Maryland Department of Health and Mental Hygiene (now MDH) dated January 19, 2012 stating that PSCF is enrolled in the Maryland Medicaid Program. (DI #9, Exh. 13).

PSCF also submitted documentation that PSCF is accredited by the Accreditation Association for Ambulatory Health Care, Inc. from February 8, 2021, through February 7, 2024. (DI # 2, Att U).

The Centers for Medicare and Medicaid Services administers the Ambulatory Surgical Center Quality Reporting (ASCQR) Program, a pay-for-reporting, quality data program.[6],[7] The ASCQR Program utilizes several quality measures to make informed decisions and quality improvement in the ambulatory surgical center (ASC) setting. For 2020, PSCF reported data for the following two quality measures: ASC-11- Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (100 percent) and ASC-13 Normothermia (97.4 percent).[8]

MHCC's Quality Reporting website[9] reports limited general information/demographic and surgical case volumes by specialty for PSCF. The website reports that the staff influenza vaccination rate for the 2019-2020 influenza season at this facility was 93.8 percent, better than the Maryland Facility average of 85.8 percent.

PSCF states it also participates in additional performance improvement and risk management programs including: the CTQ Voyance's EdgePerception™ Patient Satisfaction Surveying and Perception Management Tool; the Leapfrog ASC Survey; MHCC's Maryland Quality Reporting and Freestanding Ambulatory Surgical Facility Survey; and the National Healthcare Safety Network's (NHSN) Healthcare Personnel Influenza Vaccination Summary. (DI #9, p. 12 and Exh. 14 through 24).

(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; and

(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.

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[6] Further information on the ASCQR Program is available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ASC-Quality-Reporting.

[7] The Center for Medicare and Medicaid Services also utilizes data reported from the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, a patient satisfaction survey regarding services provided at ambulatory surgery centers. Because of the COVID 19 pandemic, the data has not been reported. Further information can be located at: https://data.cms.gov/provider-data/dataset/48nr-hqxx/.

[8] Information available at: https://data.cms.gov/provider-data/dataset/4jcv-atw7.

[9] Available at: https://healthcarequality mhcc.maryland.gov/OutpatientSurgery/Detail/129#SurgicalProcedures.

PSCF provided documentation from the Office of Health Care Quality stating the ASC was in compliance with Federal participation requirements for an Ambulatory Surgery Center participating in the Medicare and/or Medicaid programs. (DI #2, Att. Va and Vb). PSCF provided a copy of its accreditation notification from the Accreditation Association for Ambulatory Health Care, Inc. for a term of three years beginning February 8, 2021. (DI #2, Att. U).

(e) An applicant or a related entity that currently or previously has operated or owned a POSC or ambulatory surgical facility, in Maryland or outside of Maryland, in the five years prior to the applicant's filing of a request for exemption request to establish an ASF, shall address the quality of care provided at each location through the provision of information on licensure, accreditation, performance metrics, and other relevant information.

The applicant has documented its record of licensure and accreditation. MHCC has not established performance metrics for ASFs that should be considered applicable for purposes of reviewing compliance with SHP standards at this time.

Reviewer's Analysis and Findings

I find that the applicant complies with this standard.

(5) Transfer Agreements.

(a) Each ASF shall have written transfer and referral agreements with hospitals capable of managing cases that exceed the capabilities of the ASF.

(b) Written transfer agreements between hospitals shall comply with Department of Health 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.

PSCF submitted a copy of a written transfer agreement with Frederick Hospital that complies with COMAR 10.05.05.9. (DI #2, Att W). The applicant also provided a copy of the facility's Emergency Transfer Policy regarding PSCF's responsibilities for the transfer of a patient requiring a higher level of care to the hospital. (DI #2, Att X).

Reviewer's Analysis and Findings

I find that the applicant complies with this standard.

B. Project Review Standards.

The standards in this regulation 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, unless an applicant is eligible for an exemption covered in Regulation .06. of this chapter.

(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.

PSCF states that its primary service area is Frederick County, but it also serves patients who reside elsewhere in Maryland and in areas of Pennsylvania and West Virginia, noting that the state line is within 40 minutes travel time of PSCF. (DI #2, p. 28). It attached information on population density and growth in Frederick County and Maryland (DI#2, Att. Y) and socioeconomic and demographic statistics for Frederick County. (DI #41, Tab 4, Exh. 15).

The applicant provided population information for the twelve municipalities and eight planning regions within Frederick County for the period 1980 through 2000.[10] The applicant also submitted population data for the Metropolitan Washington region by jurisdiction as reported by the Metropolitan Washington Council of Governments for the years 1990 through 2030.[11] For socioeconomic data, PSCF submitted *Brief Economic Facts for Frederick County*, as reported by the Maryland Department of Commerce. (DI #41, Tab 4, Exh. 15).

PSCF did not document its existing service area based on the origin of patients served.

Reviewer's Analysis and Findings

While the applicant did not meet the letter of this standard by documenting its patient origin, I note that PSCF was not specifically questioned on this omission during the review process and that all ASFs and ASCs are asked to provide information on patient origin by zip code area as part of MHCC surveys that have been conducted on an annual basis, with some interruption during the recent years of the COVID-19 emergency. I find that the applicant's response to this standard is adequate.

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

[10] From U.S. Census and Frederick County Planning Department for the planning regions of: Adamstown, Brunswick, Frederick, Middletown, New Market, Thurmont, Urbana, and Walkersville

[11] This included population for the Maryland jurisdictions of Montgomery and Prince George's Counties, Central and Southern Maryland, and Northern Virginia.

An applicant proposing to establish or replace a hospital or ambulatory surgical facility shall:

(a) Demonstrate the need for the number of operating rooms proposed for the facility, consistent with the operating room capacity assumptions and other guidance included in Regulation .07 of this chapter.

(b) 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 initiation of surgical services at the proposed facility, consistent with Regulation .07 of this chapter.

(c) 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.

(d) 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.

PSCF proposes the addition of two operating rooms to its current complement of two ORs, constituting the establishment of this ASC as an ASF. The applicant states that by the year 2025 each OR has the potential to support 1,143 cases or more per year for a total case volume of 4,575 cases and 392,160 OR minutes for the ASF. (DI#2, p 29). PSCF provided a case and OR minute count for each practitioner for the last two years and projected future case volume and OR minutes for these practitioners and an additional practitioner anticipated to join the surgical staff. (DI#27, Exh. 8). The applicant's projections are based on historical case volume and OR time, interviews

of practitioners, population growth in the anticipated service area, and assumptions about the migration of cases from the hospital to the outpatient setting. (DI#36, Exh. 15).

Fourteen practitioners who are partners or have surgical privileges to perform surgery at PSCF are identified. Ten are orthopedic surgeons and two specialize in plastic surgery. There is one practitioner specializing in ophthalmic surgery and one specializing in oculoplastic surgery.

The PSCF physician complement changed during review of the application. The applicant reported the addition of four physicians, all specializing in orthopedic surgery and also reported that an additional ophthalmic surgeon (not specifically identified) was expected to join the staff. (DI #9, Exh. 7 and DI #11, Exh. 12). As surgical staff information was updated, utilization projections changed. After the application was docketed, the applicant submitted a new updated and revised set of information of historic and projected utilization for the facility. (DI #16, Exh. 16).

In early 2022, PSCF reported that one of the previously identified orthopedic surgeons, a partner, was leaving the state but that other identified practitioners would be absorbing the surgical case load of this existing staff member. (DI #24). The applicant again provided an update to the projected number of surgical cases by surgeon.

Finally, the applicant was requested to review and submit an update on each surgeon who would have privileges at PSCF. (DI #36, Tab 4, Exh. 14, 15, and 16). In that update, the applicant provided historic and projected utilization for the years 2020 through 2024. Based on the April 2024 target date for completion of the proposed project, the applicant was requested to resubmit and include historic utilization data for 2020 and 2021 and utilization projections for the anticipated construction period. Projected utilization through 2026 was also requested. (DI #41, Tab 3, Exh. 6 and 7). Included with the response, PSCF submitted an affiliation agreement with The Johns Hopkins University (JHU) School of Medicine in which a JHU physician would provide ophthalmic surgical services at PSCF. (DI #41, Tab 2, Exh. 5b and 5c).

Interested Party Comments – Frederick Hospital

Frederick Hospital stated that PSCF provides "minimal discussion on its existing dedicated outpatient general purpose operating room, and no discussion of the other existing operating room." (DI #22, pp. 5-6). Further, it states that no documentation is provided to support the projected surgical volume of 1,143 cases per year for each new operating room. The IP states that PSCF failed to explain how the utilization achieves "optimal capacity" without utilization hours or the nature of the case mix for projected use, (DI #22, p. 6) noting that the applicant provides per surgeon case load numbers but did not specify how the existing or proposed operating rooms have been or will be utilized in terms of time.

The IP states that while PSCF's assessment concludes that the proposed operating rooms will likely be utilized at optimal capacity or at higher levels within three years of the completion of the project, Frederick Hospital reiterates that without specific data that discusses either the historic or projected trends for specific types of surgery in Frederick County the applicant is merely

providing its own anticipated utilization without adequate support for its expectations. (DI #22, pp. 6-7).

Frederick Hospital states that the lack of surgical specialty or operating room categorization in the data submitted by PSCF makes it difficult to determine how it has utilized its existing ORs or how the two additional operating rooms will be utilized. (DI #22, p. 7). Finally, the Frederick hospital states that the applicant submitted insufficient data on the types of projected cases to be performed in each of the additional operating rooms requested, with virtually no documentation to substantiate these future volume projections. (DI #22, p. 7).

Applicant's Response to Comments

PSCF submitted revised physician case numbers and operating room minutes that revised the projected utilization for the facility to account for the practitioner departure previously noted. (DI #27, Exh. 8).

To address Frederick Hospital's remarks on case mix, the applicant submitted a list of the surgeons who would perform surgical cases at PSCF from 2020 through 2025. (DI #27, Ex. 3a and 3b, Ex. 9). These three tables list the surgeons by surgical specialty and the number of historical and projected surgical cases for each surgeon expected to provide surgical services at PSCF. In addition to listing the surgical specialties, PSCF provided a description of the type of surgical cases that will be performed by each surgeon. (DI #27, Ex. 3b). The applicant states that it expects to see a significant growth in the number of surgical cases from three surgeons recruited from Montgomery County. Using the information provided by these three surgeons, the applicant states that it expects a number of its patients to originate from northern Montgomery County near the border with Frederick County. (DI #27, pp. 8-9). As for the type of surgical cases that will be performed, PSCF expects to see an increase in orthopedic procedures that include hand and upper extremity surgical procedures and joint replacement procedures that include the shoulder, knee and hip. (DI #27, p. 10).

In addressing historic utilization, the applicant notes that surgical case volume was affected by the previously noted closure of the ASC in 2020 for 60 business days. (DI #27, pp. 4-5). The applicant states that the 60-day closure resulted in an estimated loss of 529 surgical cases in 2020. (DI #27, pp. 4-5 and Exh. 9). By adjusting the utilization to account for lost surgical cases, the applicant states that the two existing ORs at PSCF would have operated at optimal capacity for the years 2020 and 2021. (DI #27, p. 8 and Exh. 5, Table 1-2).

The applicant states that the projection of 200 total joint replacements per year by 2025 is driven by the surgeon's preference to perform their outpatient surgical cases at the ASC rather than at Frederick Hospital. (DI #27, p. 5). The applicant indicates that many surgical cases are migrating to the outpatient setting and that the PSCF surgeons have directed their outpatient appropriate patients to the ASC, only performing these cases at Frederick Hospital when OR time is not available at PSCF. (DI #27, pp. 5-6). These surgeons are not Frederick Hospital employees and the applicant states that they "want the freedom to pick their site of choice along with their patients for convenience and safety." (DI #27, p. 6). By performing these surgical cases at PSCF, it argues that patients experience less wait time, OR turnover time is efficient, the surgical schedule

runs on time, and more cases can be performed on a daily basis in less time than at Frederick Hospital. The applicant states that the ASC is a physician friendly and patient centric environment with high quality staff resulting in excellent outcomes.

PSCF states that its projection of 200 total joint replacement cases performed at the proposed ASF is a small number compared to the number of cases and procedures that these physicians will perform at Frederick Hospital. These surgeons will schedule outpatient appropriate cases at PSCF if OR time is available or move their caseload to Frederick Hospital if there is no time available at the ASF or the surgery is inpatient appropriate. The applicant states that the expansion of PSCF will have minimal impact on Frederick Hospital. (DI #27, p. 6).

Applicant's Response to Reviewer's Request for Additional Information

PSCF provided updates for each physician/surgeon who would provide surgical services at PSCF upon project completion. (DI #34, p. 4). PSCF's revisions and updates for the historic and projected surgical utilization for the proposed ASF have included the addition of five surgeons to the facility, the departure of a partner from the practice, shifting of surgical cases between the remaining surgeons, and changes in the projected surgical cases as a result of a change in the timeline for the proposed project.

Tables III-2 and III-3 provide the applicant's final account of historic and projected utilization for PSCF. (DI #41, Exh. 6).

