Health Care Transformation and Strategic Planning
3910 Keswick Road, Suite N-2200
Baltimore MD 21211
443-997-0731 Fax

JOHNS HOPKINS
MEDICINE

02/08/2019

Kevin McDonald
Chief, Certificate of Need
4160 Patterson Avenue
Baltimore, Maryland 21215

RE: White Marsh Surgery Center Certificate of Need Application

Dear Mr. McDonald:

Please see enclosed Certificate of Need application submitted by the Johns Hopkins Surgery Center Series ("JHSCS") for the addition of a second operating room to the existing White Marsh Surgery Center. Opened in 2007, the White Marsh Surgery Center, a member of JHSCS, is a multispecialty, one operating room, two procedure room Physician Outpatient Surgery Center located in the Johns Hopkins Health Care and Surgery Center, 4924 Campbell Blvd, White Marsh, Maryland 21236.

I certify that a copy of this application will be sent to the Baltimore County Health Department, which is the local planning agency.

Thank you for your consideration of this matter. I look forward to working with you and your staff during its review. I am available if you have any questions or would like additional information.

Sincerely,

Spencer Wildonger
Director of Health Planning
swildon1@jhmi.edu
443-997-0742

cc: Gregory Wm. Branch, MD, MBA, CPE, FACP, Health Officer, Baltimore County

Certificate of Need Application
White Marsh Surgery Center

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PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: White Marsh Surgery Center

Address:

4924 Campbell Boulevard Suite 250	White Marsh	21236	Baltimore County
Street	**City**	**Zip**	**County**

2. Name of Owner Johns Hopkins Surgery Centers Series

If Owner is a Corporation, Partnership, or Limited Liability Company, attach a description of the ownership structure identifying all individuals that have or will have at least a 5% ownership share in the applicant and any related parent entities. Attach a chart that completely delineates this ownership structure.

See Exhibit 1.

3. APPLICANT. *If the application has a co-applicant, provide the following information in an attachment.*

Legal Name of Project Applicant (Licensee or Proposed Lice

Johns Hopkins Surgery Centers
Series

Address:

2330 West Joppa Road, Suite 301	Lutherville	21093	MD	Baltimore County
Street	**City**	**Zip**	**State**	**County**

Telephone:

4. NAME OF LICENSEE OR PROPOSED LICENSEE, if different from the applicant:

Same as Applicant.

5. LEGAL STRUCTURE OF APPLICANT (and LICENSEE, if different from applicant).

Check ☑ or fill in applicable information below and attach an organizational chart showing the owners of applicant (and licensee, if different).

A.	Governmental	☐	
B.	Corporation		
	(1) Non-profit	☐	
	(2) For-profit	☐	
	(3) Close	☐	State & Date of Incorporation
C.	Partnership		
	General	☐	
	Limited	☐	
	Limited Liability Partnership	☐	
	Limited Liability Limited Partnership	☐	
	Other (Specify):		
D.	Limited Liability Company	☐	
E.	Other (Specify):	☒	Johns Hopkins Surgery Centers Series is an independent series of JH Ventures, LLC which is a limited liability company organized under Delaware law. (Exhibit 1)
	To be formed:	☐	
	Existing:	☐	

6. PERSON(S) TO WHOM QUESTIONS REGARDING THIS APPLICATION SHOULD BE DIRECTED

A. Lead or primary contact:

Name and Title: Anne Langley, Senior Director, Health Planning and Community Engagement

Company Name: Johns Hopkins Health System

Mailing Address:

3910 Keswick Road, Suite N-2200	Baltimore	21211	MD
Street	**City**	**Zip**	**State**

Telephone: 443-997-0727

E-mail Address (required): alangle2@jhmi.edu

Fax: 443-997-0731

If company name is different than applicant briefly describe the relationship N/A

B. Additional or alternate contact:

Name and Title: Spencer Wildonger, Director of Health Planning

Company Name: Johns Hopkins Health System

Mailing Address:

3910 Keswick Road, Suite N-2200	Baltimore	21211	MD
Street	**City**	**Zip**	**State**

Telephone: 443-997-0742

E-mail Address (required): swildon1@jhmi.edu

Fax: 443-997-0731

If company name is different than applicant briefly describe the relationship N/A

7. TYPE OF PROJECT

The following list includes all project categories that require a CON pursuant to COMAR 10.24.01.02(A). Please mark all that apply in the list below.

If approved, this CON would result in (check as many as apply):

(1) A new health care facility built, developed, or established ☐

(2) An existing health care facility moved to another site ☐

(3) A change in the ~~bed~~ OR capacity of a health care facility ☒

(4) A change in the type or scope of any health care service offered by a health care facility ☐

(5) A health care facility making a capital expenditure that exceeds the current threshold for capital expenditures found at: http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/con_capital_threshold_20140301.pdf ☐

8. PROJECT DESCRIPTION

A. Executive Summary of the Project: The purpose of this BRIEF executive summary is to convey to the reader a holistic understanding of the proposed project: what it is, why you need to do it, and what it will cost. A one-page response will suffice. Please include:

(1) Brief Description of the project – what the applicant proposes to do
(2) Rationale for the project – the need and/or business case for the proposed project
(3) Cost – the total cost of implementing the proposed project

Renovate an existing Physician Outpatient Surgery Center ("POSC"), adding a second operating room to a facility that currently has one operating room and two procedure rooms.

B. Comprehensive Project Description: The description should include details regarding:

(1) Construction, renovation, and demolition plans
(2) Changes in square footage of departments and units
(3) Physical plant or location changes
(4) Changes to affected services following completion of the project
(5) Outline the project schedule.

Johns Hopkins Surgery Centers Series ("JHSCS") applies for a Certificate of Need to renovate existing space within the Johns Hopkins Health Care and Surgery Center at White Marsh for the addition of a second operating room for the White Marsh Surgery Center ("WMSC"). The Johns Hopkins Health Care and Surgery Center at White Marsh is located at 4924 Campbell Road, Suite 200, White Marsh, MD, 21236. Opened in 2007, the White Marsh Surgery Center, a member of JHSCS, is a multi-specialty, one operating room, two procedure room Physician Outpatient Surgery Center.

Johns Hopkins Surgery Centers Series is a limited liability company series formed under JH Ventures, LLC on March 22, 2007. The Johns Hopkins Health System Corporation and the Johns Hopkins University each own 50 percent of JHSCS. The business address is 2330 West Joppa Road, Suite #301, Lutherville, Maryland 21093.

In 2007, the JHSCS (formerly White Marsh Surgery Center Series) sought and received a determination of coverage from the Maryland Health Care Commission ("MHCC"), allowing the development of a facility with one operating room and two procedure rooms in an office setting at 4924 Campbell Boulevard, Suite 250, White Marsh, Maryland, 21236. See Exhibit 2 for a copy of the letter.

A second operating room is needed at the WMSC to accommodate outpatient surgical cases currently being performed at Johns Hopkins Bayview Medical Center ("JHBMC"). JHBMC is an acute care hospital that is part of Johns Hopkins Health System located in Baltimore City, about 10 miles south west of the WMSC. Additional capacity in the form of a second operating room at the WMSC is an essential component of Johns Hopkins Medicine's vision for providing robust, high-quality outpatient surgical care in an ambulatory setting. This vision includes increasingly performing outpatient surgical procedures in the most cost-effective and medically-appropriate practice setting. Additional ambulatory operating room capacity at the WMSC is critical to achieving these goals and caring for JHM patients in the coming years.

The estimated project cost is $1,050,000.

9. Current Capacity and Proposed Changes:

Service	Unit Description	Currently Licensed/ Certified	Units to be Added or Reduced	Total Units if Project is Approved
Ambulatory Surgery	Operating Rooms	1	1	2
	Procedure Rooms	2	-	2

10. Identify any community based services that are or will be offered at the facility and explain how each one will be affected by the project.

Applicant Response:

Inapplicable.

11. REQUIRED APPROVALS AND SITE CONTROL

A. Site size: 9,883 SF currently and 10,787 upon completion ~~acres~~ square feet

B. Have all necessary State and local land use and environmental approvals, including zoning and site plan, for the project as proposed been obtained?

YES_____ NO __X___

(If NO, describe below the current status and timetable for receiving each of the necessary approvals.)

Once the Certificate Of Need is obtained, the applicant will submit its renovation documents to Baltimore County for the necessary permits. The applicant anticipates the permitting process will take approximately two months.

C. Form of Site Control (Respond to the one that applies. If more than one, explain.):

(1) Owned by: _____

(2) Options to purchase held by: _____

Please provide a copy of the purchase option as an attachment.

(3) Land Lease held by: _____

Please provide a copy of the land lease as an attachment.

(4) Option to lease held by: Johns Hopkins Surgery Center Series (formerly White Marsh Surgery Center Series)

Please provide a copy of the option to lease as an attachment.

(5) Other: _____

Explain and provide legal documents as an attachment.

Please see Exhibit 3 for additional lease details.

12. PROJECT SCHEDULE
(INSTRUCTION: IN COMPLETING THE APPLICABLE OF ITEMS 10, 11 or 12, PLEASE CONSULT THE PERFORMANCE REQUIREMENT TARGET DATES SET FORTH IN COMMISSION REGULATIONS, COMAR 10.24.01.12)

For new construction or renovation projects.
Project Implementation Target Dates

A. Obligation of Capital Expenditure ____6____ months from approval date.

B. Beginning Construction _____2_____ months from capital obligation.

C. Pre-Licensure/First Use _____6_____ months from capital obligation.

D. Full Utilization _____12_____ months from first use.

For projects not involving construction or renovations.
Project Implementation Target Dates

A. Obligation or expenditure of 51% of Capital Expenditure ___N/A_____ months from CON approval date.
B. Pre-Licensure/First Use _____N/A_____ months from capital obligation.
C. Full Utilization _____N/A_____ months from first use.

