

Craig P. Tanio, M.D.
CHAIR



Ben Steffen
EXECUTIVE DIRECTOR

For internal staff use:

**MARYLAND
HEALTH
CARE
COMMISSION**

MATTER/DOCKET NO.

DATE DOCKETED

INSTRUCTIONS: GENERIC APPLICATION FOR CERTIFICATE OF NEED (CON)
Note: Specific CON application forms exist for hospital, comprehensive care facility, home health, and hospice projects. This form is to be used for any other services requiring a CON.
(ADAPTED FOR AMBULATORY SURGERY APPLICANTS)

ALL APPLICATIONS MUST FOLLOW THE FORMATTING REQUIREMENTS DESCRIBED IMMEDIATELY BELOW. NOT FOLLOWING THESE FORMATTING INSTRUCTIONS WILL RESULT IN THE APPLICATION BEING RETURNED.

Required Format:

Table of Contents. The application must include a Table of Contents referencing the location of application materials. Each section in the hard copy submission should be separated with tabbed dividers. Any exhibits, attachments, etc. should be similarly tabbed, and pages within each should be numbered independently and consecutively. **The Table of Contents must include:**

- **Responses to PARTS I, II, III, and IV of this application form**
- **Responses to PART IV must include responses to the standards in the State Health Plan chapter that apply to the project being proposed.**
 - All Applicants must respond to the Review Criteria listed at 10.24.01.08G(3)(b) through 10.24.01.08G(3)(f) as detailed in the application form.
- **Identification of each Attachment, Exhibit, or Supplement**

Application pages must be consecutively numbered at the bottom of each page. Exhibits attached to subsequent correspondence during the completeness review process shall use a consecutive numbering scheme, continuing the sequencing from the original application. (For example, if the last exhibit in the application is Exhibit 5, any exhibits used in subsequent responses should begin with Exhibit 6. However, a replacement exhibit that merely replaces an

exhibit to the application should have the same number as the exhibit it is replacing, noted as a replacement.

SUBMISSION FORMATS:

We require submission of application materials and the applicant's responses to completeness questions in three forms: hard copy; searchable PDF; and in Microsoft Word.

- **Hard copy:** Applicants must submit six (6) hard copies of the application to:
Ruby Potter
Health Facilities Coordinator
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215
- **PDF:** Applicants must also submit *searchable* PDF files of the application, supplements, attachments, and exhibits.¹ All subsequent correspondence should also be submitted both by paper copy and as *searchable PDFs*.
- **Microsoft Word:** Responses to the questions in the application and the applicant's responses to completeness questions should also be electronically submitted in Word. Applicants are strongly encouraged to submit any spreadsheets or other files used to create the original tables (the native format). This will expedite the review process.

Applicants are strongly encouraged to submit any spreadsheets or other files used to create the original tables (the native format). This will expedite the review process.

PDFs and spreadsheets should be submitted to ruby.potter@maryland.gov and kevin.mcdonald@maryland.gov.

Note that there are certain actions that may be taken regarding either a health care facility or an entity that does not meet the definition of a health care facility where CON review and approval are not required. Most such instances are found in the Commission's procedural regulations at COMAR 10.24.01.03, .04, and .05. Instances listed in those regulations require the submission of specified information to the Commission and may require approval by the full Commission. Contact CON staff at (410) 764-3276 for more information.

A pre-application conference will be scheduled by Commission Staff to cover this and other topics. Applicants are encouraged to contact Staff with any questions regarding an application.

¹ PDFs may be created by saving the original document directly to PDF on a computer or by using advanced scanning technology

PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: Maryland Surgery Center

Address:

| | | | |
|---------------------------------|-----------|-------|------------|
| 11400 Rockville Pike Suite C 25 | Rockville | 20852 | Montgomery |
| Street | City | Zip | County |

2. Name of Owner: Maryland Surgery Center for Women, LLC

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.

AmSurg Holdings, Inc. owns 60% of Maryland Surgery Center for Women, LLC. The remaining interests are owned by 27 physicians, all of whom have a less than 5% ownership share.