Table III-2: Historic Utilization – PSCF, 2020 – 2021

Practitioner	Specialty	2020			2021			2022		
		Cases	OR Minutes	OR Minutes Per Case	Cases	OR Minutes	OR Minutes Per Case	Cases	OR Minutes	OR Minutes per Case
Andochick	Plastic	69	10,902	158.0	38	6,636	174.6	50	7,900	158.0
Steinberg	Orthopaedic	239	16,321	68.3	253	30,644	121.1	98	29,615	302.2
Silon	Orthopaedic	653	29,385	45.0	720	32,535	45.2	744	33,480	45.0
Levine	Orthopaedic	166	17,430	105.0	190	19,950	105.0	260	27,300	105.0
Mecinski	Plastic	318	15,459	48.6	321	16,655	51.9	320	16,660	52.1
Thadani	Opthalmic	516	12,384	24.0	697	16,752	24.0	725	17,400	24.0
Horton	Orthopaedic	59	4,307	73.0	250	18,615	74.5	400	29,200	73.0
Gupta	Orthopaedic	5	360	72.0	11	792	72.0	72	5,184	72.0
Henry	Oculoplastic	8	424	53.0	21	1,113	53.0	30	1,590	53.0
Sanders	Orthopaedic			-	26	2,574	99.0	70	6,930	99.0
Petruccelli	Orthopaedic			-	20	1,660	83.0	31	2,573	83.0
Evans	Orthopaedic			-	8	1,104	138.0	40	5,520	138.0
Walsh	Orthopaedic	20	1,386	69.3	12	750	62.5	140	8,820	63.0
Copaken	Orthopaedic			-			#DIV/0!	18	828	46.0
Total		**2,053**	**108,358**	**52.8**	**2,567**	**149,780**	**58.3**	**2,998**	**193,000**	**64.4**
OR Turnaround*			51,325			64,175			74,950	
Total OR Time**			159,683			213,955			267,950	
ORs Needed* **			**1.6**			**2.2**			**2.7**	

Table III-3: Projected Surgical Utilization – Physicians Surgery Center of Frederick, 2023 – 2026

Practitioner	2023			2024			2025			2026		
	Cases	OR Minutes	OR Minutes Per Case	Cases	OR Minutes	OR Minutes Per Case	Cases	OR Minutes	OR Minutes Per Case	Cases	OR Minutes	OR Minutes Per Case
Andochick	70	11,130	159.0	90	14,420	160.2	95	15,105	159.0	75	15,025	200.3
Silon	784	35,280	45.0	804	36,180	45.0	810	36,450	45.0	815	36,675	45.0
Levine	295	30,975	105.0	325	34,125	105.0	340	35,700	105.0	340	35,700	105.0
Mecinski	350	18,100	51.7	350	18,750	53.6	335	18,355	54.8	345	18,835	54.6
Thadani	790	18,960	24.0	850	20,400	24.0	860	20,640	24.0	875	21,000	24.0
Horton	475	34,675	73.0	550	40,150	73.0	625	45,625	73.0	700	51,100	73.0
Gupta	138	9,936	72.0	190	13,680	72.0	195	14,040	72.0	195	14,040	72.0
Henry	50	2,650	53.0	75	9,375	125.0	75	9,375	125.0	75	9,375	125.0
Sanders	70	6,930	99.0	70	6,930	99.0	75	7,425	99.0	75	7,425	99.0
Petruccelli	65	5,395	83.0	90	7,470	83.0	95	7,885	83.0	100	8,300	83.0
Evans	90	12,420	138.0	110	15,180	138.0	115	15,870	138.0	115	15,870	138.0
Walsh	180	11,340	63.0	210	13,230	63.0	212	13,356	63.0	215	13,545	63.0
Copaken	28	1,288	46.0	30	1,380	46.0	30	1,380	46.0	30	1,380	46.0
Total	**3,385**	**199,079**	**58.8**	**3,744**	**231,270**	**61.8**	**3,862**	**241,206**	**62.5**	**3,955**	**248,270**	**62.8**
OR Turnaround*		84,625			93,600			96,550			98,875	
Total OR Time**		283,704			324,870			337,756			347,145	
ORs Needed* **		**2.9**			**3.3**			**3.4**			**3.5**	

[1]TAT Minutes = Total number of cases x 25 minutes
[2]Total Minutes – Total Surgical Minutes + TAT Minutes
[3]Number Ors = (Total Minutes/60)/1,632 hours
Source: DI #41, Exh. 6.

Interested Party – Frederick Hospital Response to Applicant's Responses

Frederick Hospital states that the applicant's surgical volume projections are not substantiated, that the construction timeline is inconsistent, and that the revenue projections need updating. (DI #38, p. 5). The IP points out inconsistencies in the projected surgical volumes which "create direct conflicts with other information provided to the Commission." (DI #38, pp. 2-3). Additionally, the IP claims that the applicant does not include any data analytics or authoritative resource to support the projected PSCF volumes. The IP states that PSCF has projected a growing volume of surgical procedures at PSCF in 2022, 2023, and 2024 based on information from surgeon interviews. However, the construction for the two new ORs will not be completed until April 2024. (DI #38, p. 3).

Noting the applicant's numerous surgical projection updates, Frederick Hospital states that these projections "are simply newer, more recent, guesses of how many surgeries each surgeon would like to perform if PSCF has four operating rooms and additional procedure rooms in its facility." (DI #42, p. 2). The IP states that PSCF has not sufficiently supported the projections with any actual data that shows a need for additional operating rooms in Frederick County.

Frederick Hospital suggests that included in the individual practitioners' submissions are surgical procedures that are clinically appropriate for performance in a procedure room, and the

inclusion of these lower complexity surgical procedures overstates the projected OR minutes. (DI #42, pp. 2-3). The IP states that conflating OR and procedure room minutes is a poor justification for additional ORs (DI #42, p. 4).

Frederick Hospital points out several discrepancies or inconsistencies in the projected financial and utilization numbers reported by PSCF, as follows:

a) PSCF identifies 4,165 total cases in CY 2026(DI #41, Tab 2, Exh. 3). However, in the Utilization and Volume Projections table (DI #41, Tab #3, Exh. 6), the applicant indicates that the 4,155 surgical cases in CY 2026 include 200 procedure room cases and only 3,955 total OR cases. PSCF does not explain why the 200 procedure room cases are included with the 3,955 OR cases.
b) Under the Statistical Projections Table for the entire facility (DI #41, Tab 2, Exh. 3), the row titled "Total Surgical Minutes in ORs" has two rows of numbers, with the second row in italics. The applicant does not identify the difference between the two sets of numbers identified as Total Surgical Minutes in ORs.
c) Using this same table, DI #41, Tab 2, Exh. 3, PSCF reports that the "Total Surgical Minutes in OR" are the same as "Total OR and PR Minutes," though the former set of surgical minutes should be smaller and only include OR surgical minutes.

Reviewer's Analysis and Findings

Since filing the original CON application, PSCF has submitted several revisions to the OR utilization and needs assessment using the Regulation .06 assumptions of COMAR 10.24.11. Initially, the applicant submitted its needs assessment for the addition of two dedicated outpatient general purpose operating rooms with its CON application, providing historic and projected surgical utilization for the years 2020 through 2025. (DI #2, pp. 29-32).

The applicant has submitted a total of six changes and revisions to the historical and projected surgical utilization at PSCF. These changes and revisions were made to account for changes in the composition of the practitioners, which included the addition of five new practitioners and the departure of a practitioner, and also to account for revisions in the timeline for construction and completion of the new addition. Changes were also made to account for the time needed to construct the new addition and buildout the shell space for the addition. The applicant extended the projected completion and start of operation from 2024 to 2026.

I observed that the applicant submitted changes in facility utilization data without desired detail on the assumptions used to support the changes in projected caseloads and OR minutes. I substantively agree with Frederick Hospital's statement that the changes "are simply newer, more recent, guesses of how many surgeries each surgeon would like to perform if PSCF has four operating rooms and additional procedure rooms in its facility." (DI# 42.) The applicant provides no assumptions or detailed explanations for the facility's projected utilization.

I also find a number of issues with the submitted projections. In the utilization data shown in Tables III-2 and Tables III-3, the applicant reported an increase in the number of cases and surgical minutes from 2022 through 2024. The timeline for the proposed construction project was

originally Spring 2023, with the completion and start of operation expected by April 2024. During this construction period, the facility would only have two ORs and one procedure room. The utilization projections indicated that PSCF's practitioners would increase to a point where the number of surgical cases and surgical minutes would support the need for three plus ORs at optimal capacity for a dedicated outpatient general purpose operating room. The applicant did not provide an explanation or rationale for the increased utilization for this two-year period. Also, it is not credible that PCSF could increase volume if the practitioners are already working evenings and weekends.

I note that PSCF stated its practitioners have performed procedures, when appropriate, in a procedure room. It is not clear whether lower complexity procedures, appropriate for a procedure room are included in the projected utilization for the four general purpose ORs.

Frederick Hospital identified a number of discrepancies or inconsistencies in how PSCF projected utilization. During the review I have asked for clarification on PSCF's utilization projections, examining these tables and questioning both the accuracy and the basis for how these numbers were calculated and reported. I am not satisfied with the information submitted and believe the utilization projections do not support the need for the addition of surgical capacity at PSCF.

In conclusion, I have examined the applicant's historical and projected utilization numbers. While the projections may appear to support the need for the proposed addition of two ORs, I do not find them to be accurate or reliable. I find the multiple revisions and updates lack consistency and credibility, and I find that PSCF does not comply with this standard.

(3) <u>Need – Minimum Utilization for Expansion of An Existing Facility.</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 .07 of this chapter;

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

(c)Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity, consistent with Regulation .07 of this chapter. The needs assessment shall include the following:

(i) Historic and projected trends in the demand for specific types of surgery among the population in the proposed service area;

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

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

PSCF is seeking to establish an ASF rather than expand an ASF. This standard is not applicable.

(4) Design Requirements.

Floor plans submitted by an applicant must be consistent with the current Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities (FGI Guidelines):

(a) A hospital shall meet the requirements in current Section 2.2 of the FGI Guidelines.

(b) An ASF shall meet the requirements in current Section 3.7 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.

The applicant provided a copy of a letter signed by Scott A. Norberg, AIA, LEED AP, Medarch Design PLLC, that the design of the new and renovated spaces at PSCF complies with the most recent FGI Guidelines for an Outpatient Surgery Facility. (DI #2, Att. Z). A copy of the floor plans for the proposed project can be found in Appendix 3.

Reviewer's Analysis and Findings

I find that applicant complies with this standard.

(5) Support Services.

Each applicant shall agree to provide laboratory, radiology, and pathology services as needed, either directly or through contractual agreements.

PSCF states that it provides radiology services on site and provided a copy of the certification for the x-ray machines from the Maryland Department of the Environment. (DI #2, Att. A-1). Similarly, the applicant provides limited laboratory services on site and provided a copy of the permit from the Maryland Department of Health and its CMS' Certificate of Waiver from Clinical Laboratory Improvement Amendments (CLIA) for the laboratory services. (DI #2, Att. B-1). Finally, PSCF sends its specimens for diagnostic purposes off-site to either Frederick Health Hospital Laboratory Services in Frederick or HCT Pathology located in Baltimore, MD. (DI #9, p. 14).

Reviewer's Analysis and Findings

I find that applicant complies with this standard.

(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 the following safety measures were considered in planning the project (DI #2, p. 33):

1. Phased-in construction, with demolition occurring on weekends;
2. Compliance with all federal, state and local safety codes;
3. Compliance with the American with Disabilities Act (ADA) regulations;
4. Comprehensive programs on Risk Management, Infection Control, and Pharmacy and Materials Management;
5. Staff safety education and training for all equipment, utilities and applicable venues; and
6. Patient and staff call system.

The applicant states that the proposed project has been designed to conform to the 2018 FGI Guidelines and includes a summary from Scott A. Norberg, AIA, LEED AP, that provides details of the proposed project. (DI #2, Att. Z).

The applicant states that the proposed project will provide additional space, improved access, lighting, ventilation, and an efficiently organized environment with improved access for staff and patients. The applicant believes that all of these improvements will enhance patient safety and quality of care. (DI #36, Tab #8, Exh. 28).

Reviewer's Analysis and Findings

I find that applicant complies with this standard.

(7) Construction Costs.

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

(a) Hospital projects.

(i) The projected cost per square foot of a hospital construction or renovation project that includes surgical facilities shall be compared to the benchmark cost of good quality Class A hospital 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, any rate increase proposed by the hospital related to the capital cost of the project shall not include:

1. The amount of the projected construction cost and associated capitalized construction cost that exceeds the Marshall Valuation Service® benchmark; and

2. Those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

This part of the standard is only applicable to hospital projects.

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of new construction shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors. This standard does not apply to the costs of renovation or the fitting out of shell space.

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

This standard requires a comparison of the project's estimated cost for new construction, adjusted for specific construction characteristics of the proposed project, with a benchmark, or expected cost, derived using the cost-estimating methodology provided by the Marshall Valuation

Service (MVS). The cost per SF arrived at by using the MVS methodology reflects what a building of the type and quality described should cost to construct. The MVS methodology includes a variety of adjustment factors related to the specific characteristics of the project, e.g., timing of the project, the locality, the number of stories, height per story, shape of the building (e.g., the relationship of floor size to perimeter), and departmental use of space. Appendix 4 provides a detailed explanation of the methodology laid out in the MVS Guide and how it is used to derive a benchmark value that can be used to assess the appropriateness of new construction costs in a proposed project.

PSCF calculated the MVS benchmark and the estimated allowable buildout cost for the 10,955 SF shell space for the two operating rooms, one procedure room, and support space to the existing facility. It calculated an MVS benchmark to be $411 per SF utilizing the Marshall Swift CoreLogic Swift Estimator program. This MVS benchmark is for a Class A, good quality buildout of 10,955 SF of shell space. The applicant's allowable project costs are estimated at $1,712,800, or $156.35 per SF.