For projects not involving capital expenditures.
Project Implementation Target Dates

A. Obligation or expenditure of 51% Project Budget ___N/A_____ months from CON approval date.
B. Pre-Licensure/First Use _____N/A_____ months from CON approval.
C. Full Utilization _____N/A_____ months from first use.

13. PROJECT DRAWINGS

Projects involving new construction and/or renovations should include scalable schematic drawings of the facility at least a 1/16” scale. Drawings should be completely legible and include dates.

These drawings should include the following before (existing) and after (proposed), as applicable:

A. Floor plans for each floor affected with all rooms labeled by purpose or function, number of beds, location of bath rooms, nursing stations, and any proposed space for future expansion to be constructed, but not finished at the completion of the project, labeled as “shell space”.

B. For projects involving new construction and/or site work a Plot Plan, showing the "footprint" and location of the facility before and after the project.

C. Specify dimensions and square footage of patient rooms.

Applicant Response:

Please see Exhibit 4 for project drawings.

14. FEATURES OF PROJECT CONSTRUCTION

A. If the project involves new construction or renovation, complete Tables C and D of the Hospital CON Application Package

B. Discuss the availability and adequacy of utilities (water, electricity, sewage, natural gas, etc.) for the proposed project and identify the provider of each utility. Specify the steps that will be necessary to obtain utilities.

All utilities exist on site.

Applicant Response:

Please see Exhibit 5 for Table C

Table D is not applicable.

PART II - PROJECT BUDGET

Complete Table E of the Hospital CON Application Package

Note: Applicant should include a list of all assumptions and specify what is included in each budget line, as well as the source of cost estimates and the manner in which all cost estimates are derived. Explain how the budgeted amount for contingencies was determined and why the amount budgeted is adequate for the project given the nature of the project and the current stage of design (i.e., schematic, working drawings, etc.).

Applicant Response:

Please see Exhibit 6 for Table E.

White Marsh Surgery Center
Statement of Assumptions

- Revenue
  - Volume has been covered elsewhere in the application.
  - Reimbursement by specialty is based on the experience at White Marsh Surgery Center (WMSC).
  - Gross Revenue is based on expected billing rates (2.66 times Net Reimbursement by specialty) Establishing billing rates at an inflated rate is a standard practice in the Ambulatory Surgery industry. Patients, either through their third party payer or as a self-pay patient do not generally pay these billing rates (reflected in Gross Revenue).
  - Allowance for Bad Debts and Charity Care are based on experience at WMSC.
- Expenses
  - Salaries & Wages are based on WMSC experience as to number of personnel needed for each staffing area Rate of pay is based on current WMSC salary rates.
  - Benefit costs are based on WMSC experience and is comprised of payroll taxes, health insurance premiums, incentives, and employer 401(k) match. Benefit costs are 22.5% of Salary, which is based on WMSC experience.
  - There is no Project Debt because the Project will be funded by retained equity of WMSC.
  - Project Depreciation – Major Movable Equipment is being depreciated over five years; Renovations are being depreciated over fifteen years.
  - Medical Supplies are based on the experience of WMSC.
  - Incremental Rent is based on terms of lease for the additional space – 1,187 sq. feet @ $28.93 per sq. ft.
  - Drugs are based on experience at WMSC.

- Minor Equipment is an estimate of small equipment items which will be required based on experience at WMSC (Johns Hopkins capitalization policy requires an item to be a minimum of $5,000 before it can be capitalized).
- Equipment Maintenance is an estimate based on the equipment being purchased and experience at WMSC.
- Office Expense is based on experience at WMSC.
- Laundry Expense is based on experience at WMSC.
- Pentax Image Capture expense is the expense allocated by Johns Hopkins Health System to support the GI image capture system.
- EPIC will be implemented at WMSC on January 1, 2020. The EPIC charge is the expense allocation being charged by Johns Hopkins Health System for support of the system.
- Other expenses are based on regulatory requirements and experience at WMSC.

PART III - APPLICANT HISTORY, STATEMENT OF RESPONSIBILITY, AUTHORIZATION AND RELEASE OF INFORMATION, AND SIGNATURE

1. List names and addresses of all owners and individuals responsible for the proposed project and its implementation.

   W. Gill Wylie, President
   Johns Hopkins Surgery Center Series
   2330 W. Joppa Road, Suite 301
   Lutherville, MD 21093

2. Are the applicant, owners, or the responsible persons listed in response to Part 1, questions 2, 3, 4, 7, and 9 above now involved, or have they ever been involved, in the ownership, development, or management of another health care facility? If yes, provide a listing of these facilities, including facility name, address, and dates of involvement.

   Johns Hopkins at Green Spring Station
   10755 & 10753 Falls Road
   Lutherville, MD 21093
   1993-present

   Johns Hopkins at White Marsh
   4924 Campbell Boulevard
   White Marsh, MD 21236
   1998-present

   Odenton Medical Pavilion
   1106 Annapolis Road
   Odenton, MD 21113
   2003-present

   White Marsh Surgery Center
   4924 Campbell Boulevard
   White Marsh, MD 21236
   2007-present

   Green Spring Station Surgery Center
   2330 West Joppa Road
   Lutherville, MD 21093
   To Open Later in 2019

3. Has the Maryland license or certification of the applicant facility, or any of the facilities listed in response to Question 2, above, been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) in the last 5 years? If yes, provide a written explanation of the circumstances, including the date(s) of the actions and the disposition. If the applicant, owners or individuals responsible for implementation of the Project were not involved with the facility at the time a suspension, revocation, or disciplinary action took place, indicate in the explanation.

   No

4. Other than the licensure or certification actions described in the response to Question 3, above, has any facility with which any applicant is involved, or has any facility with which any applicant has in the past been involved (listed in response to Question 2, above) received inquiries in last from 10 years from any federal or state authority, the Joint Commission, or other regulatory body regarding possible non-compliance with any state, federal, or Joint Commission requirements for the provision of, the quality of, or the payment for health care services that have resulted in actions leading to the possibility of penalties, admission bans, probationary status, or other sanctions at the applicant facility or at any facility listed in response to Question 2? If yes, provide for each such instance, copies of any settlement reached, proposed findings or final findings of non-compliance and related documentation including reports of non-compliance, responses of the facility, and any final disposition or conclusions reached by the applicable authority.

   No

5. Have the applicant, owners or responsible individuals listed in response to Part 1, questions 2, 3, 4, 7, and 9, above, ever pled guilty to or been convicted of a criminal offense in any way connected with the ownership, development or management of the applicant facility or any of the health care facilities listed in response to Question 2, above? If yes, provide a written explanation of the circumstances, including as applicable the court, the date(s) of conviction(s), diversionary disposition(s) of any type, or guilty plea(s).

   No

One or more persons shall be officially authorized in writing by the applicant to sign for and act for the applicant for the project which is the subject of this application. Copies of this authorization shall be attached to the application. The undersigned is the owner(s), or Board-designated official of the proposed or existing facility.

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information and belief.

2/5/2019
Date

Signature of Owner or Board-designated Official
President, Johns Hopkins Surgery Center Series
Position/Title
Walker G. Wylie
Printed Name

PART IV - CONSISTENCY WITH GENERAL REVIEW CRITERIA AT COMAR 10.24.01.08G(3):

INSTRUCTION: Each applicant must respond to all criteria included in COMAR 0.24.01.08G(3), listed below.

An application for a Certificate of Need shall be evaluated according to all relevant State Health Plan standards and other review criteria.

If a particular standard or criteria is covered in the response to a previous standard or criteria, the applicant may cite the specific location of those discussions in order to avoid duplication. When doing so, the applicant should ensure that the previous material directly pertains to the requirement and to the directions included in this application form. Incomplete responses to any requirement will result in an information request from Commission Staff to ensure adequacy of the response, which will prolong the application's review period.

10.24.01.08G(3)(a). <u>The State Health Plan</u>.

Every applicant must address each applicable standard in the chapter of the State Health Plan for Facilities and Services[1]. Commission staff can help guide applicants to the chapter(s) that applies to a particular proposal.

Please provide a direct, concise response explaining the project's consistency with each standard. Some standards require specific documentation (e.g., policies, certifications) which should be included within the application as an exhibit.

[1] [1] Copies of all applicable State Health Plan chapters are available from the Commission and are available on the Commission's web site here:http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp

COMAR 10.24.11 GENERAL SURGICAL SERVICES

.05 Standards.

A. General Standards.

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

(1) Information Regarding Charges.

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

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

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

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

Applicant Response:

(a) WMSC makes information regarding charges for the full range of surgical services provided readily available to the public, upon inquiry, or as required by applicable regulations or laws.

(b) The applicant is not aware of any complaints to the Consumer Protection Division of the Office of the Attorney General of Maryland or the Maryland Insurance Administration.

(c) The applicant understands that making this information available shall be a condition of any CON issued by the Commission.

(2) Information Regarding Procedure Volume.

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

Applicant Response:

The WMSC provides to the public upon inquiry information concerning the volume of specific surgical procedures performed.

For a list of the top CPT codes for the WMSC for FY18, please see Exhibit 7.

(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.

(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.

(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.

Applicant Response:

(a) It is the policy of Johns Hopkins Medicine to provide financial assistance based on indigence or high medical expenses for patients who meet specified financial criteria and request such assistance. The WMSC provides medically necessary care, free of charge or at a reduced rate, for patients who meet the Johns Hopkins Surgery Center Series ("JHSCS") Financial Assistance Policy criteria (Exhibit 8).