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

Legal Name of Project Applicant (Licensee or Proposed Licensee):

Maryland Surgery
Center for
Women, LLC

Address:

| | | | | |
|----------------------|--------------|-------|-------|------------|
| 11400 Rockville Pike | Rockville | 20852 | MD | Montgomery |
| Street | City | Zip | State | County |
| Telephone: | 301 761 4760 | | | |

4. NAME OF LICENSEE OR PROPOSED LICENSEE, if different from the 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): _____
- To be formed:
- Existing:

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

A. Lead or primary contact:

Name and Title: Brent Longenecker, MSPT, MBA
 Division Vice President
 Operations

Company Name AmSurg

Mailing Address:

1A Burton Hills Boulevard Nashville 37215 Tennessee
 Street City Zip State

Telephone: 484 588 4508

E-mail Address (required): blongenecker@amsurg.com

Fax:

If company name is different than applicant briefly describe the relationship

AmSurg Holdings, Inc. owns 60% of Maryland Surgery Center for Women, LLC.

B. Additional or alternate contact:

Name and Title: Carolyn Jacobs

Company Name: Jacobs & Dembert, PA

Mailing Address:

One South Street Baltimore 21202 MD
Street City Zip State

Telephone: 410 727 4433

E-mail Address (required): cjacobs@jdlaw.com

Fax: 410 752 8105

If company name is different than applicant briefly describe the relationship Legal counsel

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 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

Executive Summary of the Project: Maryland Surgery Center, LLC (the “Center”) proposes to convert one of its 5 procedure rooms to a sterile operating room, resulting in a total of 2 sterile ORs. The Center, which historically has provided primarily gynecology services, has outgrown its single OR. With changes to technology and the transition of some of the higher acuity gynecology cases to outpatient centers, the Center has had significant difficulty trying to accommodate the additional volume in a manner that provides the level of customer service that its patients and physicians deserve. The high acuity cases require lengthy OR time and extended recovery time, often pushing patients out until evening hours or requiring the Center to be open on Saturdays. In addition, the Center has added general surgery and urology to its specialty mix resulting in an even greater need for more OR time as the Center increases the number of cases that cannot medically be performed without the aid of an anesthesia machine and general intubation in the OR. Aside from patient and physician satisfaction, the Center will benefit from the decreased overtime and overhead that will result from the addition of an OR.

Prior to the Center's expansion project that was completed in January 2018, the procedure room for which the Center is seeking approval to convert into an OR, in fact, was used as the Center's only sterile operating room which results in the need for very little structural change or cost to convert back to a sterile operating room. Construction requirements would be to move the entry door into the restricted corridor and close off the existing door that opens to the recovery room. Moving the doorway to the restricted hallway would create the need to replace the existing single scrub sink with a double sink to accommodate both ORs. Minor changes related to the waste gas line installation for an anesthesia machine also would be required. The estimated construction cost of the changes is \$107,211. Capital equipment additions would be restricted to the cost of an anesthesia machine and related monitors totaling an estimated \$43,900.

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.

Construction/renovation requirements are (a) moving the entry door into the restricted corridor and (b) closing off the existing door that opens to the recovery room. Moving the doorway to the restricted hallway will require replacing the existing single scrub sink with a double sink to accommodate both ORs. Minor changes related to the waste gas line installation for an anesthesia machine also will be required. The square footage of each room will be not change.

The Project is expected to be completed within three (3) months as follows:

Renovation will commence 1 month after the CON is obtained. Renovation is expected to be completed within one month. The OR will be operational after final inspections which are expected to be completed one month after renovation is completed.

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 | 5 | -1 | 4 |

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.

Not applicable

11. REQUIRED APPROVALS AND SITE CONTROL

- A. Site size: _____ acres
- 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 (If NO, describe below the current status and timetable for receiving each of the necessary approvals.)

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

(1) Owned by: Hines USVF North Bethesda Place LP

(2) Options to purchase held by: _____
Please provide a copy of the purchase option as an attachment.

- (3) Land Lease held by: Hines USVF North Bethesda Place LP
Please provide a copy of the land lease as an attachment.
See Attachment 1
- (4) Option to lease held by: _____
Please provide a copy of the option to lease as an attachment.
- (5) Other: _____
Explain and provide legal documents as an attachment.

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 – upon approval date.
- B. Beginning Construction – one (1) month from capital obligation.
- C. Pre-Licensure/First Use – three (3) months from capital obligation.
- D. Full Utilization – thirty-six (36) months from first use.

For projects not involving construction or renovations.

Project Implementation Target Dates

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

For projects not involving capital expenditures.

Project Implementation Target Dates

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

See Attachment 2.

14. FEATURES OF PROJECT CONSTRUCTION

A. CON Application Package

See Attachment 3 Tables B, C, D.

- 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.

| |
|---------------------------------|
| Existing utilities are adequate |
|---------------------------------|

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.).

See Attachment 4

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.