The applicant's calculations for both the MVS benchmark value and the estimated allowable project costs can be found in Appendix 4, Tables 1 and Table 2.

Reviewer's Analysis and Findings

I completed my own calculations of the MVS benchmark and the estimated allowable buildout cost for the two operating rooms, one procedure room, and support space to the existing facility and arrived at a MVS benchmark of $550.31 per SF using the values reported in the Marshall Valuation Service as of November 2022. The estimated allowable project cost for the buildout of shell space is estimated to be $160.10 per SF. The differing MVS benchmarks calculated by me and PSCF can be attributed to the timelines and when the analyses were performed (PSCF in October 2021 and my calculation based on MVS data available as of November 2022). The use of the more current MVS data would consider factors such as the effect of the COVID-19 pandemic and the subsequent economic factors that have impacted labor costs and construction materials. The respective calculations and assumptions the applicant and I used for estimating the allowable cost per SF measured against the MVS benchmark is found in Appendix 4.

My calculations for the MVS benchmark value of $550.31 per SF exceeds the applicant's MVS benchmark of $411 per SF by $139.31 per SF, approximately 25.3%. This trend is also consistent with the applicant's allowable project costs, and my estimated project cost of $160.10 per SF slightly exceeds the applicant's value of $156.35 per SF, a difference of $3.75 per SF, approximately 2.3%. My analysis and the applicant's calculations demonstrate that the estimated allowable construction cost for this proposed project do not exceed the MVS benchmark for this project.

I find that applicant complies with this standard.

(8) Financial Feasibility.

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

(a) An applicant shall document that:

(i) Utilization projections are consistent with observed historic trends in use of each applicable service 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.

The applicant submitted the historical and projected surgical case volumes for its surgeons from the years 2020 through 2025 (DI #9, Exh. 31), as well as the historical number of surgical cases performed, and the revenue generated for the years 2018 through April 2021. (DI #9, Exh. 31a). Further, the applicant submitted a table with the historic and projected number of surgical cases, including PSCF revenue from 2018 through 2025. For projected revenue, PSCF provides the average annual revenue collected per surgical case to calculate the projected revenue for the years 2018 through 2025. (DI #9, Exh. 32).

PSCF projects a need to hire an additional 12.7 full time-equivalent staff at an estimated expense of $666,210 million to staff the proposed ASF. (DI #41, Tab 2, Exh. 5). The staffing costs are reportedly based on PSCF's current personnel cost experienced. (DI #9, Ex. 33 – Table L – Workforce Information).

The applicant's revenue and expense schedule identify PSCF as generating excess net revenue for the first three years of operation after the completion of the proposed project. (DI #9, Exh. 34).

Interested Party – Frederick Hospital

Frederick Hospital states the applicant has failed to demonstrate that its project is financially feasible and that it also failed to specify that it meets the required elements in Standards .05B(8)(a)(i) through (iv). It also comments that PSCF did not provide a statement concerning the assumptions used to develop the applicant's projections. (DI #22, p. 7).

Applicant's Response to Interested Party Comments

In response to the IP comments, PSCF provided a statement from the "Accounting Team"[12] that outlines the assumptions used for Table 3 – Revenue and Expense Statement – Entire Facility and Table 4 – Revenues and Expense Statement – Proposed Project. (DI #27, Exh. 7). According to this statement, the applicant's assumptions are:

1. Total cases are projected to increase over the current actual cases in the first three years of full utilization (2023 to 2025) by 40%, 59%, and 74%, respectively;

2. Revenue projections are based on the historic trend of average collections per case. The most recent two-year average collections per case are $2,024 and $2,139. From 2023 through 2025, the applicant's projected average collections per case assumes an average annual increase of 1.1%, with per case charges of $2,150 in 2023, $2,175 in 2024, and $2,200 in 2025;

3. The applicant based its staffing and operating expenses on the historic trend in the ratio of staffing and expenses to revenue. The cost of staffing assumes sufficient head count increases relative to case projections;

4. Facility costs, including rent, debt servicing, plant and equipment depreciation are included as expenses in Table 4; and

5. The projections demonstrate excess revenues over total expenses for the first three years of full utilization. The applicant projects net income as 14 percent of revenue based on the recent trend experienced by PSCF, and projects 13-14% of revenue as net income for the first three years of operation after project completion.

As previously noted, PSCF assumes that "All of Dr James Steinberg's (surgical) cases will be absorbed by Mid-Maryland Musculoskeletal Institute's partner/surgeons." (DI #27, p. 10).

Applicant's Response to Reviewer's Request for Additional Information

[12] This statement is not on letterhead, signed or attested to by the individual making the statement.

In response to my request for additional information, PSCF updated several documents and tables.[13] This included the individual physician's submissions for historical and projected cases (DI#36, Exh. 16) and the "Financial Feasibility" statement on the assumptions used to document future surgical volumes (DI#36, Exh. 15). The applicant states that the financial projections assume a 20% increase in revenue based on historic and current revenue, the addition of practitioners and the additional OR capacity. Lastly, PSCF projects operating expenses for staff and supplies as a percentage of revenue using its current experience. (DI#36, Exh. 22).

Interested Party Response to Applicant's Responses to Reviewer's Additional Questions

Frederick Hospital points out areas where it believes the applicant's responses are either incomplete or conflict with other information provided to the Commission. (DI#38, p. 2). These include the applicant's basis for case volume projections which it characterizes as "surgeons' best guesses." (DI#38, p. 2 and 3). The IP states that the applicant does not provide data analytics or authoritative resources to support the projected service volume and that the applicant "projects an increasing number of procedures at PSCF in 2033, 2023, and 2024 – long before PSCF even projects to have completed construction on its two operating rooms by April 2024." (DI#38, p.3). Frederick Hospital questions the physicians' projections as presumptions based on each practitioner's anticipated cases. It also states that the assumptions are based upon PSCF interviews with the practitioners, which implies that the basis for the projections are the practitioners' "self-confidence" or simply that the facility is planning more OR capacity in the future, even though the applicant's timeline indicates the project will not be completed earlier than April 2024. (DI #38, p. 3).

The IP states that the surgical minutes provided on the forms do not align with the total surgical minutes in the operating rooms in Exhibit 21. (DI# 38, p. 4). Frederick Hospital notes that the applicant projects an increasing number of procedures before construction of the new ORs is completed. While the timeline for the construction of the project has been revised, Frederick Hospital notes that the applicant has not modified the budget projections to account for the delay in completion of the project or accounted for recent economic fluctuations. (DI #38, pp. 3-4). Frederick Hospital points out that project costs such as the estimated $167,800 in renovation costs, or an update to the Marshall Swift Valuation costs per square foot have remain unchanged from the applicant's original CON application submission in July 2021, notwithstanding the extended timeline. (DI# 38, p. 4). The IP also states that the updated financial projections have no accounting for bad debt and charity care.

Frederick Hospital points out that the applicant has not explained how past levels of charity care provision by PSCF were appropriate to the needs of the community. Finally, the IP states that the applicant has not adequately addressed the impact of the proposed ASF on Frederick Hospital.

Reviewer's Analysis and Findings

[13] Please see the discussion at COMAR 10.24.01.08G(3)(d) Viability of the Proposal, (infra) for a discussion on the ongoing revisions and updates during the course this review.

Since the filing of the original CON application, the applicant's historic and projected surgical cases and minutes were revised seven times in the course of this review. (DI#'s 2, 9, 11, 16, 24, 27, 36 and 41). The applicant includes projections for a yet to be hired ophthalmologist, which increases the utilization projections for 2023 through 2025, but then removed the prospective eye surgeon's numbers from my second request for additional information (DI# 41). When I review the last two submissions in response to my request for more information, it appears that the utilization is the same in both submissions for 2020 through 2024, however the future projections from 2024 to 2025 do not appear to account for construction in 2023-2024. The applicant does not explain the increase in utilization during the construction or how the facility will accommodate the projected increases in the existing ORs during construction.

I am also concerned about the validity of the PSCF use projections in light of the IP's comments related to moving cases between procedure rooms and ORs "when appropriate" and whether the utilization projections include procedure room cases. The applicant does not provide any explanation of how the utilization projections correlated to the service area, which includes other states and Montgomery County, as well as the Frederick County population.

The applicant also submitted very few revisions to the project budget estimate or its revenue and expense projections during the review of this application. The applicant has stated the project budget will only increase from the original application submission of approximately $5.2 million to $5.7 million, an approximate 8% increase. It has not raised any significant budgetary implications resulting from the pandemic or how the rising costs of labor and materials have affected the project's construction costs. PSCF's budget revisions were limited to clarifying the source of funds needed to finance the project and the revenue and expense revisions occurred as a result of the extension of time to account for the construction and buildout for the proposed project. However, the estimated $167,800 in renovation costs or an update to the analysis of the MVS costs per square foot have remained unchanged from the applicant's original CON application submission in July 2021, notwithstanding the extended timeline.

I have observed that the applicant's changes in the revenue and expense statements are simply newer estimates based on PSCF's historic expenses. The applicant does not provide authoritative assumptions or adequately explain the basis for the facility's expectations that the project will be profitable based on historic case volume and expenses.

Each opposing comment and request for information during this review was an opportunity for PSCF to satisfy its burden to demonstrate that the proposed project complies with the applicable criteria and standards. Although the record is voluminous with multiple exhibits and tables that changed over time, there continue to be inconsistencies that create doubt about the financial feasibility of the proposed project. I find that applicant does not comply with this standard.

(9) <u>Impact.</u>

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

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

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

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

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

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

(ii) The operating room capacity assumptions in Regulation .06A of this Chapter and the operating room inventory rules in Regulation .06C of this Chapter shall be used in the impact assessment.

The applicant states that the surgeons who perform surgical cases primarily work at PSCF and Frederick Hospital. (DI #2, p. 38). The applicant states that the increase in surgical cases from Frederick Hospital will primarily be total shoulder and hip replacements, based on Medicare's approval of this type of surgery as suitable for the outpatient surgical setting in 2021. PSCF states that it expects the migration of the joint replacement procedures to have a minimal impact on Frederick Hospital.

The applicant states that all the current surgical cases performed by PSCF practitioners at the existing facility are cases most suitable for an outpatient setting. It reports that PSCF practitioners have experienced an increase in case volumes and that the surgical cases that PSCF cannot accommodate because of a lack of OR time are performed at Frederick Hospital. The applicant indicates that these cases are only moved to Frederick Hospital as a last option, with most cases being rescheduled or, if appropriate, performed in a procedure room. (DI #2, p. 38). The applicant states that a majority of PSCF practitioners perform their cases primarily at PSCF and Frederick Hospital, with one the exception of one practitioner who performs cases at Meritus

Medical Center in Hagerstown and another at a facility in West Virginia. (DI#2, p. 38). It states that PSCF practitioners do not provide services at surrounding facilities and that therefore the impact to other facilities will be negligible. (DI#2, p. 38).

Interested Party Comments

Frederick Hospital highlights the applicant's projection of a 39% increase in surgical cases at PSCF between the years 2020 and 2025. (DI #22, p. 8). To support the projection of this growth, the IP states that PSCF relies upon the case volume of Dr. James Steinberg, an orthopedic surgeon who has practiced for 25 years in Frederick County and specializes in joint replacement and repair for surgical cases at PSCF. Frederick Hospital states that Dr. Steinberg's practice has historically represented a significant number of cases at PSCF (he performed 229 cases in 2020, representing approximately 11.1% of the surgical cases performed at the ambulatory surgery center for that year). Frederick Hospital asserts that Dr. Steinberg's practice is highly specialized and not easily replicated. (DI #22, p. 8).

Frederick Hospital states that Dr. Steinberg is leaving Maryland in 2022 and cites a letter from Dr. Steinberg confirming the termination of his Medical Directorship and his planned relocation to Georgia. (DI #22, pp. 8-9). Frederick Hospital argues that the loss of Dr. Steinberg's surgical caseload will have a significant impact on PSCF's volume projections and expects that it will be "difficult to envision where a new surgical facility would be able to reach its financial pro forma projections if over 10% of its projected (surgical) procedures disappear." (DI #22, Table B, p. 9). The IP states that the loss of Dr. Steinberg's surgical minutes will reduce PSCF's projected surgical minutes by approximately 10.7% in 2022 and 8.7% in 2025. (DI #22, Table B, p. 9).

Additionally, Frederick Hospital responds to PSCF's assumption that CMS will permit certain surgeries, such as joint reconstruction, in an outpatient setting, despite CMS's long-standing "'Inpatient Only' restriction on these procedures." (DI #22, pp. 9-10). It states that CMS "Inpatient Only" category of surgical procedures is based on medical complexity and that these procedures require additional safety features and other resources that are only available in a hospital setting. Frederick Hospital states that "CMS has reversed this position[14] with regard to roughly 228 surgical procedures due to safety concerns.[15]" (DI #22, p. 10). Frederick Hospital states that many of the projected surgeries that PSCF expects to perform upon project completion "are no longer subject to reimbursement by Medicare in an ambulatory surgical facility setting." (DI #22, p. 10). The IP states that because the applicant does not provide sufficient specificity as to the numbers and specialty types of procedures in its projections, the projected number of procedures affected by CMS changes to the Inpatient Only list may vary from about 5% to 20% of its total projected volume. (DI #22, p. 12).