(a)(i) The policy requires, and WMSC provides, a determination of probable eligibility within two business days.

Please see Charity Care POLICY, Page 1, *Procedures*, 3, a:

"All Financial Assistance applications will be processed within two business days and a determination will be made as to probable eligibility…"

(a)(ii) Please see Charity Care POLICY, Page 1, *Purpose*, paragraph 2:

"Ambulatory Surgery Centers that are part of the JHSCS will provide notice and information of the facility's charity care policy through methods designed to reach the service area's population. Notice will be posted at all patient registration sites and in the business office of the facility. Prior to a patient's arrival for surgery, facilities shall address any financial concerns of patients, and individual notice regarding the facility's Financial Assistance policy shall be provided to the patient."

(a)(iii) Please see Charity Care POLICY, Page 2, 8:

"8. Patients who have health coverage and are at or below 200% of Federal Poverty Guidelines can ask for help with out of pocket expenses (co-payments and deductibles) for medical costs resulting from medically necessary care and shall be required to submit a Financial Assistance Application."

Please see Charity Care POLICY, Page 2, 9:

"9. The JHSCS Financial Assistance Policy is consistent with the current policy for The Johns Hopkins Hospital (JHH), Johns Hopkins Bayview Medical Center, Inc. Acute Care Hospital and Special Programs (JHBMC), and the Chronic Specialty Hospital of the Johns Hopkins Bayview Care Center (JHBCC), with respect to the determination of financial assistance allowances. If a patient is determined eligible for financial assistance at JHH, JHBMC, or JHBCC and is at or below 200% of the Federal Poverty Line, he or she is deemed eligible for JHSCS Financial Assistance."

Please see Charity Care POLICY, Page 4, 4:

"4. Patients will be eligible for Financial Assistance if their maximum family (husband and wife, same sex married couples) income (as defined by Medicaid regulations) level does not exceed 200% of the Federal poverty guidelines that are currently in effect."

(3) Charity Care Policy.

(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.

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

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

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

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

(d) A health maintenance organization, acting as both the insurer and provider of health care services for members, if applying for a Certificate of Need for a surgical facility project, shall make a commitment to provide charitable services to indigent patients. Charitable services may be surgical or non-surgical and may include charitable programs that subsidize health plan coverage. At a minimum, the amount of charitable services provided as a percentage of total operating expenses for the health maintenance organization will be equivalent to the average amount of charity care provided statewide by ASFs, measured as a percentage of total ASF expenses, in the most recent year reported. The applicant shall demonstrate that:

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

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

(iii) If the health maintenance organization's track record is not consistent with the expected level for the population in the proposed service area, the applicant shall demonstrate that its historic level of charity care was appropriate to the needs of the population in the proposed service area.

Applicant Response:

(b) Standard does not apply.

(c)(i) The applicant commits to provide charitable surgical services to indigent patients that is equivalent to at least the average amount of charity care provided by ASFs in Maryland in the most recent year reported, measured as a percentage of total operating expenses.

The most recently reported average level of charity care by ASFs in Maryland is 0.52% of total operating expenses.[2]

The White Marsh Surgery Center's track record in the provision of charitable health care facility services is as follows:

	FY2015	FY2016	FY2017	FY2018
Total Operating Expenses	$ 2,421,484	$ 2,683,111	$ 3,012,485	$ 3,617,225
Charity Care	$ 5,196	$ 21,581	$ 7,002	$ 30,484
% Charity Care	**0.21%**	**0.80%**	**0.23%**	**0.84%**

The applicant exceeded the statewide average of 0.52% in FY18 and FY16.

Prior to the beginning of FY18, the WMSC evaluated its internal processes regarding the provision of charity care. As a result, the following were actions taken:

- When scheduling patients, the WMSC accepts charity approval from other Johns Hopkins entities (provided by the patient) and treats the case as a charity case;
- The WMSC sends its third billing statement (for outstanding balances that have not been paid) with information in the form of a letter noting the availability of the charity program and an application.
- The WMSC calls patients with large, outstanding balances. During that call, the WMSC makes the patient aware of the charity program and offers to send an application.

As a result of these actions, WMSC provided more charity care in FY18 than any previous year. Through the mid-point of FY19, the WMSC has provided $31,540 of charity care, already surpassing its previous historical high for the provision of charity care.

At the end of FY19, the WMSC will have exceeded the statewide average in three of the previous four years. WMSC's recent track record and the success of the FY18 action plan for increasing charity care suggest that WMSC will meet or exceed the statewide average for charity

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[2] In the MHCC's "In The Matter Of Innovations Surgery Center, P.C. - Docket No. 18-15-EX001 - Staff Report & Recommendation - Exemption From Certificate Of Need To Establish An Ambulatory Surgical Facility" (Available here: http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con/documents/2018_decisions/chcf_innovations_exemption_20180621.pdf), MHCC staff notes the following:

> "… the 2016 statewide reported average level of charity care by ASFs (0.52% of total operating expenses)" [Page 4, paragraph 1]

care in future years.

(c)(ii) See answer to (c)(i) above

(c)(iii) See answer to (c)(i) above

(d) Standard does not apply.

(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.

Applicant Response:

(a) WMSC is licensed, in good standing, by the Maryland Department of Health. Please see Exhibit 10.

(4) Quality of Care.

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

Applicant Response:

(b) Standard does not apply.

(4) Quality of Care.

(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.

Applicant Response:

(c)(i) WMSC is in compliance with the conditions of participation of the Medicare and Medicaid programs; see Exhibit 9.

(c)(ii) Please see Exhibit 11 for WMSC's Joint Commission Accreditation.

(c)(iii)

Performance Quality Measures Adopted By CMS

WMSC is enrolled in the recently-initiated CMS Ambulatory Surgery Center Quality Reporting (ASCQR) Program. Please see Exhibit 12.

JHM Ambulatory Surgery Quality Council

JHM has a robust patient safety and quality infrastructure for ambulatory surgery centers including the JHM Ambulatory Surgery Quality Council (ASQC). The mission of the JHM ASQC, with representation from each of Hopkins' nine ambulatory surgery centers, is to provide exceptional high quality patient-centered care at all Johns Hopkins Medicine Ambulatory Surgery Centers, and an experience consistent at all sites. The ASQC leadership team includes:

- A physician lead
- The director of Johns Hopkins Medical Management Corporation
- A regulatory representative
- A quality representative
- The medical director and nurse manager from each ASC
- An infection control specialist

While each center coordinates its own regulatory and quality compliance independently at the site level, the ASQC allows the sites to draw on best practices from across the health system, learning from each other to provide the safest, highest quality patient-centered care. Each ASC reports quality data to the ASQC dashboard. The ASQC dashboard data are then reviewed at the Patient Safety and Quality subcommittee of the JHM Board of Trustees. The dashboard, to which all members of the ASQC have access, is robust, and includes numerous measures including surgical site infections (SSI), hand hygiene, burns, falls, unexpected transfers/admissions, wrong site/patient/procedure, prophylactic antibiotic timing, adverse drug reactions, grievances, complications other than SSI, and code/cardiac arrest. Each ASC is responsible for quarterly data entry into the dashboard, and the data are constantly monitored by the ASQC leadership. Targeted interventions, when needed, are designed by the ASQC leadership team.

The JHM ASQC meets bi-monthly. The ASQC's objectives are to:

1.) Oversee operations and standardization of Johns Hopkins ASC services.
2.) Monitor regulatory compliance.
3.) Monitor and report quality measures from all of the Johns Hopkins ASCs.

ASQC meetings include nursing and physician representatives from each ASC, as well as regulatory representatives for risk management, infection control, and quality. The ASQC oversees regulatory measurement from oversight bodies that include: The Joint Commission, the Centers for Medicare and Medicaid, and Department of Health and Mental Hygiene CDS reporting.

(4) Quality of Care.

(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.

(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.

Applicant Response:

(d) Standard does not apply.

(e) Standard does not apply.

(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.

Applicant Response:

(a) The White Marsh Surgery Center has existing transfer and referral agreements with two hospitals, the Franklin Square Hospital Center and the Johns Hopkins Bayview Medical Center, both located near WMSC. The transfer agreements are included as Exhibit 13.

(b) The Standard does not apply.

(c) Additionally, both transfer agreements exceed the minimum requirements in COMAR 10.05.05.09, which includes the written transfer agreement with a local Medicare participating hospital, mechanisms for notifying the hospital and arranging appropriate transportation to the hospital, and a manner in which a facility sends a copy of the patient's medical record to the hospital. Information regarding these requirements is in *Section 2. Conditions of Transfer* in the transfer agreements.

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) <u>Service Area.</u>

An applicant proposing to establish a new hospital providing surgical services or a new ambulatory surgical facility shall identify its projected service area. An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall document its existing service area, based on the origin of patients served.

Applicant Response:

Please see Exhibit 14 for the WMSC Primary (first 60%) and Secondary (next 25%) Service Area map and zip codes list.

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

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

(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.

Applicant Response:

(a)

White Marsh Surgery Center – Historical OR Volume

Specialty	Surgeon	OR Volume Performed at WMSC		
		FY2016	FY2017	FY2018
ORTHO	Wilckens	220	238	226
	Humbyrd	96	109	168
	Ingari	94	86	79
	Zikria	91	99	9
	Ficke	-	-	1
	Tanaka	14	-	-
	Cosgera	2	-	-
ENT	Boahene	82	102	92
	Ishii	107	89	82
Plastics	Lifchez	68	68	58
	Dorafshar	35	27	25
	Plastic Surgery Residents	39	12	22
	Gordon	1	-	-
	Rosson	3	-	-

WMSC TOTAL CASES	852	830	762
WMSC TOTAL MINUTES (including TAT)	92,509	94,410	91,665
WMSC MIN/CASE	108.6	113.7	120.3

The table above shows the historical OR volumes at the WMSC by surgeon for FY16-FY18. In FY18, the center performed 762 cases, totaling 91,665 minutes (including turnaround time), and averaged 120.3 minutes per case.

White Marsh Surgery Center – Volume Projections

Specialty	Surgeon	Actual 1 OR	Projection 1 OR		Projection (Year 1 - 3) 2 ORs		
		FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
ORTHO	Wilckens	226	226	226	226	226	226
	Humbyrd	168	168	168	168	168	168
	Ingari	79	79	79	79	79	79
	Zikria	9	9	9	9	9	9
	Ficke	1	1	1	1	1	1
ENT	Boahene	92	92	92	92	92	92
	Ishii	82	82	82	82	82	82
Plastics	Lifchez	58	58	58	58	58	58
	Dorafshar	25	25	25	25	25	25
	Plastic Surgery Residents	22	22	22	40	40	40
WMSC TOTAL CASES		762	762	762	780	780	780
WMSC TOTAL MINUTES (including TAT)		91,665	91,665	91,665	95,985	95,985	95,985
WMSC MINUTES/CASE		120.3	120.3	120.3	123.1	123.1	123.1

All surgeons currently practicing at the WMSC, excluding the Plastic Surgery Residents, will continue to practice at the WMSC and are projected to maintain FY18 case volumes in FY19, FY20, FY21 (Year 1), FY22 (Year 2), and FY23 (Year 3). This is a conservative projection, given current market forces and reimbursement trends promoting the shift of outpatient surgical procedures from a hospital setting to an ambulatory setting. While these factors make it likely that physician volumes will increase at WMSC, the applicant has chosen to base its projections on case volume currently at the WMSC.

The only exception is an increase in cases performed by the Plastic Surgery Residents from 22 cases to 40 cases per year. This residency training program at the WMSC is specifically designed to allow residents to gain valuable experience in an ambulatory surgical setting. The number of cases in the program is currently restricted due to a lack of capacity. The program plans to return to utilization levels seen in FY16 of approximately 40 cases per year once additional capacity is available.

The increase of Plastic Surgery Resident cases from 22 to 40 results in an incremental increase of 18 Total Cases at the WMSC in FY21, FY22, and FY23. The average case length for these cases is 240 minutes per case. This adds an additional 4,320 minutes per year to the projections.

In summary, by FY21 (Year 1), the surgeons currently practicing at WMSC are projected to perform 780 cases, totaling 95,985 minutes, at WMSC.

Please see Exhibit 15 for a letter of support from Lisa Ishii, M.D., M.H.S., Senior Vice President for Operations of Johns Hopkins Health System and the Medical Director of the White Marsh Surgery Center. In her letter, Dr. Ishii commits to the volume projections detailed above, and stresses the importance of adding operating room capacity to the WMSC in order to provide JHM patients with access to high quality, cost-effective care in a medically-appropriate setting.

New Surgeons Joining White Marsh Surgery Center – Volume Projections

New Surgeons Joining WMSC

Current Campus	Specialty	Surgeon	Outpatient OR Volumes At Current Campus			Projection (Year 1-3)		
			FY2016	FY2017	FY2018	FY2021	FY2022	FY2023
JHH	Peds Surgery	Garcia	-	82	123	50	50	50
		Stewart	-	186	191	50	50	50
JHBMC	Plastics	Broderick	31	102	126	36	36	36
	GYN	Powell	-	-	63	39	39	39
		Borahay	-	76	99	39	39	39
		Robinson	87	138	155	39	39	39
		Bourque	12	20	12	12	12	12
		Chen	14	15	23	23	23	23
		Yazdy (RH)	-	-	-	39	39	39
	Urology	Wright	80	149	198	89	89	89
		Herarti	-	-	143	149	149	149
		Fellowship	-	-	139	119	119	119
	Burn	Caffrey	19	137	202	350	350	350
		Hultman (RH)	-	-	2	200	200	200
	ENT	Clark (RH)	-	-	10	120	120	120

(RH) = recent hire

The table above lists the surgeons that will join the WMSC when additional capacity is available, by specialty. Additionally, the table reports historical outpatient OR volume for each surgeon based on each surgeon's current hospital campus (Source: Johns Hopkins Medicine Perioperative Dashboard). Additional information detailing the basis for projections of cases to be performed at WMSC is included below:

Pediatric Surgery:

- Drs. Garcia and Stewart currently perform their outpatient surgical cases at The Johns Hopkins Hospital. Each project to shift a proportion of their current volume to the WMSC.

Plastics:

- Dr. Broderick currently performs outpatient surgical cases at JHBMC and projects to shift a proportion of this volume to the WMSC.

Gynecology:

- Drs. Powell, Borahay, Robinson, Bourque, and Chen currently perform outpatient surgical cases at JHBMC and project to shift all or a proportion of this volume to the WMSC.

- Dr. Yazdy is a recent hire, with projected volume equal to that of Drs. Powell, Borahay, and Robinson.

Urology:

- Dr. Wright currently performs outpatient surgical cases at JHBMC and is projected to shift a proportion of this volume to the WMSC.
- Dr. Herarti performed 143 outpatient OR cases at JHBMC in FY18 and 105 cases in the WMSC Procedure Room. Dr. Herarti is projected to shift 44 outpatient OR cases from JHBMC to the WMSC and to shift all of the 139 cases from the WMSC Procedure Room to the WMSC Operating Room. This shift will provide more efficiency for Dr. Herarti. The projected case total of 149 at the WMSC is the sum of 44 and 105.
- The Fellows from the Urology Fellowship Program performed 139 outpatient OR cases at JHBMC in FY18, and are projected to shift a proportion of that volume to the WMSC.

Burn:

- Dr. Caffery performed 202 outpatient OR cases at JHBMC in FY18 and is projected to perform 350 cases at JHBMC in future years. This increase in projected volume is due to the fact that current capacity restrictions have constrained Dr. Caffery's volume at JHBMC, resulting in multiple-month wait times for patients. With fewer restrictions on OR time, the practice is projected to perform more cases per year, and the total volume will shift to WMSC.
- Dr. Hultman is a recent hire.

ENT:

- Dr. Clark is a recent hire.

Please see Exhibit 15 for a letters of support from the Department of Otolaryngology – Head and Neck Surgery, the Brady Urology Institute, the Department of Gynecology and Obstetrics, the Department of Plastic and Reconstructive Surgery, and the Division of Pediatric Surgery. Each department commits to the volume projections outlined above.

New Surgeons Joining White Marsh Surgery Center – Minutes Projections

Current Campus	Specialty	Surgeon	Projection (Year 1-3)			Estimated Minutes Per Case (including TAT)	TOTAL MINUTES
			FY2021	FY2022	FY2023		
JHH	Peds Surgery	Garcia	50	50	50	90	4,500
		Stewart	50	50	50	90	4,500
JHBMC	Plastics	Broderick	36	36	36	240	8,640
	GYN	Powell	39	39	39	90	3,510
		Borahay	39	39	39	90	3,510
		Robinson	39	39	39	90	3,510
		Bourque	12	12	12	90	1,080
		Chen	23	23	23	90	2,070
		Yazdy (RH)	39	39	39	90	3,510
	Urology	Wright	89	89	89	100	8,900
		Herarti	149	149	149	75	11,175
		Fellowship	119	119	119	81	9,675
	Burn	Caffrey	350	350	350	75	26,250
		Hultman (RH)	200	200	200	90	18,000
	ENT	Clark (RH)	120	120	120	90	10,800

NEW SURGEONS JOINING - TOTAL CASES	1,354	1,354	1,354
NEW SURGEONS JOINING - TOTAL MINUTES	119,630	119,630	119,630
NEW SURGEONS JOINING - MINUTES/CASE	88.4	88.4	88.4

The table above shows projected total cases, total minutes including turnaround time, and minutes/case for the new surgeons joining the WMSC. Beginning with Year 1, or FY21, the number of projected cases is held constant through Year 3. This is a conservative estimate.

The applicant requested average case length estimates (including turnaround time) from the new surgeons joining the WMSC in order to convert surgeon volume projections to minutes projections. In the table above, FY21 volume projections were multiplied by minutes-per-case estimates to calculate the total minutes projected for new surgeons joining the WMSC.

New surgeons joining the WMSC are projected to perform 1,354 cases in FY21, totaling 119,630 minutes, and are projected to maintain this number of cases and minutes in FY22 and FY23.

Projections Summary & Calculation of ORs Needed

		Projection FY2021 (Year 1)
CASES	WMSC Subtotal	780
	New Surgeons Joining Subtotal	1,354
	TOTAL	**2,134**
MINUTES INCLUDING TAT	WMSC Subtotal	95,985
	New Surgeons Joining Subtotal	119,630
	TOTAL	**215,615**
ORS NEEDED	**97,920 Minutes/OR**	**2.20**

In the table above, the applicant calculates the total number of cases, total minutes including turnaround time, and the number of ORs Needed in Year 1 of the project. These values are equivalent for FY21 (Year 1), FY22 (Year 2), and FY23 (Year 3) because, as noted above, the volume projections are held constant beginning in FY21 (Year 1).

The case volume for surgeons currently performing cases at the WMSC in FY21 is projected at 780 cases. The projected volume for new surgeons joining the WMSC in FY20 is 1,354 cases. The total cases projected at the WMSC in FY20 is 2,134 cases.

The corresponding minutes projected for FY20 for surgeons currently performing cases at the WMSC is 95,985 minutes. Similarly, the minutes projected for new surgeons joining the WMSC in FY20 is 119,630 minutes. The total minutes projected at WMSC in FY20 is 215,615 minutes.