The Frederick hospital indicates that the impact of the CMS reversal on the Inpatient Only list on the financial viability of PSCF's proposed project will be significant. (DI #22, pp. 10-11).

[14] Of approving the performance of surgical procedures as outpatient procedures

[15] Frederick Health Hospital cites the following article, CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1753FC), available at https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.

Frederick Hospital states that "the CMS decision to release the Inpatient Only list and to not add several hundred musculoskeletal procedures to the APC-CPL (Covered Procedure List)" should result in a reduction of approximately 20% in orthopedic surgical procedures performed at PSCF.

Finally, Frederick Hospital states that PSCF's volume projections for OR turn-around-times (TAT) calculated between surgical cases for all of its projected surgical cases is inflated by inclusion of the first and last cases of each day that do not have a TAT. (DI #22, p. 12). PSCF uses a TAT of 25 minutes between cases for 100% of the projected surgical cases performed in the ASC. (DI #22, p. 12). Based on the 2,060 surgical cases performed at PSCF in 2020, Frederick Hospital calculates a daily average of 8.2 surgical cases, assuming PSCF is open and in operation for 251 days annually. Frederick Hospital states that the removal of the first and last cases from the daily average yields a reduction of two cases or about 24% of case volume (from 8.2 to 6.2 cases). The IP concludes that this decrease in the surgical cases reduces the calculated number of minutes needed between surgical cases and as a result reduces the total number of surgical minutes that PSCF uses to calculate the projected number of operating rooms needed at PSCF upon project completion. (DI #22, p. 12).

Frederick Hospital states that these three factors will significantly reduce PSCF's projected need for additional operating rooms. Frederick Hospital provides Table F in its IP comments that calculates this impact, which is included in Appendix 6. (DI #22, Table F, pp. 13-14). Table F demonstrates how the three factors (i.e., the loss of the Steinbert surgical cases, the CMS ruling reducing the number of surgical procedures reimbursable in an ambulatory surgical facility, and the assertion that TAT is inflated) decreases PSCF's need for additional operating rooms.

Frederick Hospital's calculations indicate that the PSCF projection of OR need is inflated by approximately one OR, (a reduction from 2.84 ORs to 1.86 ORs or about 34% by 2025). (DI #22, pp. 13-14). Frederick Hospital notes that the applicant's own data (based on the numbers provided in its CON application) indicates a need for only 2.84 ORs, which is less than the four total ORs requested by PSCF in its proposed project.

Applicant's Response to IP Comments

The applicant states that its case volume is growing with two orthopedic surgeons affiliated with PSCF increasing case volume and three new orthopedic surgeons in the process of becoming partners at PSCF. (DI #27, p. 11). In addition, a third orthopedic surgeon who joined PSCF in 2020 is experiencing a rapid increase in surgical cases. (DI #27, p. 11). PSCF states its belief that its projection of cases is conservative and will not have an impact on Frederick Hospital. (DI #27, p. 11). Further, the applicant indicates that the growth in surgical cases will be sustained by the present and future surgeons who practice at PSCF.

The applicant states that set up and tear down time is considered in the projections because this is time that the OR's could be used for surgery. While turn over times can be longer for more complicated cases, the applicant indicates that the average turnaround time at PSCF is 25 minutes based on its operating history. (DI #27, p. 11).

The applicant states that PSCF does not rely exclusively on Dr. Steinberg's surgical case volume to meet future surgical case projections and the need for additional ORs. (DI #27, p. 12). The applicant states that Dr. Steinberg worked with the Mid-Maryland Musculoskeletal Institute (MMI), a group of orthopedic specialists serving Frederick, Hagerstown, and Urbana, to develop an exit strategy that would "ensure that all of his cases remain in the Frederick community and are absorbed by his Colleague Peers at MMI." (DI #27, p. 12). In support of this exit plan, the applicant states that five orthopedic surgeons are credentialed at PSCF and will take over the patient caseload and volumes previously provided by Dr. Steinberg (these practitioners are Drs. Horton, Nesbit-Silon, Levine, Walsh, and Gupta). (DI #24, p. 1).

PSCF also states that it expects that the recruitment of three new surgeons from Montgomery County will provide an influx of new surgical cases into Frederick County and prevent cases from moving out of the jurisdiction. (DI #27, p. 13). The applicant also expects that these new surgeons will help recruit other physicians to bring their surgical cases to PSCF when the proposed additional ORs are available.

PSCF also addresses Frederick Hospital's comments with respect to the CMS Inpatient Only list of surgical cases and notes that while Frederick Hospital does not specifically identify which cases would be affected, it assumes it is referring to procedures such as shoulder replacements and ankle reconstructions. (DI #27, pp. 13-14). PSCF states that the facility will perform only surgical procedures that are approved by Medicare (or other insurance companies) and confirmed as appropriate for the outpatient setting. The applicant states that the utilization projections in its CON application were based upon knowledge of the PSCF business, its historic use trends, and the partners' input. (DI #27, p. 14).

Finally, the applicant addresses Frederick Hospital's statement that the joint replacement procedures performed at PSCF will adversely affect the surgical services provided at the hospital. The applicant notes that many of these cases will be performed by the "Montgomery County Surgical Team of Surgeons." (DI #27, p. 14). The applicant indicates that the small number of cases moved to Frederick Hospital will be the result of a surgeon determining that a procedure cannot be performed at PSCF due to a lack of available operating room time to meet the surgeon's and patient's needs. The applicant states that it does not perform acute joint replacements if the surgery is unsuitable for the outpatient setting and the patient needs more comprehensive care to ensure his or her safety. (DI #27, p. 15).

Applicant's Response to Reviewer's Request for Additional Information

My second request for additional information asked the applicant to specifically discuss the impact of the proposed project on Frederick Hospital, Holy Cross Hospital of Germantown (Holy Cross) located in Montgomery County, and Meritus Medical Center (Meritus) in Hagerstown (Washington County), as shown in Table III-4 below.

Table III-4: Impact Surgical Cases by PSCF Surgeons on Hospitals, 2020-2021

Physician Name	2020						2021					
	Frederick Hospital		Holy Cross		Meritus		Frederick Hospital		Holy Cross		Meritus	
	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes
Andochick	24	3,792		0		0	24	3,792		0		0
Steinberg	213	14,484		0		0	154	10,472		0		0
Silon	40	1,800		0		0	26	1,170		0		0
Levine	144	15,120		0		0	94	9,870		0		0
Mecinski	69	3,312		0	26	1,248	80	3,840		0	27	1,296
Thadani	0	0		0		0		0		0		0
Horton	12	876		0		0	45	3,285		0		0
Gupta	271	19,512		0		0	267	19,224		0		0
Henry	10	530		0		0	8	424		0		0
Sanders	0	0	30	2,970		0		0	15	1,485		0
Petruccelli	0	0	6	498		0		0	5	415		0
Evans	0	0	260	35,880		0		0	260	35,880		0
Walsh	219	13,688		0		0	200	12,500		0		0
Copaken	0	0		0		0	32	800		0		0
Total	1,002	73,114	296	39,348	26	1,248	930	65,377	280	37,780	27	1,296
Total PSCF Surgical minutes + TAT[a]		**98,164**		**46,748**		**1,898**		**88,627**		**44,780**		**1,971**
Total No. Ors at Hospitals[b]		11		5		11		11		5		11
Optimal Capacity – Mixed Use General Purpose Ors[c]		114,000		114,000		114,000		114,000		114,000		114,000
Total Optimal Capacity Minutes at Hospital Annually[d]		1,254,000		570,000		1,254,000		1,254,000		570,000		1,254,000
% Impact[e]		**7.8%**		**8.2%**		**0.2%**		**7.1%**		**7.9%**		**0.2%**

Source: DI #36, Tab 4, Ex. 14

Notes:
(a) PSCF Surgical minutes plus (TAT=Number cases times 25 minutes)
(b) Annual Report on Selected Maryland Acute Care and Special Hospital Services, Fiscal Year 2018, Table 18, p. 27 available at: https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_hospital/documents/acute_care/chcf_Annual_Rpt_Hosp_Services_FY2018.pdf.
(c) COMAR 10.24.11.06A(1)(a)(ii) Mixed-use general-purpose operating room optimal capacity is "1,900 hours per year and includes the time during which surgical procedures are being performed and room turnaround time (TAT) between surgical cases.".
(d) Total No. Ors times 114,000 minutes
(e) (Total PSCF Surgical Minutes + TAT) / Total Optimal Capacity Minutes at Hospital Annually

The applicant responded by providing the following table on the impact of the proposed project on these three hospitals without identifying the data source for these assumptions. For Frederick Hospital, PSCF's projections show that it will have the largest impact on Frederick Hospital in 2021, with the impact decreasing overall as the utilization of the operating rooms increases by year 2026. (DI. #41, Tab #5, p. 1). The applicant projects the impact of the proposed project will increase from 2021 to 2026 on Holy Cross. (DI #41, Tab #5, pp. 1-2). Finally, PSCF projects the proposed project will have a negligible impact on Meritus. (DI #41, Tab #5, p. 2).

Table III-5: Impact of PSCF on Frederick Hospital Hospital, Holy Cross Hospital of Germantown, and Meritus Hospital

		Frederick Hospital	Holy Cross	Meritus
2021	Cases	527	54	27
	Impact	3.29%	0.77%	0.17%
2022	Cases	362	141	29
	Impact	2.50%	2.00%	0.18%
2023	Cases	303	225	31
	Impact	1.90%	3.50%	0.21%
2024	Cases	364	270	33
	Impact	2.38%	4.02%	0.22%
2025	Cases	128	285	35
	Impact	0.84%	4.30%	0.24%
2026	Cases	123	290	37
	Impact	0.81%	4.37%	0.25%

Source: DI #41, Tab #5, Exh. 18, Exh. 19, and Exh. 20.

Interested Party Response to Applicant's Responses to Reviewer's Request for Additional Information

Frederick Hospital states that the applicant's proposed project will have a significant impact and that the applicant's data demonstrates that PSCF surgeons "who currently perform surgery at Frederick Hospital anticipate a dramatic decrease in surgeries at the hospital, and an increase at PSCF." (DI #38, p. 9). Frederick Hospital states that its own data shows that the involved PSCF surgeons historically have had large volumes of both inpatient and outpatient surgical volumes at Frederick Hospital and this project will have an impact on the hospital. (DI #38, p. 10). The IP states that PSCF's tables are incorrect as they assume that the only impact is that PSCF's additional volume is not performed at Frederick Hospital. (DI#42, p.5). Further that impact should include a retroactive look at historical data, then prospectively project the impact of the decrease in historical volume. (DI#42, p. 5).

Frederick Hospital states that PSCF has not met the impact standard by failing to address the shift of patient volume and simply concluding that "its projected volume of procedures…will not account for a large number of patients." (DI#22, p.17). Frederick Hospital states the actual impact of the surgical cases moved from the hospital to PSCF should be added cumulatively from year-to-year and not one year at a time. (DI #41, p. 6). Adding the moved surgical cases cumulatively would show an increasing negative impact of PSCF's project on the hospital.

Frederick Hospital states that the applicant's assumptions are incorrect, the calculations are flawed, that the applicant's own data shows that no additional operating room capacity is warranted, and, finally, that the applicant has failed to satisfy the regulatory requirements with reliable and accurate information. (DI#42, p. 6).

Reviewer's Analysis and Findings

I have concerns about the credibility of the historic and projected case volumes that PSCF has provided in this review. The volume projections have changed with each submission, are inconsistent, and the basis of the applicant's assumptions is not clear. As I have reviewed the information provided in Tables III-4 and III-5 above, I am concerned that given multiple opportunities, the applicant did not provide a response that clarifies submitted data, and again, did not identify the assumptions used in its impact projections.

The data in Table III-4 shows an average of 1,300 cases for all three hospitals over a two-year period, an average of approximately 140,000 surgical minutes per year performed by PSCF-affiliated doctors at Frederick Hospital, Holy Cross and Meritus and it appears that future projections are based on this historic data. As PSCF projects a utilization increase of 39%, the applicant itself states that much of this increase will be from physicians choosing to perform surgeries at PSCF instead of Frederick Hospital, Holy Cross and Meritus.

The historic data provided was for two years during the height of the COVID-19 pandemic emergency, when surgical numbers were reduced, especially for elective procedures. I believe it is therefore likely that the projected numbers provided are an underestimate of the impact to the three hospitals who are trying to maintain their own surgical programs. While the applicant claims that these hospitals will only be minimally affected, presumably based on calculations that suggest that no hospital in the service area will see OR minutes significantly reduced by a PSCF physician. I do not find the applicant's case volume projections reliable, and I do not believe they provide any substantive assurance on the actual impact of the proposed project. I am not convinced that the prospect of losing hundreds of surgical cases each year will not adversely affect Frederick Hospital or, potentially, other hospitals.

For these reasons, I find that the applicant has not presented a credible assessment of the impact of its proposed project and, as such, I cannot find PSCF as compliant with this standard.

B. **Need**

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

This criterion directs the Commission to consider the "applicable need analysis in the State Health Plan," 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…Facility.

Interested Party – Frederick Hospital Comments

Frederick Hospital questions the accuracy of the volume projections and states "The need is simply not justified due to the inherently incorrect assumptions relied upon by the Applicant." (DI #22, p. 14). For purposes of brevity, the reader is referred to the IP comments outlined earlier

in this Recommended Decision that were provided with respect to the applicable need standard of the SHP.