The optimal utilization of one operating room is defined as 97,920 minutes per year. Therefore, a total of 215,615 minutes projected in FY20 indicates a need for 2.20 operating rooms. These projections demonstrate that optimal capacity will be reached for both operating rooms by Year 1 of the proposed project, and maintained for Year 2 and Year 3.

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

(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.

Applicant Response:

(b)

We are confident that two operating rooms at WMSC will be used at or above optimal capacity because the WMSC is not requesting the ability to add a second operating room on the basis of predicted market growth or anticipated shifts of cases from existing, competing ASCs. A second operating room is needed at WMSC simply to accommodate existing case volume currently being performed at Johns Hopkins facilities. There is increasing pressure from payors to perform outpatient cases in a lower cost setting when medically appropriate. A second operating room at WMSC will allow cases currently being performed at JHH and JHBMC to be moved to this lower-cost setting.

In FY2018, utilization of the existing WMSC operating room totaled 91,665 minutes. For the surgeons currently practicing at the WMSC, utilization is projected to increase to 95,985 minutes in FY2021. The cases committed to move from JHH and JHBMC in FY2021 total 119,630 minutes. These two categories (case volume of physicians currently performing cases at WMSC and those moving cases to WMSC) total 215,615 minutes.

Regulation .07 of this chapter deems an outpatient operating room to be optimally utilized at 97,920 minutes/year. This means that optimal utilization of two operating rooms is 195,840 minutes/year. The minutes associated with the case volume that will be performed at WMSC in FY2021 (215,615), which is within one year of initiation of surgical services at the proposed two-room facility, exceeds the amount needed to achieve optimal capacity by 19,775 minutes, indicating a need for 2.20 ORs.

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

(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.

Applicant Response:

(c) Standard does not apply.

(d)(i)

The volume projections for this project derive from three sources:

1) Cases from physicians currently practicing at WMSC
2) Cases shifting to WMSC that would otherwise be performed at JHBMC
3) Cases shifting to WMSC that would otherwise be performed at JHH

Historic use trends for Cases from physicians currently practicing at WMSC are detailed below:

Specialty	Surgeon	OR Volume Performed at WMSC		
		FY2016	FY2017	FY2018
ORTHO	Wilckens	220	238	226
	Humbyrd	96	109	168
	Ingari	94	86	79
	Zikria	91	99	9
	Ficke	-	-	1
	Tanaka	14	-	-
	Cosgera	2	-	-
ENT	Boahene	82	102	92
	Ishii	107	89	82
Plastics	Lifchez	68	68	58
	Dorafshar	35	27	25
	Plastic Surgery Residents	39	12	22
	Gordon	1	-	-
	Rosson	3	-	-

Historic use trends for Cases from physicians moving cases to the WMSC are detailed below:

Current Campus	Specialty	Surgeon	Outpatient OR Volumes At		
			FY2016	FY2017	FY2018
JHH	Peds Surgery	Garcia	-	82	123
		Stewart	-	186	191
JHBMC	Plastics	Broderick	31	102	126
	GYN	Powell	-	-	63
		Borahay	-	76	99
		Robinson	87	138	155
		Bourque	12	20	12
		Chen	14	15	23
		Yazdy (RH)	-	-	-
	Urology	Wright	80	149	198
		Herarti	-	-	143
		Fellowship	-	-	139
	Burn	Caffrey	19	137	202
		Hultman (RH)	-	-	2
	ENT	Clark (RH)	-	-	10

(RH) = recent hire

(d)(ii)

The proposed project will combine the OR volume currently at WMSC with cases shifting from JHH and JHBMC.

The Total OR minutes, and minutes/cases estimates for cases currently at WMSC are included below:

Specialty	Surgeon	Actual 1 OR	Projection 1 OR		Projection (Year 1 - 3) 2 ORs		
		FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
ORTHO	Wilckens	226	226	226	226	226	226
	Humbyrd	168	168	168	168	168	168
	Ingari	79	79	79	79	79	79
	Zikria	9	9	9	9	9	9
	Ficke	1	1	1	1	1	1
ENT	Boahene	92	92	92	92	92	92
	Ishii	82	82	82	82	82	82
Plastics	Lifchez	58	58	58	58	58	58
	Dorafshar	25	25	25	25	25	25
	Plastic Surgery Residents	22	22	22	40	40	40
WMSC TOTAL CASES		762	762	762	780	780	780
WMSC TOTAL MINUTES (including TAT)		91,665	91,665	91,665	95,985	95,985	95,985
WMSC MINUTES/CASE		120.3	120.3	120.3	123.1	123.1	123.1

All surgeons currently practicing at the WMSC, excluding the Plastic Surgery Residents, are projected to maintain FY18 case volumes in FY19, FY20, FY21 (Year 1), FY22 (Year 2), and FY23 (Year 3).

The only exception is an increase in cases performed by the Plastic Surgery Residents from 22 cases to 40 cases per year. The increase of Plastic Surgery Resident cases from 22 to 40 results in an incremental increase of 18 Total Cases at the WMSC in FY21, FY22, and FY23. The average case length for these cases is 240 minutes per case. This adds an additional 4,320 minutes per year to the projections. In summary, by FY21 (Year 1), the surgeons currently practicing at WMSC are projected to perform 780 cases, totaling 95,985 minutes, at WMSC.

Please see the column “Estimated Minutes Per Case (including TAT)” (below) for OR minute, by surgeon, projected to shift to WMSC. The total minutes and a minutes/case calculation, by year, are also included:

Current Campus	Specialty	Surgeon	Outpatient OR Volumes At Current Campus			Projection (Year 1-3)		
			FY2016	FY2017	FY2018	FY2021	FY2022	FY2023
JHH	Peds Surgery	Garcia	-	82	123	50	50	50
		Stewart	-	186	191	50	50	50
JHBMC	Plastics	Broderick	31	102	126	36	36	36
	GYN	Powell	-	-	63	39	39	39
		Borahay	-	76	99	39	39	39
		Robinson	87	138	155	39	39	39
		Bourque	12	20	12	12	12	12
		Chen	14	15	23	23	23	23
		Yazdy (RH)	-	-	-	39	39	39
	Urology	Wright	80	149	198	89	89	89
		Herarti	-	-	143	149	149	149
		Fellowship	-	-	139	119	119	119
	Burn	Caffrey	19	137	202	350	350	350
		Hultman (RH)	-	-	2	200	200	200
	ENT	Clark (RH)	-	-	10	120	120	120

These two categories sum to:

CASES	2,134
MINUTES INCLUDING TAT	215,615
MINUTES/CASE	101.04

(d)(iii)

Please see response to (2) Need - Minimum Utilization for Establishment of a New or Replacement Facility. (d)(i) above for documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.

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

An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall:

(a) Demonstrate the need for each proposed additional operating room, utilizing the operating room capacity assumptions and other guidance included at Regulation .07 of this chapter;

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

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

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

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

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

Applicant Response:

Standard does not apply.

(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.

Applicant Response:

(a) Standard does not apply.

(b) Please see Exhibit 4 for the project Drawing. The proposed renovation conforms to FGI guidelines. Please see Exhibit 16 for architect's attestation.

(c) Standard does not apply.

(5) Support Services.

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

Applicant Response:

The White Marsh Surgery Center provides point of care testing on site, specifically glucometer, dip stick urinalysis, and pregnancy testing. For testing that cannot be done on site, all lab specimens are sent to two different labs with whom White Marsh Surgery Center maintains contractual agreements: Johns Hopkins Lab and Dianon Pathology. For radiology services, the facility has a radiation technician on site to perform pain management procedures. In the instances that a patient needs additional radiology testing, the patient is transferred to a nearby hospital for urgent cases and referred to a primary care physician for non-urgent cases.

(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.

Applicant Response:

(a) Planning:

JHM has a robust patient safety and quality infrastructure for ambulatory surgery centers including the JHM Ambulatory Surgery Quality Council (ASQC). The mission of the JHM ASQC, with representation from each of Hopkins' nine ambulatory surgery centers, is to provide exceptional high quality patient-centered care at all Johns Hopkins Medicine Ambulatory Surgery Centers, and an experience consistent at all sites. The ASQC leadership team includes:

- A physician lead
- The director of Johns Hopkins Medical Management Corporation
- A regulatory representative
- A quality representative
- The medical director and nurse manager from each ASC
- An infection control specialists

The JHM ASQC played an integral role in the planning of the WMSC second operating room design.

(b) Design Features:

Design features for the second operating room at the WMSC will include:

- The second operating room has been designed similarly to the existing OR, in an effort to minimize the need for additional training and allow staff to move between the two operating rooms with minimal chance of confusion
- The design maintains the recommended clearances and space requirements as outlined by the FGI
- The design includes proper finish selections to maximize the ability to sanitize the second operating room
- The HVAC system will meet the required air changes in the operating room
- All call systems, medical gases, and power will meet the guidelines

(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.

(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.

Applicant Response:

(a) Standard does not apply as this is not a hospital project

(b)(i) This standard is not applicable. The project will not involve new building construction; only renovation of existing space.

(b)(ii) This standard is not applicable. The project will not involve new building construction; only renovation of existing space.

(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.

Applicant Response:

(a)(i) Please see response to COMAR 10.24.11(2)(a) Need, which demonstrates that the utilization projections are consistent with observed historic trends, both for the surgeons currently practicing at the WMSC, and for the new surgeons joining the WMSC.

(a)(ii) The revenue projections are consistent with the utilization projections. Please see Table 3, Table 4, and the "Statement of Assumptions" in section 10.24.01.08G(3)(d). Viability of the Proposal, below, for additional information.

(a)(iii) Staffing and overall expense projections are consistent with the utilization projections. Please see Table 3, Table 4, and the "Statement of Assumptions" in section 10.24.01.08G(3)(d).

Viability of the Proposal, below, for additional information.

(a)(iv) The facility will generate excess revenue over total expenses if utilization forecasts are achieved.

(b) This standard does not apply.

(9) Impact.

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

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

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

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

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

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

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

Applicant Response:

(a)(i)

Surgeons Currently At WMSC

Specialty	Surgeon	Actual 1 OR	Projection 1 OR		Projection (Year 1 - 3) 2 ORs		
		FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
ORTHO	Wilckens	226	226	226	226	226	226
	Humbyrd	168	168	168	168	168	168
	Ingari	79	79	79	79	79	79
	Zikria	9	9	9	9	9	9
	Ficke	1	1	1	1	1	1
ENT	Boahene	92	92	92	92	92	92
	Ishii	82	82	82	82	82	82
Plastics	Lifchez	58	58	58	58	58	58
	Dorafshar	25	25	25	25	25	25
	Plastic Surgery Residents	22	22	22	40	40	40

WMSC TOTAL CASES	762	762	762	780	780	780
WMSC TOTAL MINUTES (including TAT)	91,665	91,665	91,665	95,985	95,985	95,985
WMSC MINUTES/CASE	120.3	120.3	120.3	123.1	123.1	123.1

New Surgeons Joining WMSC

Current Campus	Specialty	Surgeon	Outpatient OR Volumes At Current Campus			Projection (Year 1-3)		
			FY2016	FY2017	FY2018	FY2021	FY2022	FY2023
JHH	Peds Surgery	Garcia	-	82	123	50	50	50
		Stewart	-	186	191	50	50	50
JHBMC	Plastics	Broderick	31	102	126	36	36	36
	GYN	Powell	-	-	63	39	39	39
		Borahay	-	76	99	39	39	39
		Robinson	87	138	155	39	39	39
		Bourque	12	20	12	12	12	12
		Chen	14	15	23	23	23	23
		Yazdy (RH)	-	-	-	39	39	39
	Urology	Wright	80	149	198	89	89	89
		Herarti	-	-	143	149	149	149
		Fellowship	-	-	139	119	119	119
	Burn	Caffrey	19	137	202	350	350	350
		Hultman (RH)	-	-	2	200	200	200
	ENT	Clark (RH)	-	-	10	120	120	120

(RH) = recent hire

These two categories sum to:

		Projection FY2021 (Year 1)
CASES	WMSC Subtotal	780
	New Surgeons Joining Subtotal	1,354
	TOTAL	**2,134**
MINUTES INCLUDING TAT	WMSC Subtotal	95,985
	New Surgeons Joining Subtotal	119,630
	TOTAL	**215,615**
ORS NEEDED	**97,920 Minutes/OR**	**2.20**

Of the minutes shifting:

Current Campus	Total Minutes
JHH	9,000
JHBMC	110,630
TOTAL	**119,630**

(a)(ii)

Historical volume for WMSC, by specialty and physician, is included below:

Specialty	Surgeon	OR Volume Performed at WMSC		
		FY2016	FY2017	FY2018
ORTHO	Wilckens	220	238	226
	Humbyrd	96	109	168
	Ingari	94	86	79
	Zikria	91	99	9
	Ficke	-	-	1
	Tanaka	14	-	-
	Cosgera	2	-	-
ENT	Boahene	82	102	92
	Ishii	107	89	82
Plastics	Lifchez	68	68	58
	Dorafshar	35	27	25
	Plastic Surgery Residents	39	12	22
	Gordon	1	-	-
	Rosson	3	-	-

Historical volume for the new surgeons joining WMSC, by site, specialty, and physician, are included below:

Current Campus	Specialty	Surgeon	Outpatient OR Volumes At		
			FY2016	FY2017	FY2018
JHH	Peds Surgery	Garcia	-	82	123
		Stewart	-	186	191
JHBMC	Plastics	Broderick	31	102	126
	GYN	Powell	-	-	63
		Borahay	-	76	99
		Robinson	87	138	155
		Bourque	12	20	12
		Chen	14	15	23
		Yazdy (RH)	-	-	-
	Urology	Wright	80	149	198
		Herarti	-	-	143
		Fellowship	-	-	139
	Burn	Caffrey	19	137	202
		Hultman (RH)	-	-	2
	ENT	Clark (RH)	-	-	10

(RH) = recent hire

(a)(iii)

Impact on JHBMC

The goal of the project is to shift volume from the Johns Hopkins Bayview Medical Center (JHBMC) and The Johns Hopkins Hospital (JHH) to the lower cost setting of the White Marsh Surgery Center. As indicated in Need Section 2(d) (ii), approximately 1,354 total cases and 119,630 total minutes will be moved from JHH and JHBMC to the White Marsh Surgery Center.

Approximately 93.6% of this volume (1,254 cases and 110,630 minutes) will come from JHBMC and the remainder will come from JHH. As indicated in the table below, JHBMC currently operates 14 ORs with 1.8 million total minutes of operating and turnaround time. The total minutes projected to shift from JHBMC (110,630 minutes) to White Marsh account for 6.1% of the total minutes at JHBMC.

In CY2017 and CY2018, JHBMC's OR's were operating in excess of the standard for optimal OR use by approximately 263,7945 minutes in CY2017 and 206,920 minutes in CY2018. Therefore, a shift of 110,630 minutes would allow both the JHBMC and White Marsh ASC to operate at optimal capacity. It should be noted that the cases and minutes provided in the table below are organized by calendar year as opposed to fiscal year. However, there is no material difference between total operating room minutes organized on a calendar year versus a fiscal year basis.

Johns Hopkins Bayview Medical Center

OR Cases and Minutes

	CY2016	CY2017	CY2018
Cases	9,719	10,181	9,963
Minutes/Case	145	141	139
OR Minutes	1,411,007	1,440,337	1,389,455
TAT Minutes/Case	41	41	42
Total TAT	394,591	419,457	413,465
Total Minutes	**1,805,598**	**1,859,794**	**1,802,920**
ORs	14	14	14
Optimal Capacity Per Mixed Use OR*	114,000	114,000	114,000
Total Optimal Minutes in 14 ORs	1,596,000	1,596,000	1,596,000
Minutes in Excess of Optimal OR Use	**209,598**	**263,794**	**206,920**

*Optimal Capcity is defined as 1,900 hours annually which yields 114,000 minutes.

Total minutes shifted in 2021	110,630
Percent of total JHBMC Volume	6.1%

JHBMC New Inpatient Building

On February 5, 2018, JHBMC submitted a CON application, Matter Number 18-24-2414, for the capital expenditures associated with a campus redevelopment project that includes construction of a new inpatient building and renovation of two existing buildings on its campus ("New Inpatient Building CON"). The application was docketed on January 4, 2019.

For the applicant's response to COMAR 10.24.11.05B(2) – Need- Minimum Utilization for Establishment of a New or Replacement Facility, please see Exhibit 17.

In its response, the applicant projected JHBMC's OR need through CY2025. The CY2025 Total Minutes projection (including turnaround time), was 1,738,654 minutes, or 15.25 ORs at optimal capacity (rounded to 15 on page 129 of Exhibit 17).

Given that 14 ORs utilized at optimal capacity totals 1,596,000 minutes, the projection of OR minutes in the New Inpatient Building CON exceeds 14 optimally utilized ORs by 142,654 minutes. This exceeds the projection number of minutes projected to shift to WMSC as a result of this projection, which is 110,630 minutes. This indicates that the implementation of a second OR at WMSC, and the shifting of cases as projected, will not impact the proposed New Inpatient Building CON project. Even with shifting the cases to WMSC as proposed, there is still a demonstrated need for 14 ORs on the JHBMC campus and in the New Inpatient Building CON project.

Impact on JHH

The project will shift cases from two pediatric surgeons from JHH to WMSC. Including turnaround time, these cases will total 9,000 minutes annually.

The JHH has 54 operating rooms; 46 mixed-use and 8 outpatient. That equates to an annual capacity of:

OR Type	Count	Hours/Year	Min/Hour	Full Capacity
Outpatient	8	2,040	60	979,200
Mixed Use	46	2,375	60	6,555,000
Total ORs	**54**	-	-	**7,534,200**

These 9,000 minutes represent approximately 0.12% of that capacity, making the impact of moving these cases away from JHH immaterial

(b)(i)

The only facilities impacted by this proposed additional OR capacity are JHH and JHBMC. The total volume that is being shifted from JHH is only 0.12% of the total JHH volume, and the total volume being shifted from JHBMC is only 6.1% of volume. Therefore, this standard does not apply.

(b)(ii)

The operating room capacity assumptions in Regulation .07A of this chapter were used in the impact assessment.

(10) Preference in Comparative Reviews.

In a comparative review of CON applications to establish an ambulatory surgical facility or provide surgical services, preference will be given to a project that commits to serve a larger proportion of charity care and Medicaid patients. An applicant's commitment to provide charity care will be evaluated based on its past record of providing such care and its proposed outreach strategies for meeting its projected level of charity care.

Applicant Response:

This standard does not apply.

10.24.01.08G(3)(b). Need.

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.

INSTRUCTIONS: Please discuss the need of the population served or to be served by the Project.

Responses should include a quantitative analysis that, at a minimum, describes the Project's expected service area, population size, characteristics, and projected growth. If the relevant chapter of the State Health Plan includes a need standard or need projection methodology, please reference/address it in your response. For applications proposing to address the need of special population groups, please specifically identify those populations that are underserved and describe how this Project will address their needs.