Applicant's Response to Comments

The applicant submitted revised utilization projections for the surgeons who will perform their procedures at PSCF. (DI #24). These revisions were for Drs. Silon, Levine, Horton, Gupta, and Walsh, who each were assigned increases in projected surgical cases and OR minutes to compensate for the loss in projected surgical cases and time attributed to the departure of Dr. Steinberg.

In response to Frederick Hospital's comments regarding the exclusion of both before the first and after the last surgical cases of the day, the applicant submitted two updated surgical utilization tables to project the need for additional operating rooms: the first was Table 1-2 Exhibit 4, which included TAT after each surgical case as originally calculated by the applicant; and the second Table 1-2 Exhibit 5, which removed the 25 minute TAT both prior to the first case and after the last surgical case. (DI #27, Exh. 4 and 5).

Reviewer's Analysis and Findings

In my review of the applicable State Health Plan need standard (Project Review Standard 2, Need-Minimum Utilization for Establishment of a New or Replacement Facility pp. 16-22). I outlined the basis for my finding that PSCF's needs assessment lacked consistency and reliability. I concluded that PSCF did not comply with the applicable need analysis standard of the SHP. Therefore, I must find that the applicant has not demonstrated a need for the proposed project.

(C) Availability of More Cost-Effective Alternatives

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

The applicant states that the proposed construction of a new addition with two operating rooms and a procedure room and renovations to the existing facility is the most cost-effective alternative. It states that the primary goals and objectives for the proposed expansion project are "to achieve the most cost-efficient process for the addition of two operating rooms and one procedure room" for PSCF. (DI #2, p. 42). The applicant states that the proposed project will:

- Increase space for the projected growth in surgical procedures;
- Provide space for supplies, sterile processing, increased comfort for patients and their waiting families, and for pre- and post-operative care in the facility;
- Allow PSCF to relocate the business office from off-site to the main campus, making the operation of PSCF more cost effective and efficient. The applicant will use the cost of leasing this office space to help offset the current costs incurred with the additional ORs and the additional procedure room;

- Expand the space to store inventory needed for operations in one central area appropriate for the receipt, storage, and stocking of clean and sterile supplies; and
- Increase space for in-house storage of linens and biohazardous waste. While the applicant currently stores linens and waste in external storage units, the proposed project will include space within the facility to store these items. An interior storage space will improve the security and well-being of staff.

(DI #2, pp. 42-43).

To explore the options for gaining additional OR capacity, the applicant assessed other outpatient surgical facilities in Frederick County and states they have existing high surgical volumes. (DI #2, p. 43). The other alternative PSCF considered was relocating and establishing a new ASF in the City of Frederick. The applicant stated the cost of building a new facility with four operating rooms and two procedure rooms and the impact on staff would be too costly and not financially feasible at this time. (DI #2, p. 43).

PSCF leases the space for the ASC from Andochick Properties, LLC. (DI #9, Exh. 54). The applicant states that this landlord will be financially responsible for building the space that will contain the additional ORs and the procedure room. PSCF will lease the new space and be responsible for remodeling and renovation of the existing building space. (Please see Appendix 5, Project Budget).

The applicant indicates that the buildout of the shell space will not interrupt the existing operations of the ASC, allowing the facility to generate revenue, provide patient care, and provide work force stability while the project is implemented. (DI #2, pp. 43-44). The proposed project will allow PSCF to expand and avoid incurring relocation expenses and the increased costs to lease sufficient Class A space for an ASF. The proposed project will minimize cost and service disruption and eliminate the need to temporarily relocate or layoff staff. With the completion of the proposed project, the applicant will adjust the current lease to account for the additional square footage. (DI #2, p. 44).

Interested Party Comments

Frederick Hospital indicates that the applicant does not meet its burden of proof in addressing the most cost-effective solution it perceives, the continued use of its existing OR capacity, stating "the Applicant did not contact Frederick Hospital to identify or assess if the existing capacity existed to support the need for its projected needs." (DI #22, p. 15).

Frederick Hospital indicates that hospital based ORs provide multiple benefits that extend beyond economics and that the "cost effective" standard does not mean "cheapest provider." (DI #22, p. 15). In general, Frederick Hospital states that hospitals provide higher caliber staff and have more intensive resources and can manage a higher complexity of cases, assuring more dynamic interactions with providers in emergencies. It claims that hospitals utilize specialized care coordination planners for pre-surgical intake and offer post-surgery discharge planning for more consistent surgical and post-acute care outcomes, better integrating services, providing for better information flow and more resources to implement best practices. (DI #22, pp. 15-16). By

not conferring with Frederick Hospital, the applicant did not satisfy its burden of proof with regard to addressing more cost-effective alternatives. (DI #22, p. 15).

Additionally, Frederick Hospital states that the applicant failed to consider a hospital-planned expansion as a potentially cost-effective alternative. Frederick Hospital states a hospital-based ambulatory surgical facility could be part of an integrated care delivery model. This proposed ASF would be part of a hospital-guided physician alignment strategy that shifts lower intensity surgical procedures to the hospital-owned facility while providing the physicians access to the hospital for inpatient surgical cases and the performance of more complex outpatient procedures in a hospital-based setting. (DI #22, p. 16). Finally, Frederick Hospital states it ha incentives under the Maryland Total Cost of Care model to manage health care spending appropriately across the entire Frederick Hospital system, the parent organization to the hospital. (DI #22, p. 16).

Applicant's Response to Comments

The applicant states that "PSCF does not plan to draw significant cases from the hospital" (DI #27, p. 17) and that PSCF provides a convenient location and safe and cost-effective alternative for both the surgeon and the patient.

PSCF states that it serves the same growing area as Frederick Hospital and expects that both will benefit in a positive manner from the growth in this jurisdiction. The applicant states that it has recruited and is partnering with surgeons from Montgomery County who will assist to support growth and retain patients, with the expectation that the recruitment of these surgeons "will promote retention and confidence in care received in Frederick County." (DI #27, p. 17).

PSCF states that it utilizes the same anesthesia group that serves Frederick Hospital to administer high-quality anesthesia services. The applicant's surgeons are not employed by Frederick Hospital, and "the decision to have a patient receive care at PSCF is between the surgeon, patient and their insurance carrier." (DI #27, p. 17). The applicant indicates that the strong reputation of PSCF in Frederick makes it an attractive choice because of its "location, safe environment, quality staffing, and anesthesia services" for those persons seeking treatment by this facility.

The applicant indicates it works on a continual basis "with vendors and insurance carriers to promote the most productive, safe and cost-effective surgical care without compromise to quality." (DI #27, pp. 17-18). PSCF states that the facility works to keep overhead costs down, utilizes flexible and intelligent scheduling of services to assist in minimizing duplication of services, equipment, and staff, and maintains consistent staffing to minimize the cost of turnover and to promote smooth surgical schedule flow. It also states that it employs an ongoing education and training program to promote staff excellence among all of the care providers and encourages high quality care to minimize complications and infections. leading to excellent patient outcomes.

The applicant states that "[a]ll projections submitted are in good faith and concluded to the best of our knowledge and abilities…..," and makes the following statement in its response to the hospital's comments:

PSCF stands by its projections and with the current growth, expressed interest by other surgical providers, and increasing complexity of cases feels confident it will meet Optimal to Full Capacity on or before 2025. We do not believe the projections are calculated on incorrect assumptions as Frederick Hospital stipulates and a plan is in place to maintain the volume. Frederick Hospital is not fully aware of PSCF relationships and surgeon commitments being anything other than what we have stated in good faith. Anything to the contrary is speculation by Frederick Hospital. (DI #27, p. 18)

The applicant closes by stating that "[PSCF] would like to continue a mutually strong and supportive relationship with Frederick Hospital" for the benefit of the patients who receive surgical services at both the ASC and the hospital.

PSCF states that it provides a cost-effective alternative for outpatient surgery services that meets all Medicare criteria (DI #27, p. 19) and that the facility possesses a solid record of quality, safety and satisfaction (patient, surgeon and staff). The applicant enjoys a very low infection and complication rate and indicates that it works diligently to maintain that record. The applicant acknowledges Frederick Hospital's ability to manage higher complexity cases and those cases that are not candidates for the outpatient setting. PSCF screens prospective cases pre-operatively so that they are not performed at PSCF. (DI #27, p. 20). All patients determined not to meet outpatient medical assessment screening criteria are referred to Frederick Hospital for scheduling.

Reviewer's Analysis and Findings

I find that the applicant has provided information that, within the narrow context of its proposed expansion, supports the cost effectiveness of its approach to implementing the proposed expansion. However, I have also found, as indicated previously in this Recommended Decision, that the PSCF has not met its burden of proof that establishing itself as an ASF is needed to provide the public with an adequate supply of operating rooms. Thus, my favorable view of the project planning that has been undertaken by PSCF must be viewed as secondary to the question of need for the project. Without proven need for the proposed project, the question of whether or not a project sponsor has made appropriate choices in planning a project does not provide effective support of approval of the project.

D. Viability of the Proposal.

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

FCB Bank submitted a "Financing Proposal" for the project involving a loan not to exceed $2.2 million for a period of 24 months utilizing a combination of fixed and variable interest rates, with the loan secured by a first lien on the business assets of PSCF. (DI #11, Ex. 11). The applicant provided a copy of PSCF's 2019 and 2020 Tax Returns and its proposed Revenue and Expense statements that document it has sufficient assets to support the $550,000 in cash equity anticipated.

(DI #2, Exh. H-1a and H-1b and DI #41, Exh. 4. Table 3). Finally, FCB Bank submitted a letter stating that "All of their loans [those of the applicant entity] are handled in a satisfactory manner" and that it maintains an aggregate deposit balance in excess of $500,000 with the FCB Bank. (DI #9, Exh. 36).

The applicant submitted revisions and updates of its schedule of revenues and expenses over the course of this review. These included a first update and revision in response to completeness questions (DI #9, Exh. 34), a second update and revision in its first response to the Reviewer's request for additional information. (DI #36, Tab #5, Exh. 18, Table #3 and Exh. 19, Table #4), and a third update and revision in its response to my second request for additional information (DI #41, Tab #2, Exh. 4, Table 3 and Exh. 5, Table 4). This final schedule projects that operations at PSCF will generate a net profit of approximately $650,000 based on net operating revenue of approximately $8.5 million in 2024. (DI #41, Exh. 4).

Availability of Resources to Sustain the Proposed Project

The applicant states that PSCF currently employs 30.0 FTE staff, of which 16.9 FTE staff provide direct care (i.e., registered nurses and surgical technicians). (DI #36, Tab 5, Exh. 20, Table L). With the completion of the proposed project, the new ASF will hire an additional 12.7 FTE staff, including 7.2 FTE staff in direct care, at a cost of $638,542. PSCF states that it does not expect having any difficulty hiring these additional staff. The applicant proposes to use online recruitment, relationships with local nursing and medical technician programs, word of mouth, and community events to recruit the needed additional staff. (DI #9, pp. 26-27).

Community Support

The applicant submitted four letters from patients. (DI #36, Exh. 24, 25, 26, and 27). The applicant also provided a two-page petition showing support for the project with 88 signatures. (DI #36, Exh. 23).

Interested Party Comments

Frederick Hospital states that the applicant does not provide evidence that there is community support for the project and that PSCF did not seek such support from Frederick Hospital. (The immediately above-noted material was submitted by the applicant after this comment was made.)

Frederick Hospital also states that "the anticipated revenue is largely dependent upon misguided volume projections and a significant increase in outpatient surgeries removed from Frederick Hospital." (DI #22, pp. 16-17). Lastly, Frederick Hospital states the PSCF revenue projections are inaccurate and should not be relied upon to determine the viability of the application.

Frederick Hospital states that PSCF reports a discrepancy for the projected costs in "salaries, wages, and professional fees" for the hiring of the additional employees and staff after project completion. (DI #42, p. 5). In its June 23, 2022 response (DI #41, Tab 2, Exh. 5), Frederick

Hospital states that PSCF reports the cost for hiring these 12.7 FTEs is $666,210 by CY 2026 in its Table 4 – Revenue and Expenses – Proposed Project, and this amount is not consistent with the total cost for regular employees reported in its Table L – Workforce Information, which indicates a total cost of $2,515,024 by year 2026. (DI #36, Tab 5, Exh. 20). Frederick Hospital notes a discrepancy of almost $2 million, which draws into question the budget and financial feasibility of PSCF's project. (DI#42, p. 5).

Applicant's Response to IP Comments

PSCF states that Frederick Hospital operates Frederick Surgical Center[16], an integrated hospital-owned ambulatory surgical facility that is affiliated with the hospital and a part of an integrated care delivery model. The applicant states that PSCF surgeons have access to Frederick Hospital at their choosing. PSCF contends it can provide the safest, high-quality care possible in an efficient and patient-centric environment at a reduced cost. (DI #27, pp. 20-21).

The applicant states that it has observed support for the services provided at PSCF through "patient satisfaction reports, surgeon testimonials, and by its sound reputation, increased charity care, and outreach program." (DI #27, p. 21).

Reviewer's Analysis and Findings

In my Analysis and Findings to the State Health Plan's Financial Feasibility standard earlier in this Recommended Decision, I noted that PSCF made several adjustments to it financial documents to support a finding of financial feasibility for the proposed project. These revisions, spurred, to some extent, by opposing comments, give me concern with respect to their reliability. I also found that the applicant did not provide a comprehensive set of assumptions supporting its projection that require strong documentation supporting their reasonableness.