If the project involves modernization of an existing facility through renovation and/or expansion, provide a detailed explanation of why such modernization is needed by the service area population. Identify and discuss relevant building or life safety code issues, age of physical plant issues, or standard of care issues that support the need for the proposed modernization.

Please assure that all sources of information used in the need analysis are identified. List all assumptions made in the need analysis regarding demand for services, utilization rate(s), and the relevant population, and provide information supporting the validity of the assumptions.

Complete Tables 1 and/or 2 below, as applies.

Applicant Response:

Need Analysis

Please see response to COMAR 10.24.11(2)(a) Need.

Modernization

The WMSC currently operates one OR and is applying for approval to operate a second OR. This project is proposed in order to accommodate JHM faculty moving their site of care from JHBMC and JHH to the WMSC.

Tables

Please see Table 1 and Table 2 below.

[(INSTRUCTION: Complete Table 1 for the Entire Facility, including the proposed project, and Table 2 for the proposed project only using the space provided on the following pages. Only existing facility applicants should complete Table 1. All Applicants should complete Table 2. Please indicate on the Table if the reporting period is Calendar Year (CY) or Fiscal Year (FY)]

TABLE 1: STATISTICAL PROJECTIONS - ENTIRE FACILITY

	Two Most Actual Ended Recent Years		Current Year Projected	Projected Years (ending with first full year at full utilization)	
FY	**2017**	**2018**	**2019**	**2020**	**2021**
a. Number of operating rooms (ORs)	1	1	1	1	2
● Total Procedures in ORs	-	-	-	-	-
● Total Cases in ORs	830	762	762	762	2,134
● Total Surgical Minutes in ORs**	73,660	72,615	72,615	72,615	162,265
b. Number of Procedure Rooms (PRs)	2	2	2	2	2
● Total Procedures in PRs	3,577	4,894	5,300	5,300	5,575
● Total Cases in PRs	-	-	-	-	-
● Total Minutes in PRs**	107,310	146,820	159,000	159,000	167,250

*Number of beds and occupancy percentage should be reported on the basis of licensed beds.

**Do not include turnover time.

TABLE 2: STATISTICAL PROJECTIONS - PROPOSED PROJECT
(INSTRUCTION: All applicants should complete this table.)

Table 2 Cont.	**Projected Years (Ending with first full year at full utilization)**
FY	**2021**
a. Number of operating rooms (ORs)	1
● Total Procedures in ORs	-
● Total Cases in ORs	1,354
● Total Surgical Minutes in ORs**	85,780
b. Number of Procedure Rooms (PRs)	-
● Total Procedures in PRs	-
● Total Cases in PRs	-
● Total Minutes in PRs**	-

*Do not include turnover time

10.24.01.08G(3)(c). Availability of More Cost-Effective Alternatives.

The Commission shall compare the cost effectiveness of the proposed project with the cost effectiveness of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

INSTRUCTIONS: Please describe the planning process that was used to develop the proposed project. This should include a full explanation of the primary goals or objectives of the project or the problem(s) being addressed by the project. It should also identify the alternative approaches to achieving those goals or objectives or solving those problem(s) that were considered during the project planning process, including the alternative of the services being provided by existing facilities.

For all alternative approaches, provide information on the level of effectiveness in goal or objective achievement or problem resolution that each alternative would be likely to achieve and the costs of each alternative. The cost analysis should go beyond development cost to consider life cycle costs of project alternatives. This narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective goal and objective achievement or the most effective solution to the identified problem(s) for the level of cost required to implement the project, when compared to the effectiveness and cost of alternatives including the alternative of providing the service through alternative existing facilities, or through an alternative facility that has submitted a competitive application as part of a comparative review.

Applicant Response:

Planning Process & Primary Goals

Adding operating room capacity in an ambulatory setting is essential for JHM to continue to offer robust, high-quality outpatient care. JHM is mindful of current market forces and reimbursement trends promoting the shift of outpatient surgical procedures from a hospital setting to an ambulatory setting. By adding additional ambulatory operating room capacity, JHM will be able to perform outpatient surgical procedures in the most cost-effective and medically appropriate setting.

At the direction of JHM leadership, outpatient cases were identified that are currently performed in Johns Hopkins Bayview Medical Center and The Johns Hopkins Hospital that could safely be performed in an ambulatory setting. In order to shift these cases to an ambulatory setting effectively, the following goals were enumerated:

1. Proximity of the ASC to where cases are currently performed
2. Expand operating room capacity in a cost-effective manner
3. Maximize economies of scale with current ambulatory operations

The intent of the proposed project is to shift surgery volumes from Johns Hopkins Bayview Medical Center and The Johns Hopkins Hospital to a high-quality, lower-cost setting. In addition to the proposed project of renovating the existing facility and adding an additional OR, three

alternatives are explored below.

Option #1 = Status Quo

Maintaining the status quo is the first alternative, which would require no capital costs or additional overhead, such as the increase of staffing to meet the demands of expanded capacity. This would require keeping cases projected to shift from JHBMC at JHBMC and cases projected from JHH at JHH. This option ignores current market forces and reimbursement trends. Eventually, a hospital setting will no longer be a price-competitive setting for these cases. In fact, JHM is experiencing immediate pressure from payors to move certain types of cases out of the rate-regulated acute care hospital setting, and there is significant evidence that this pressure will grow and the types of cases will expand in the coming months and years. Therefore, this option is not viable and will not enable JHM to meet the demands of payors to shift cases to a lower cost setting.

Option #2 = Acquire an Existing Facility

Acquiring an existing, one operating room facility would address JHM's need to shift cases out of JHBMC and JHH into an ambulatory setting. This option could likely be achieved more quickly than competing options, given the lack of construction and regulatory approvals it would require. A certificate of need would not be required for this option. However, this approach would be shortsighted. It would result in a second facility that would create unnecessary overhead and would eliminate any benefits of economies of scale in operations. While cases could be shifted almost immediately, it would be far less cost effective to operate a second, one operating room facility, when a one, two operating room facility would be inherently more efficient long-term.

Option #3 = Building a New Facility

Building a one operating room facility would address JHM's need to shift cases out of JHBMC and JHH into an ambulatory setting. It would also allow for more flexibility, in terms of where the facility could be located, given that it wouldn't be dependent on existing options. This option would not require a certificate of need. It would be less desirable from a timing perspective, relative to acquiring an existing facility, given the amount of time required for contracting and construction. This approach, like option #2, would be shortsighted. It would result in a second facility that would create unnecessary overhead and would eliminate any benefits of economics of scale. Further, constructing an entirely new facility would be significantly more expensive than acquiring an existing facility or renovating space in an existing facility. While cases could be shifted to the new facility with minimal regulatory approval required, it would be far less cost effective to build and operate a second, one operating room facility, when one, two operating room facility would be inherently less expensive, and more efficient long-term.

Option #4 = Expand WMSC's OR Capacity From 1 OR to 2 ORs

The proximity of the WMSC to JHBMC makes it a desirable option for JHBMC and JHH surgeons to shift a proportion of their cases to this ambulatory setting. It is inherently more cost effective to add a second operating room to an existing facility than acquiring or building a second, one operating room facility. Further, economies of scale that are realizable in a two operating room facility, such as staffing, supplies, rent, major equipment, and information systems, cannot be achieved in two, one operating room facilities.

Primary Goals	Option #1	Option #2	Option #3	Option #4
Proximity	0	3	4	4
Cost Effective	0	3	3	5
Economies of Scale	0	0	0	5
TOTAL	**0**	**6**	**7**	**14**

Score of 5 = optimally achieves goal
Score of 0 = does not achieve goal or unknown

10.24.01.08G(3)(d). Viability of the Proposal.

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.

INSTRUCTIONS: Please provide a complete description of the funding plan for the project, documenting the availability of equity, grant(s), or philanthropic sources of funds and demonstrating, to the extent possible, the ability of the applicant to obtain the debt financing proposed. Describe the alternative financing mechanisms considered in project planning and provide an explanation of why the proposed mix of funding sources was chosen.

- Complete Tables 3 and/or 4 below, as applicable. Attach additional pages as necessary detailing assumptions with respect to each revenue and expense line item.

- Complete Table L (Workforce) from the Hospital CON Application Table Package.

- Audited financial statements for the past two years should be provided by all applicant entities and parent companies to demonstrate the financial condition of the entities involved and the availability of the equity contribution. If audited financial statements are not available for the entity or individuals that will provide the equity contribution, submit documentation of the financial condition of the entities and/or individuals providing the funds and the availability of such funds. Acceptable documentation is a letter signed by an independent Certified Public Accountant. Such letter shall detail the financial information considered by the CPA in reaching the conclusion that adequate funds are available.

- If debt financing is required and/or grants or fund raising is proposed, detail the experience of the entities and/or individuals involved in obtaining such financing and grants and in raising funds for similar projects. If grant funding is proposed, identify the grant that has been or will be pursued and document the eligibility of the proposed project for the grant.

- Describe and document relevant community support for the proposed project.

- Identify the performance requirements applicable to the proposed project (see question 12, "Project Schedule") and explain how the applicant will be able to implement the project in compliance with those performance requirements. Explain the process for completing the project design, obtaining State and local land use, environmental, and design approvals, contracting and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that the project can be completed within the applicable time frame(s).

Applicant Response:

Tables

Please see Table 3 and Table 4 below. Please see Exhibit 18 for additional detail regarding line "2. Expenses" "j. Other Expenses (Specify)."