As noted, Frederick Hospital highlighted discrepancies among the work force tables provided by PSCF. I find these comments credible but, of equal concern, is my lack of confidence in the projected case volume increases that underly revenue projections. The applicant has stated that its practitioners are working late nights and weekends due to inadequate capacity and space. This is inconsistent with the case volume increases projected to occur during the time in which the proposed project will be implemented.

I have already determined that PSCF failed to demonstrate need for the project because its projected utilization numbers were inconsistent and unreliable. Without confidence that PSCF will be able to achieve the volumes projected, I similarly cannot find that the project will be viable.

[16] Frederick Surgical Center is an ambulatory surgical facility that operates with four operating rooms and four procedure rooms at 45 Thomas Jefferson Drive in Frederick, Maryland in Frederick County. Further information available on MHCC website at: https://healthcarequality.mhcc.maryland.gov/OutpatientSurgery/Detail/125.

E. Compliance with Conditions of Previous Certificates of Need

COMAR 10.24.01.08G(3)(e) An applicant shall demonstrate compliance with all terms and conditions of each previous Certificate of Need granted to the applicant, and with all commitments made that earned preferences in obtaining each previous Certificate of Need, or provide the Commission with a written notice and explanation as to why the conditions or commitments were not met.

The Commission issued a CON in 2010 unconditionally authorizing the addition of an OR at PSCF, which at that time was a one-OR ASC. (Docket No. 09-10-2302). (DI #2, Att. L-1). PSCF implemented the approved project in compliance with the terms of its CON.

Reviewer's Analysis and Findings

I find that the applicant has demonstrated compliance with all terms and conditions of each previous CON it obtained.

F. Impact

COMAR 10.24.01.08G(3)(f) Impact on Existing Providers and the Health Care Delivery System. An applicant shall provide information and analysis with respect to the impact of the proposed project on existing health care providers in the health planning region, including the impact on geographic and demographic access to services, on occupancy, on costs and charges of other providers, and on costs to the health care delivery system.

The applicant states that its practitioners primarily work at PSCF and Frederick Hospital and that the impact of the proposed project will be either minimal or negligible on either the hospital or other existing providers of ambulatory surgery. (DI #2, p. 52). Since the applicant expects the surgeons to refer and perform surgical cases "at Frederick Health when a patient is not a candidate for the outpatient setting," PSCF states that the proposed addition of two ORs will have a negligible impact to the hospital. (DI #2, p. 53).

The applicant states that the facility typically re-schedules surgical cases when OR time is not available or performs the surgery late in the day. (DI #2, p. 53). However, if there is a lack of available surgery time in an OR, the surgeon may schedule the procedure at Frederick Hospital. Therefore, the applicant does not expect the proposed project will have an adverse impact on either Frederick Hospital or on other providers in its service area. (DI #2, p. 53).

Interested Party Comments

Frederick Hospital states that the applicant has not addressed the proportion of case volume expected to shift from other providers such as Frederick Hospital. As Frederick Hospital states in it comments with respect to the Impact standard of the SHP, previously reviewed in this Recommended Decision (pp. 31-37), "the Applicant inconsistently concludes" the proposed project will not account for a large number of patients and surgical volume that would otherwise be performed at Frederick Hospital. (DI #22, p. 17). The IP states that PSCF provides total case

volume projections but does not convincingly account for the source of projected case volume. It believes the potential shift of case volume from Frederick Hospital is understated. Frederick Hospital states that the record produced by PSCF does not make it possible to reliably determine the actual volume likely to shift from existing facilities to the proposed ASF. (DI#22, p. 17)

Applicant's Response to IP Comments

PSCF states that its projected case volumes are based on the choice of patients and surgeons and states that the impact of the proposed project on the outpatient surgical caseload of Frederick Hospital is "in good faith expected to be minimal." (DI #27, p. 21). While the applicant states that the facility's surgeons and patients have the right to choose where they go for their health care in a free market, it also states that "PSCF does not target or defer Frederick Health case load" to the proposed ASF. The applicant states that it emphasizes patient choice when it pre-operatively screens and admits its patients, informs patients that they may choose an alternative site for their care, which includes Frederick Hospital if their surgeon is credentialed there as well, and can discuss options for their health care at any time prior to the commencement of their surgery. (DI #27, pp. 21-22). PSCF states that it is not the goal of the facility "to negatively impact the simultaneously growing Frederick Health community health system." (DI #27, pp. 21-22). The applicant indicates that since it is not able to predict the number of surgical cases that may be drawn from Frederick Hospital to PSCF at this time, it will not speculate on something that cannot be measured. (DI #27, pp. 21-22).

For the projected surgical case volumes, the applicant states that the IP assumes that the PSCF surgeon partners may wish to take many of their appropriate surgical cases to Frederick Hospital. While this may be true for their inpatient cases, the applicant states that the surgeon's primary preference for outpatient surgical cases is PSCF "due to the ease in scheduling, ability to be more productive, staff quality, familiarity, and access to resources, safety, and satisfaction in a pleasant setting." (DI #27, p. 22).

For physician recruitment, the applicant states that PSCF is forming a "partnership" with three surgeons from Montgomery County which Frederick Hospital does not account for in its comments on PSCF's projected case volumes. (DI #27, pp. 22-23). Frederick Hospital's focus on Dr. Steinberg's departure does not acknowledge the exit strategy that will increase other surgeons' projected surgical caseload. (DI #27, p. 23).

The applicant expects that the proposed project will have a positive impact on Frederick Hospital. The applicant expects PSCF's surgeons will assist in keeping orthopedic patients within Frederick County and in the fold of the Frederick Hospital system. PSCF describes this as a shared goal of PSCF and the IP, offering mutual benefits. (DI #27, p. 23). The applicant expects that the proposed addition of two operating rooms at PSCF will not result in a negative impact to Frederick Hospital, with the surgeons from Montgomery County "playing a role that will benefit Frederick Hospital as an additional source of inpatient referrals." Should the applicant's request for two additional ORs be denied, PSCF states it cannot predict if the new surgeons will continue to treat patients in Frederick County or refer these cases elsewhere in Maryland.

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

PSCF projects that the Medicare and Medicaid proportion of total cases performed at PSCF will increase after its proposed establishment as a four-OR ASF. (DI #9, p. 28 and Exh. 46).

Interested Party Comments

Frederick Hospital states that "the Applicant's six identified surgeons have a payer mix that is 61% commercial, with virtually no (less than 1%) charity care." (DI #22, p. 18). The IP expects the proposed expansion project will remove less complex, more reimbursable procedures, and leave more complex, less reimbursable procedures to be performed at Frederick Hospital, which the Hospital will serve consistent with its indigent care policy.

The hospital also indicates the proposed project will have a negative impact on staffing, which may impact patient safety. (DI #22, p. 18). PSCF shows in Table L, Workforce Information, that the facility will hire 21 FTE employees to support the expansion to ASF capacity. The IP states that PSCF does not discuss how it intends to develop or hire this staff.

Frederick Hospital notes that, due to the pandemic, the health care industry is experiencing a significant staffing shortage. (DI #22, p. 18). Referencing an article from the Harvard Business Review,[17] Frederick Hospital states that health care worker resignations increased about 3.6% year over year, between 2020 and 2021. The Advisory Board,[18] citing Bureau of Labor Statistics data in 2021, reported that 534,000 U.S. workers in health care or social assistance positions resigned or quit their jobs in August of that year. Finally, Frederick Hospital states that the Association of Perioperative Registered Nurses (AORN) reports that 20% of the nation's surgical nurses will reach retirement age in the next five years.[19]

The hospital indicates that "Frederick Hospital has not been immune from the present staffing crisis." (DI #22, pp. 18-19). In a letter addressed to Governor Hogan,[20] Thomas Kleinhanzl, President & CEO of Frederick Hospital, states that Frederick Hospital (FH) faced "an unprecedented workforce crisis" due to the pandemic and aging of its community. (DI #22, Exhibit A). The letter states that "the FH vacancy rate is currently 16% compared to 10% in 2019," with registered nurses, nursing assistants, respiratory therapists, and medical assistants the positions most challenging to hire. Mr. Kleinhanzl also states that one of the issues that the hospital has

[17] Harvard Business Review, Who Is Driving the Great Resignation?, available at: https://hbr.org/2021/09/who-is-driving-the-great-resignation

[18] Advisory Board, Daily Briefing, October 18, 2021, The 'Great Resignation' Is Coming for Health Care. How Can you Respond?, available at: https://www.advisory.com/daily-briefing/2021/10/18/employees-quitting

[19] Association of periOperative Registered Nurses(AORN), AORN Addresses Critical Shortage of OR Nurses, available at: https://www.aorn.org/outpatient-surgery/articles/news-archive/2021/august/chamberlain

[20] The letter states it supports the Maryland Hospital Association's request for the State to create a one-time $100 million fund to support critical workforce needs in hospitals in 2022. (DI #22, Exhibit A).

experienced is a reduction in surgical capacity due to fewer operating room RNs. (DI #22, Exhibit A).

Frederick Hospital states that it is crucial that it retain the staff that the hospital "has dedicated significant time and expense to nurture and train." (DI #22, p. 19). The IP indicates that the result of a healthcare staffing shortage could lead to higher infection rates, as well as other patient safety and care quality issues. The hospital states that PSCF has no apparent plan to fill its staffing needs other than to recruit the highly specialized and highly trained surgical specialty registered nurses employed at Frederick Hospital. With the need for the hospital to recruit and train new surgical nurses, the IP states that "those surgical cases at the hospital requiring the greatest care from complex co-morbidities will be supported by less experienced nurses, which will negatively impact the sickest of the surgical patients." (DI #22, p. 19).

Applicant's Response to Comments

The applicant states that the PSCF case mix is around 67-70% orthopedic surgery, with the potential for a significant increase in surgical cases due to the continued number of orthopedic surgeons joining the facility and the expected expansion of operating rooms with the project approval. (DI #27, p. 23). PSCF states it will continue to serve all patients regardless of their ability to pay. Before it can provide a response on the surgical procedures that will be referred to the hospital, the applicant states that Frederick Hospital needs to provide further clarification and be more specific on the types of surgical cases they believe "PSCF will reject."

PSCF states that it "actively recruits staff on a continual basis through word-of-mouth referrals, advertisements, Maryland Ambulatory Surgery Association, Baltimore Nurse Group, surgeon recommendations, and distance recruiting." (DI #27, pp. 23-24). PSCF states that the ASC is not currently experiencing a staffing shortage, currently staffed with a large base of full-time, highly skilled nurses despite the COVID pandemic. The applicant states that while Frederick Hospital staff have reached out to PSCF for employment, most were not hired due to non-match qualifications and the stability of our current workforce with few vacancies.[21] PSCF indicates it does not have a problem in recruiting high quality staff when needed. (DI #27, p. 24).

Regarding the personnel currently employed by the ASC, PSCF states that only one member of its staff is close to retirement age, and this individual has indicated she would like to continue to work and has no plans to retire at this time. (DI #27, p. 24). Most of the staff have been with PSCF from five to ten years. The applicant states that, about three years ago, it recruited two staff members who were previously employed by Frederick Hospital. PSCF states that the ASC provides a strong orientation, education, and training program to ensure the quality of care by its staff. Because of the pleasant environment, employee support, comradery and highly skilled team employed by the center, PSCF states that it cannot be responsible for Frederick Hospital employees choosing to seek new employment. (DI #27, p. 24).

Reviewer's Analysis and Findings

[21] Note: PSCF states that it has experienced a small number of staff resignations who wish to gain temporary financial benefits in those health care facilities that pay very high wages to treat COVID patients. It states that, subsequently, many of the staff that left PSCF under those conditions have returned.

In considering the Impact standard of the SHP earlier in this Recommended Decision (pp.31-37), I found that the likely impact of the proposed project on surgical case volumes at Frederick Hospital would be significant. I do not think the project will have a positive impact on any hospitals, but I believe the potential impact on the Germantown and Hagerstown hospitals will be far less detrimental.

I find that the IP's argument concerning the likely impact on case mix and payor mix is persuasive. It is logical to assume that shifting outpatient surgery cases from a hospital to an ASF setting will have the result of raising the average acuity level of the cases remaining at the hospital and changing the payor mix of that remaining volume. I note that the direct negative impact on hospital revenues is somewhat mitigated by Maryland's regulation of hospital charges. One would expect PSCF to follow a business model aimed at maximizing income generation and the market forces operating in ambulatory surgery, which include the effects of Maryland's regulation of hospital charges, which would result in these impacts on Frederick Hospital.

Charity care is not a key factor in this review with respect to facility financial health because it is not needed by a large sector of the population. Frederick Hospital will continue to be the community safety net in this regard even if PSCF moves from the no charity care posture with which it has historically operated to a future of providing charitable services equivalent to around 0.7% of total expenses.

The impact of the project on staffing Frederick Hospital appears to be an incremental ratcheting up of the pressure on what is already an acute cost and operational problem for the hospital and other health care providers with no short-term relief in sight. It is an important factor in the overall consideration of impact required by this criterion at this time. In my view, PSCF has downplayed this impact in its analysis.

I find that the proposed program will have a substantive impact on existing health care providers in the region, specifically Frederick Hospital and its utilization. To the extent that outpatient surgical services will shift from Frederick Hospital to PSCF as a consequence of the proposed project, I believe that a finding could be made that the proposed project will have a positive impact on charges by payers for the surgery, which will be lower in the ASF setting as compared to the hospital setting.

However, this positive impact implies a likely increase in the unit costs of providing surgery at Frederick Hospital, which is likely to yield lower levels of excess revenue from the important surgical business line. Recovering higher surgical service costs in the hospital setting may be difficult under the constrained Maryland hospital payment system.

On balance, my consideration of the issue leads me to find that the likely impact of the project served by PSCF on Frederick Hospital is not acceptable or offset by the likely benefits of the proposed project.

IV. SUMMARY AND REVIEWER RECOMMENDATION

Based on my review of the proposed project and the project's compliance with the applicable review criteria and standards, I conclude that the proposed project does not comply with four SHP standards:

COMAR 10.24.11.05A(3), Charity Care Policy;
COMAR 10.24.11.05B(2), Need–Minimum Utilization for Establishment of a New or Replacement Facility;
COMAR 10.24.11.05B(8), Financial Feasibility; and
COMAR 10.24.11.05B(9), Impact.

Some of the SHP standards for general surgical services overlap with the six general criteria adopted in MHCC's procedural regulations (COMAR 10.24.01.08G) for consideration of all CON applications. For this reason, my negative findings on three specific SHP standards (Need, Financial Feasibility, and Impact) have led me to also conclude that the applicant has failed to meet the Need, Viability, and Impact criteria.

Ultimately, it is PSCF's burden to demonstrate that its project meets all relevant SHP standards and criteria for review by a preponderance of the evidence. COMAR 10.24.01.08G(1). PSCF has not provided consistent and reliable data or documented convincing support for the assumptions undergirding its projections of use (and thus, its financial projections) or impact. For these reasons, I cannot recommend approval of this application for a Certificate of Need. I recommend that the Maryland Health Care Commission deny this Certificate of Need application.

IN THE MATTER OF	*	
	*	
ANDOCHICK SURGICAL	*	**BEFORE THE**
	*	
CENTER, LLC d/b/a	*	
	*	**MARYLAND HEALTH**
PHYSICIANS SURGERY	*	
	*	
CENTER OF FREDERICK	*	**CARE COMMISSION**
	*	
Docket No. 21-10-2451	*	
	*	

* *

FINAL ORDER

Upon consideration of the full record of this review, the Reviewer's Recommended Decision, and any exceptions taken thereto, it is, this 16th day of March, 2023:

ORDERED, that the Recommended Decision of the Reviewer is adopted as the final decision of the Maryland Health Care Commission; and it is further

ORDERED, that the Recommended Decision's findings of fact and conclusions of law are adopted by the Maryland Health Care Commission and incorporated into this order; and it is further

ORDERED, that the application of Andochick Surgical Center, LLC d/b/a Physicians Surgery Center of Frederick for a Certificate of Need to establish an ambulatory surgical facility by adding two operating rooms to the two-operating room ambulatory surgery center it currently operates in Frederick is hereby **DENIED**.

MARYLAND HEALTH CARE COMMISSION

MARYLAND HEALTH CARE COMMISSION

APPENDIX 1: Record of the Review

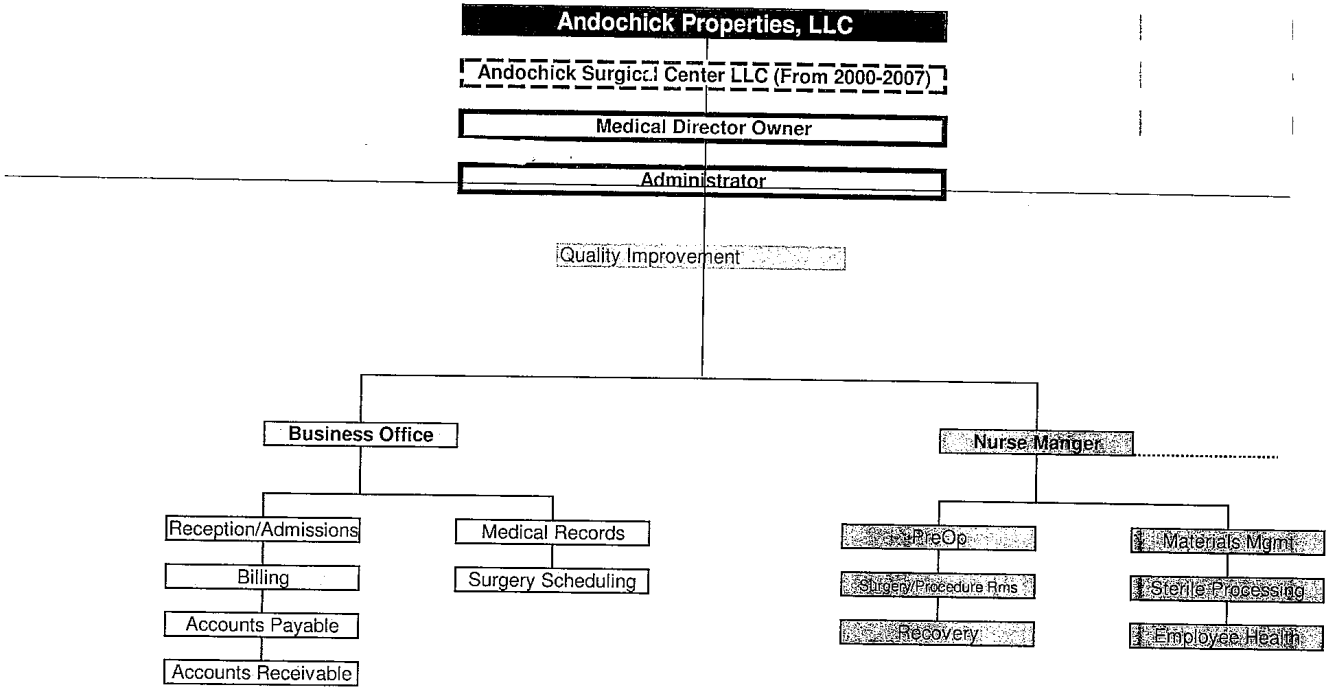
Docket Item #	Description	Date
1	MHCC acknowledged receipt of Andochick Surgical Center, LLC, d/b/a Physicians Surgery Center of Frederick's (PSCF) letter of intent to file a Certificate of Need application.	5/18//2021
2	PSCF submitted a Certificate of Need application proposing the addition of two operating rooms and one procedure room, establishing an ambulatory surgical facility with four operating rooms and two procedure rooms	7/9/2021
3	MHCC acknowledges receipt of CON application.	7/13/2021
4	MHCC requested publication of notification of receipt of the Andochick Surgical Center's application in the *Frederick Post.*	7/13/2021
5	MHCC requested publication of notification of receipt of the Andochick Surgical Center's application in the *Maryland Register*.	7/13/2021
6	MHCC Request for completeness information.	8/27/2021
7	PSCF requested additional time to submit completeness information.	9/13/2021
8	MHCC granted an extension for submission of completeness information to October 12, 2021.	9/21/2021
9	MHCC received completeness responses from PSCF.	10/12/2021
10	MHCC second completeness questions.	10/28/2021
11	PSCF submitted responses to the second completeness.	11/9/2021
12	MHCC notified PSCF the application would be docketed for formal review as of December 3, 2021.	11/19/2021
13	MHCC requested publication of the notice of formal start of review in the *Maryland Register*	11/19/2021
14	MHCC sent a form requesting comments from Frederick County Department of Health.	11/19/2021
15	Via email, MHCC requested clarification on completeness response.	11/22/2021
16	MHCC received response to request for clarification on completeness response question.	11/29/2021
17	Via emails, MHCC received additional information regarding response to request for additional information.	12/21/2021
18	Via email, MHCC received Addendum B for Dr. Cory Walsh.	12/1/2021
19	Via emails, MHCC received clarification on response for Dr. Cory Walsh.	12/1/2021
20	Via emails, MHCC received additional clarification on response for Dr. Cory Walsh.	12/3/2021
21	Via email, MHCC received response for additional clarification.	12/6/2021
22	Frederick Health Hospital, Inc., submitted comments in opposition to Applicant's CON application and seeks Interested Party status.	12/30/2021
23	MHCC notified applicant regarding receipt of Interested Party Comments from Frederick Health Hospital and information on submission of documents during contested review.	1/6/2022
24	MHCC received from PSCF letter of attestation and revised Addendum B physician surgical case volumes.	1/7/2022
25	Via email, MHCC received updated Table E, Project Budget.	1/13/2022
26	Via email, MHCC notified applicant's that response to Interested Party Comments is due on January 18, 2022.	1/14/2022
27	MHCC received Applicant response to Interested Party Comments.	1/18/2022
28	Exchange of emails between MHCC, Applicant and Interested Party.	3/3/2022
29	Reviewer/Commissioner Trupti Brahmbhatt ruling on interested party status	3/15/2022
30	Applicant and interested party, Frederick Health Hospital, submitted a joint request to MHCC for a stay in the review of the CON application.	3/29/2022

31	Reviewer/Commissioner Trupti Brahmbhatt ruling granting a stay of review	5/2/2022
32	Applicant and interested party, Frederick Health Hospital, request Reviewer to lift the stay.	5/10/2022
33	Via email, Applicant inquires if the MHCC will consider the addition of only one instead of two operating rooms.	6/3/2022
34	Reviewer/Commissioner Trupti Brahmbhatt submitted her ruling lifting the stay on the review and a request for updates regarding Applicant's CON application.	6/9/2022
35	MHCC responded to Applicant's June 3, 2022 email	6/9/2022
36	Applicant submits information in response to the Reviewer's June 9, 2022 request for updates.	6/23/2022
37	Applicant sends charity care information to Barbara A. Brookmyer, MD, Frederick County Health Department.	6/23/2022
38	Interested party response to PSCF's June 23, 2022 updates regarding its CON application.	7/7/2022
39	Exchange of emails between applicant, Interested party, and Barbara Brookmyer, M.D., Frederick County Health Officer, regarding publication of Applicant's Charity Care policy in Frederick News-Post.	7/13/2022 – 7/20/2022
40	Notice of Change in Ownership of Andochick Surgical Center, LLC	7/22/2022
41	Reviewer/Commissioner Trupti Brahmbhatt submitted a second request for information to supplement the record.	8/3/2022
42	Applicant submits response to Reviewer's August 3, 2022 request for information.	8/17/2022
43	Interested Party response to Applicant's August 17, 2022 supplement to its CON application.	8/26/2022

MARYLAND HEALTH CARE COMMISSION

APPENDIX 2:

Organizational Chart



* *Includes Medical Staff Oversight and Peer Review*

** See Tab: Patient Care Committee (PCC)

EXHIBIT 2

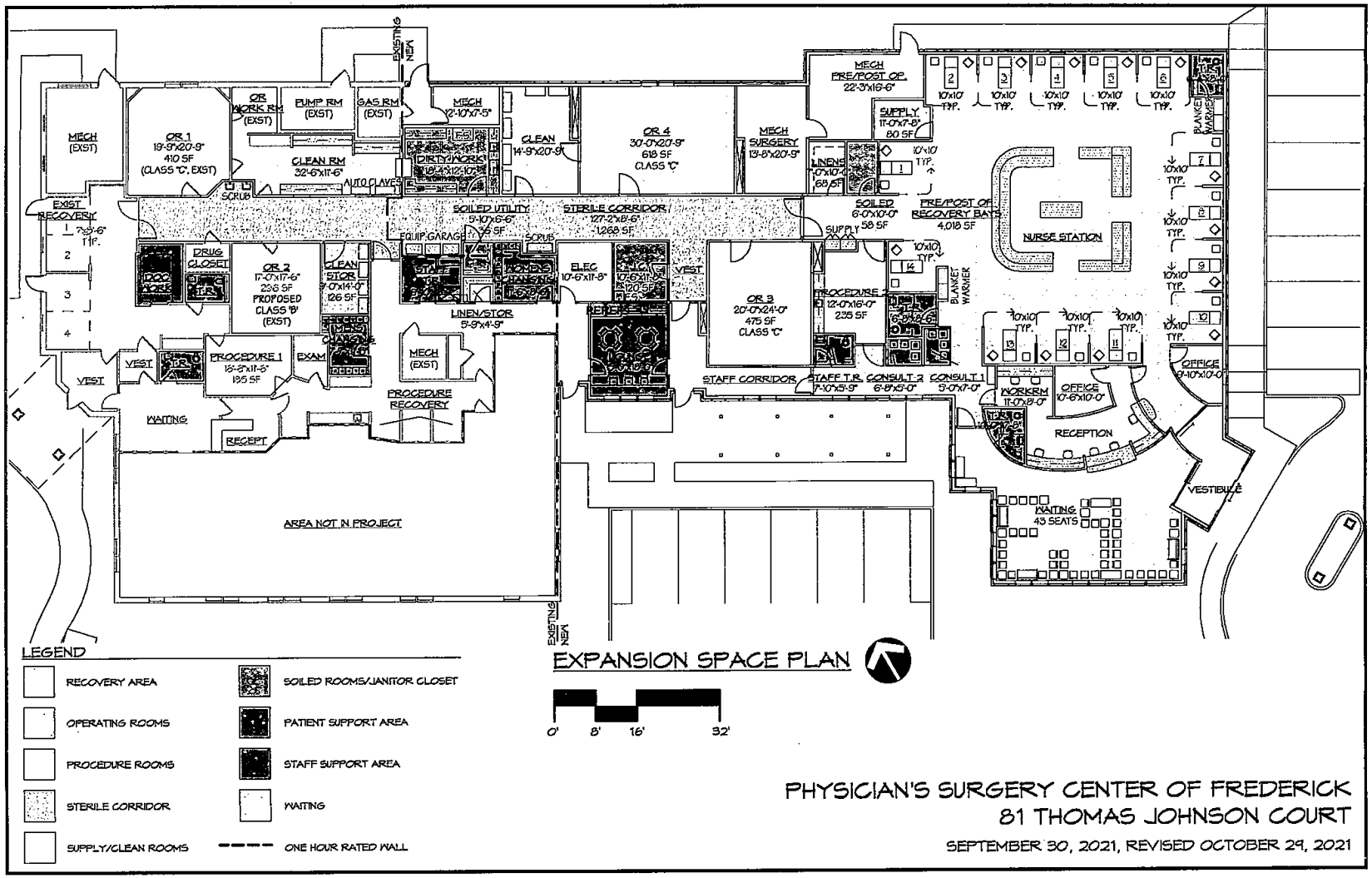
On July 22, 2022, Andochick Surgical Center, LLC, d/b/a Physicians Surgery Center of Frederick, submitted notification to the MHCC regarding a notice for change of ownership. (DI# 40):