TABLE 3: <u>REVENUES AND EXPENSES - ENTIRE FACILITY</u> (including proposed project)

(INSTRUCTION: ALL EXISTING FACILITY APPLICANTS MUST SUBMIT AUDITED FINANCIAL STATEMENTS)

	Two Most Actual Ended Recent Years		Current Year Projected	Projected Years (ending with first full year at full utilization)	
FY	**2017**	**2018**	**2019**	**2020**	**2021**
1. Revenue					
a. Inpatient services					
b. Outpatient services	7,122,946	10,162,885	12,621,700	13,167,000	16,226,000
c. Gross Patient Service Revenue	7,122,946	10,162,885	12,621,700	13,167,000	16,226,000
d. Allowance for Bad Debt	45,734	71,230	80,000	80,000	100,000
e. Contractual Allowance	3,692,549	5,720,282	7,761,700	8,102,000	9,981,000
f. Charity Care	7,002	30,484	35,000	35,000	45,000
g. Net Patient Services Revenue	3,377,661	4,340,889	4,745,000	4,950,000	6,100,000
h. Other Operating Revenues (Specify)					
i. Net Operating Revenue	3,377,661	4,340,889	4,745,000	4,950,000	6,100,000

Table 3 Cont.	Two Most Actual Ended Recent Years		Current Year Projected	Projected Years (ending with first full year at full utilization)	
FY	**2017**	**2018**	**2019**	**2020**	**2021**
2. Expenses					
a. Salaries, Wages, and Professional Fees, (including fringe benefits)	1,285,904	1,627,244	1,699,600	1,764,000	2,285,000
b. Contractual Services	150,000	174,000	457,050	475,500	579,000
c. Interest on Current Debt	68,843	60,179	51,000	41,000	30,000
d. Interest on Project Debt					
e. Current Depreciation	240,349	253,632	280,000	270,000	270,000
f. Project Depreciation					130,000
g. Current Amortization					
h. Project Amortization					
i. Supplies	642,651	748,880	780,000	790,000	900,000
j. Other Expenses (Specify)	624,738	753,289	774,800	819,800	985,000
k. Total Operating Expenses	3,012,485	3,617,224	4,042,450	4,160,300	5,179,000
3. Income					
a. Income from Operation	365,176	723,665	702,550	789,700	921,000
b. Non-Operating Income	54	1,015	6,185	-	-
c. Subtotal	365,230	724,680	708,735	789,700	921,000
d. Income Taxes	-	-	-	-	-
e. Net Income (Loss)	365,230	724,680	708,735	789,700	921,000

Table 3 Cont.	Two Most Actual Ended Recent Years		Current Year Projected	Projected Years (ending with first full year at full utilization)	
FY	**2017**	**2018**	**2019**	**2020**	**2021**
4. Patient Mix: A. Percent of Total Revenue					
1. Medicare	17	21	21	21	21
2. Medicaid	6	10	9	10	10
3. Blue Cross	30	29	28	28	28
4. Commercial Insurance	44	38	40	39	39
5. Self-Pay	3	2	2	2	2
6. Other (Specify)	-	-	-	-	-
7. TOTAL	100%	100%	100%	100%	100%
B. Percent of Patient Days/Visits/Procedures (as applicable)					
1. Medicare	18	19	20	20	20
2. Medicaid	6	8	8	9	9
3. Blue Cross	29	28	28	28	28
4. Commercial Insurance	44	42	42	41	41
5. Self-Pay	3	3	2	2	2
6. Other (Specify)	-	-	-	-	-
7. TOTAL	100%	100%	100%	100%	100%

TABLE 4: REVENUES AND EXPENSES - PROPOSED PROJECT

(INSTRUCTION: Each applicant should complete this table for the proposed project only)

	Projected Years (Ending with first full year at full utilization)
FY	**2021**
1. Revenues	
a. Inpatient Services	
b. Outpatient Services	3,059,000
c. Gross Patient Services Revenue	3,059,000
d. Allowance for Bad Debt	20,000
e. Contractual Allowance	1,879,000
f. Charity Care	10,000
g. Net Patient Care Service Revenues	1,150,000
h. Total Net Operating Revenue	1,150,000
2. Expenses	
a. Salaries, Wages, and Professional Fees, (including fringe benefits)	521,000
b. Contractual Services	103,500
c. Interest on Current Debt	(11,000)
d. Interest on Project Debt	
e. Current Depreciation	
f. Project Depreciation	130,000
g. Current Amortization	
h. Project Amortization	
i. Supplies	110,000
j. Other Expenses (Specify)	165,200
k. Total Operating Expenses	1,018,700
3. Income	
a. Income from Operation	131,300

Table 4 Cont.	Projected Years (Ending with first full year at full utilization)
FY	**2021**
b. Non-Operating Income	
c. Subtotal	131,500
d. Income Taxes	
e. Net Income (Loss)	131,500
4. Patient Mix: A. Percent of Total Revenue	
1. Medicare	21
2. Medicaid	10
3. Blue Cross	28
4. Commercial Insurance	39
5. Self-Pay	2
6. Other (Specify)	-
7. TOTAL	100%
B. Percent of Patient Days/Visits/Procedures (as applicable)	
1. Medicare	20
2. Medicaid	9
3. Blue Cross	28
4. Commercial Insurance	41
5. Self-Pay	2
6. Other (Specify)	-
7. TOTAL	100%

Complete Table L (Workforce)

Please see Exhibit 19 for Table L of the Hospital CON Application Package.

Audited Financial Statements

Please see Exhibit 20 for unaudited financial statements for FY2018.

Please see Exhibit 21 for audited financial statements for FY2018 for The Johns Hopkins Health System Corporation and Affiliates.

Debt Financing

There will be no debt financing or grants or fund raising for this project. The project will be funded with cash.

Support

This project has substantial support within the Johns Hopkins community. Please see Exhibit 22 for letter of support from Richard G. Bennett, M.D., the President of Johns Hopkins Bayview Medical Center.

Performance Requirements

The existing WMSC is a POSC.[3] With this application, WMSC seeks to become an Ambulatory Surgery Facility[4] and therefore is establishing a Healthcare Facility.[5]

Per COMAR 10.24.01.12C(3)(c), "…a proposed new health care facility has up to 18 months to obligate 51 percent of the approved capital expenditure, and up to 18 months after the effective date of a binding construction contract to complete the project.

As indicated in the Project Schedule, the applicant currently anticipates it will obligate 51 percent of the approved capital expenditure within 6 months of the CON approval date, begin

[3] Exhibit 2

[4] COMAR 10.24.01.01B(4) defines an Ambulatory Surgery Facility as "an entity or part of an entity with two or more operating rooms."

[5] COMAR 10.24.01.01B(12)(a)(iv) defines an ambulatory surgery center as a Health Care Facility.

construction within 2 months of the capital obligation, and complete the project within 6 months of the capital obligation. This schedule is well within the applicable performance requirements. The applicant will submit its renovation documents to Baltimore County for the necessary permits once the Certificate of Need is obtained. The applicant expects the permitting process will take approximately two months.

Project designs are include in Section B. (4): Design requirements.

10.24.01.08G(3)(e). Compliance with Conditions of Previous Certificates of Need.

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.

INSTRUCTIONS: List all of the Maryland Certificates of Need that have been issued to the project applicant, its parent, or its affiliates or subsidiaries over the prior 15 years, including their terms and conditions, and any changes to approved Certificates that needed to be obtained. Document that these projects were or are being implemented in compliance with all of their terms and conditions or explain why this was not the case.

Applicant Response:

The applicant, Johns Hopkins Surgery Center Series, has been issued one CON. On September 20th, 2016, it was issued a CON for the Green Spring Station Surgery Center (Docket No. 15-03-23-69) and it is in compliance with all terms and conditions.

The Johns Hopkins Surgery Centers Series will diligently adhere to any terms or conditions that accompany approval of this project.

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.

INSTRUCTIONS: Please provide an analysis of the impact of the proposed project. Please assure that all sources of information used in the impact analysis are identified and identify all the assumptions made in the impact analysis with respect to demand for services, payer mix, access to service and cost to the health care delivery system including relevant populations considered in the analysis, and changes in market share, with information that supports the validity of these assumptions. Provide an analysis of the following impacts:

a) On the volume of service provided by all other existing health care providers that are likely to experience some impact as a result of this project;

b) On the payer mix of all other existing health care providers that are likely to experience some impact on payer mix as a result of this project. If an applicant for a new nursing home claims no impact on payer mix, the applicant must identify the likely source of any expected increase in patients by payer.

c) On access to health care services for the service area population that will be served by the project. (State and support the assumptions used in this analysis of the impact on access);

d) On costs to the health care delivery system.

If the applicant is an existing facility or program, provide a summary description of the impact of the proposed project on the applicant's costs and charges, consistent with the information provided in the Project Budget, the projections of revenues and expenses, and the work force information.

Applicant Response:

a) Please see response to COMAR 10.24.11(2)(9) Impact (iii).

b) The volume to be shifted from JHH and JHBMC was not identified on a payor basis but rather by individual physician. As a result, the impact should be roughly equal across payors and should not impact the payor mix.

c) The intent of the project is to shift outpatient surgical cases from a higher cost setting at an acute care hospital to a lower cost setting at the White Marsh Surgery Center. By moving individual providers to this lower cost setting, financial barriers to accessing services are being mitigated. The working assumption is that the total cost for patients will be significantly lower at the White Marsh Surgery Center than at JHH or JHBMC. Therefore, financial accessibility will

be improved as a result of this project and access to health care services for patients within the facility's service area will also improve.

d) The stated goal of the application is to reduce overall costs by shifting cases that are medically appropriate to be performed in an ambulatory setting from a higher cost to a lower cost setting. Through shifting 1,354 cases from a hospital setting to an ambulatory surgery center, there will be savings to the health care delivery system overall as the White Marsh Surgery Center is a lower cost setting than both JHBMC and JHH.

Please see Exhibit 23 for affirmations.