Name	Title	% Partnership
Scott Andochick, M.D.	President, Medical Director	31.2%
Kristin Nesbitt Silon, M.D.	Partner, MEC Chair	20.5%
Steve Horton, M.D.	Partner	12.0%
Sunil Thadani, M.D.	Partner	11.2%
Adam Mecinski, M.D.	Partner	11.1%
Matthew Levine, M.D.	Partner	5.0%
Gabe Petruccelli, M.D.	Partner	3.0%
Korboi Evans, M.D.	Partner	3.0%
Samuel Sanders, M.D.	Partner	3.0%

MARYLAND HEALTH CARE COMMISSION

APPENDIX 3:

Project Floor Plans



PHYSICIAN'S SURGERY CENTER OF FREDERICK
81 THOMAS JOHNSON COURT

SEPTEMBER 30, 2021, REVISED OCTOBER 29, 2021

Ex 8

MARYLAND HEALTH CARE COMMISSION

APPENDIX 4:

MARSHALL VALUATION SERVICE REVIEW

Marshall Valuation Service Review

The Marshall Valuation System – what it is, how it works

In order to compare the cost of a proposed construction project to that of similar projects as part of a cost-effectiveness analysis, a benchmark cost is typically developed using the Marshall Valuation Service ("MVS"). 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.

The base cost reported in the MVS guide are based on the actual final costs to the owner and include all material and labor costs, contractor overhead and profit, average architect and engineering fees, nominal building permit costs, and processing fees or service charges and normal interest on building funds during construction. It also includes: normal site preparation costs including grading and excavation for foundations and backfill for the structure; and utilities from the lot line to the structure figured for typical setbacks.

The MVS costs *do not include* costs of buying or assembling land, piling or hillside foundations (these can be priced separately), furnishings and fixtures not found in a general contract, general contingency set aside for some unknown future event such as anticipated labor and material cost increases. Also not included in the base MVS costs are site improvements such as signs, landscaping, paving, walls, and site lighting. Offsite costs such as roads, utilities, and jurisdictional hook-up fees are also excluded from the base costs.[22]

MVS allows staff to develop a benchmark cost using the relevant construction characteristics of the proposed project and the calculator section of the MVS guide. In developing the MVS benchmark costs, the base costs are adjusted for a variety of factors (e.g., an add-on for sprinkler systems, the presence or absence of elevators, number of building stories, the height per story, and the shape of the building. The base cost is also adjusted to the latest month and the locality of the construction project.)

The MVS methodology does not offer data for renovation projects; thus, any effort to compare proposed renovation costs to a benchmark can only be made to the benchmarks for new construction. (In general, the MVS benchmarks are typically higher than the costs estimated by applicants for the renovation portion of projects.) Thus, the $167,800 in renovation costs for 1,065 SF (an average of $157.56 per SF) is below the MVS benchmark of $550.31 per SF calculated for the proposed project.

Developing the MVS Benchmark for the Proposed Project

Both PSCF and the Reviewer performed independent analyses to arrive at MVS benchmark value calculated for the proposed project. PSCF calculated the MVS benchmark value of $411 per SF, while I arrived at an MVS value of $550.31 per SF. Both PSCF and I based its MVS calculations for a Type A, Good Quality construction for an ambulatory surgical facility. PSCF's MVS calculations were submitted as a response to completeness questions in October 2021, and

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

were based on the MVS information that were available at that time. (DI #9, pp. 14-15). The Reviewer's calculations used updated MVS information that was available as of November 2022. These calculated MVS benchmark values are shown below.

Table 1: Calculation of Marshall Valuation Service Benchmark for PSCF Build Out – December 2022

	Applicant Calculation	Reviewer Calculation
	New Construction	New Construction
Class	A	A-B
Quality	Good	Good
Floors	1	1
Square Footage	10,955	10,955
Average Perimeter	444	444
Weighted Average Wall Height	10	10
Gross Base Cost		$481.00
Perimeter Multiplier		0.951
Story Height Multiplier		0.953
Multipliers		0.906
Refined Square Foot Cost		$435.91
Sprinkler Add-on		$5.65
Adjusted Refined Square Foot cost		$441.56
Current Cost Modifier		1.21
Local Multiplier - Silver Spring		1.03
CC & Local Multipliers		1.246
MVS Building Cost Per SF	$411.00	$550.31
Building Square Footage	10,955	10,955
MVS Building Costs	$4,502,505	$6,028,698
Final MVS Cost Per Square Foot	$411.00	$550.31

Source: DI #9, pp. 14-15
DI #36, Exh. 3 and 4.

PSCF utilized the Marshall Swift CoreLogic Swift Estimator program to assist it in arriving at the $411 per SF MVS benchmark value, using data that was available to the applicant as of October 2021. (DI #9, pp. 14-15 and Exh. 28). The Reviewer used the most current MVS data that was reported as of November 2022 to calculate MVS benchmark value. The timeliness of the data used and external factors such as the Covid pandemic and the increase in costs for labor and construction materials play a significant factor in the difference in calculated MVS benchmark values between the applicant and the Reviewer.

Comparing Estimated Project to the MVS Benchmark

PSCF estimates the allowable cost of building out 10,955 SF in shell space constructed by the landlord is $156.35 per SF, while the Reviewer calculated a cost of $160.10 per SF, a difference of $3.75 per SF (about 2.3% difference). Please see Table 2 below for these calculations.

Table 2: PSCF and Reviewer's Comparison of Allowable Construction Costs to Marshall Valuation Service Benchmark

	Applicant	Reviewer
Building	$1,913,800	$1,913,800
Fixed Equipment	$50,000	$50,000
Arch./Eng. Fees	$140,500	$140,500
Permits	$33,500	$33,500
Subtotal	$2,137,800	$2,137,800
Adjustments-Exclude from MVS		
Site Demolition	$25,000	$25,000
Storm Drains	$30,000	$30,000
Rough Grading	$40,000	$40,000
Paving	$60,000	$60,000
Exterior Signs	$7,500	$7,500
Landscaping	$22,000	$22,000
Yard Lighting	$10,000	$10,000
Storm Water Management	$230,500	$230,500
Total Site & Off-site Costs excluded from MVS (subtract)	$425,000	$425,000
Net Project Costs	$1,712,800	$1,712,800
Allocated Financing Exp. (add)	0	$40,387
Project Cost for MVS Comp	$1,712,800	$1,753,873
Square Footage	10,955	10,955
Cost Per Square Ft.	$156.35	$160.10
Adj. MVS Cost/Square Foot	$411.00	$550.31
Over(Under)	($254.65)	($390.22)
Over(Under) Costs	($2,789,705)	($4,274,825)

Source: DI #9, pp. 14-15
DI #36, Exh. 3 and 4.

As shown above, the difference in allowable construction costs is that I included a proportion of the Allocated Construction Financing Costs ($65,000), which the applicant did not take into consideration.

Both the applicant and the Reviewer indicate that the allowable construction costs to build out the 10,955 SF in shell space do not exceed the MVS benchmark. PSCF indicates that the calculated allowable construction cost of $156.35 per SF does not exceed the MVS benchmark of $411 per SF; the Reviewer shows that the calculated allowable construction cost of $160.10 per SF is less than the MVS benchmark of $550.31 per SF.

MARYLAND HEALTH CARE COMMISSION

APPENDIX 5:

Project Budget

PSCF - PROJECT BUDGET

	PSCF Build Out and Renovations	*Landlord/ Building*	*Total Cost*
USE OF FUNDS			
CAPITAL COSTS			
New Construction			
Building	$1,913,800	$1,681,200	$3,595,000
Fixed Equipment	$50,000	$0	$50,000
Site and Infrastructure	$0	$425,000	$425,000
Development Fees		$18,500	$18,500
Architect/Engineering Fees	$140,500	$154,500	$295,000
Permits (Building, Utilities, Etc.)	$33,500	$31,500	$65,000
SUBTOTAL	**$2,137,800**	**$2,310,700**	**$4,448,500**
Renovations			
Building	$127,800	$0	$127,800
Architect/Engineering Fees	$35,000	$0	$35,000
Permits (Building, Utilities, Etc.)	$5,000	$0	$5,000
SUBTOTAL	**$167,800**	**$0**	**$167,800**
Other Capital Costs			
Movable Equipment	$300,000	$0	$300,000
Contingency Allowance	$105,000	$95,000	$200,000
SUBTOTAL	***$405,000***	***$95,000***	**$500,000**
TOTAL CURRENT CAPITAL COSTS	**$2,710,600**	**$2,405,700**	**$5,116,300**
Land Purchase		$375,000	$375,000
TOTAL CAPITAL COSTS	**$2,710,600**	**$2,780,700**	**$5,491,300**
Financing Cost and Other Cash Requirements			
Loan Placement Fees	**$11,000**	**$10,000**	$21,000
CON Application Assistance	$10,000		$10,000
Phase 1 Hazard Ins.		$7,500	$7,500
Flood Plain Cert		$2,500	$2,500
Construction Financing	$65,000	$51,000	$116,000
Startup Operations	$8,700	$0	$8,700
SUBTOTAL	***$94,700***	***$71,000***	**$165,700**
Working Capital Startup Costs			$0
TOTAL USES OF FUNDS	***$2,805,300***	***$2,851,700***	***$5,657,000***
SOURCE OF FUNDS			
Cash	$550,000	$500,000	$1,050,000
Mortgage	$58,000		$58,000
Working Capital Loans	$2,197,300	$1,976,700	$4,174,000
Owner Contribution of Land	$0	$375,000	$375,000
TOTAL SOURCES OF FUNDS	***$2,805,300***	***$2,851,700***	**$5,657,000**

Source: DI #41, Exhibit 1, Table E

MARYLAND HEALTH CARE COMMISSION

APPENDIX 6:

FREDERICK HEALTH HOSPITAL'S

OPERATING ROOM NEED ANALYSIS

FOR PHYSICIANS SURGERY CENTER OF FREDERICK

Frederick Health Hospital Operating Room Need Analysis –
Impact of PSCF Assumptions on Overall Volume Projections

PSCF Assu111ptions	Note	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**
Surgical Cases	**A**	2,060	2,865	3,275	37,800	4,175	
Surgical Minutes	**B**	108,883	151,845	196,500	222,000	250,500	274,500
Turn-Around-Times	**C**	1.566	2.177	2.489	28.728	3.173	
Total Minutes	D	110,449	154,022	198,989	250,728	253,673	277,977
Hours	E	1,841	2,567	3,316	4,179	4,228	4,633
State Minimum	F	1,632	1,632	1,632	1,632	1,632	1,632
Number OR(s) Needed	G	**1.13**	**1.57**	**2.03**	**2.56**	**2.59**	**2.84**
Technically Incorrect Assumptions							
Steinberg Leaving	**H**		(0.34)	(0.41)	(0.43)	(0.45)	(0.47)
CMS IPO List (5%)	**I**		(0.12)	(0.17)	(0.19)	(0.22)	(0.25)
Reconciled TAT	**J**		(0.13)	(0.18)	(0.20)	(0 23)	(0.26)
Adjusted Number of OR	K		**(0.59)**	**(0.76)**	**(0.83)**	**(0.89)**	**(0.97)**
Actual Number OR(s) PSCF Needs	L		**0.98**	**1.27**	**1.74**	**1.70**	**1.86**

[1] **Table Notes and Assumptions:**

A - The number of projected surgical cases for the facility, Standard 0.05B(9) Impact, page 36.

B - Surgical minutes abstracted from Table 2: Statistical Projections, page 41.

C - Turn-around-time at 25 minutes per case, does not include first and last case or 24% of cases.

D - Surgical minutes+ Turn-around-times.

E - Total surgical minutes divided by 60 to establish hours.

F - State minimum is per operating room.

G - Total projected surgical hours divided by the State minimum.

H - Projected surgical cases by provider, Standard 0.05(9)(i) Impact, page 36, multiplied by 90 minutes average procedure (ii) time for Dr. Steinburg.

I - Total cases projected reduced by 5%, multiplied by 90 minutes and accounting for turn-around-time that would not be required. This assumes conservatively that only 5% of Applicant's projected **volume was from now IPO precede.**

J - An average number of cases per day (251 days) is equal to 8 - first and last cases (2) = 6 cases with Turn-around-Time. 6/8 = 76%.