Brent Longenecker MSPT, MBA
1A Burton Hills Boulevard
Nashville, Tennessee 37215

Brooke Smith, CASC
Maryland Surgery Center
11400 Rockville Pike
Rockville, Maryland 20852

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.

Brent Longenecker, MSPT, MBA

See Attachment 5

Brooke Smith

Andochick Surgical Center, 81 Thomas Johnson Ct., Frederick MD 21702

2000-2003

Central Maryland Surgery Center, 197 Thomas Johnson Dr., Frederick, MD 21702

2003-2006

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 applicant regarding the project proposed in the application.

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.

Date



Signature of Owner or Board-designated Official

Board Chairman Division Vice President
Position/Title

Bronx Longmarch
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). The State Health Plan.

Every applicant must address each applicable standard in the chapter of the State Health Plan for Facilities and Services². 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.

SURGERY 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.

Standard .05(A) (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.

² [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

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

Response: The Center will provide to the public, upon inquiry (or as required by applicable regulations or law), information concerning charges for the full range of surgical services provided.

Information will be communicated via the Center's website.

The Center is unaware of any complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration concerning its providing information regarding charges to the general public.

Standard .05(A) (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.

Response: Upon an individual's inquiry, the Center shall provide to the public information concerning the volume of its 10 most frequently performed surgical procedures performed at the Center location for the most recent 12 months available (which information shall be updated at least annually).

Standard .05(A) (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.

(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.

Response: The Center has 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 the policy above.

See Attachment 7 Charity Care Policies and **Attachment 8** Financial Assistance Form

The Charity Care Policy includes:

- (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.

Policy

Per Procedure No. 1.

"Center will make a determination of 2 business days upon the receipt of the requested documents." (The requested "financial hardship" documentation shall be completion of the Financial Assistance Form.)

- (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.

Notice:

Notices regarding the Center's charity care policy shall be posted in the registration area and business office of the Center.

Per Procedure No. 5.

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

- (ii) 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.

Per Procedure No. 4.

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.

Provision of Charity Care: The Center provides approximately \$1,000,000 in charity care (free or reduced care) during each annual period; almost 2% of gross charges in 2018.

Per Policy

"The center is committed to provide services for 50 cases from the Montgomery County Health Department annually."

In particular, the Center offers the "Laparoscopic Tubal Ligation Program". This program is designed to afford indigent members of the Center's service area the ability to have laparoscopic tubal ligation at a deeply discounted, self pay rate. For many years the Center has performed these procedures through a small group of physicians who are known to the referring physicians of the Community Health Centers in both Montgomery and Prince George County, Free Clinics such as the Community Clinic, Inc., which is one of the oldest and largest providers of medical services to medically under-served people in Montgomery and northwestern Prince George's counties. Additionally, Holy Cross Hospital (a Catholic hospital) does not allow sterilization procedures to be performed at its facilities and refers low income patients to the Center's group.

Standard .05(A) (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.

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

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

(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.

(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.

Response: The Center is licensed, in good standing, by the Maryland Department of Health.
See Attachment 9

The Center is in compliance with the conditions of participation of the Medicare and Medicaid programs.

See Attachment 10

The Center is Accredited by the Accreditation Association for Ambulatory Health Care.

See Attachment 11

The Center is enrolled in the Ambulatory Surgery Center Quality Reporting program and submitted its data.

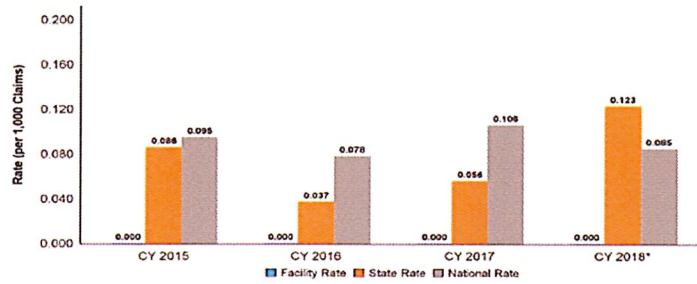
See Attachment 12

Maryland Surgery Center for Women has a defined Quality Assurance Performance Improvement program which incorporates quality measures adopted by CMS, as well as other benchmark measures which have been developed by the ASC Quality Collaboration. Comparison to national and state benchmarks enables the Center to monitor its comparative performance and develop improvement strategies as indicated by the performance metrics.

On the most recent 2018 Mid-Year Status Report issued by CMS, the Center compares favorably to both state and national benchmarks on the following measures: Burns, Falls, Wrong Site Surgery, and Hospital Transfers. Years of comparison on that particular report include 2015 through 2018 YTD. The graph below is an example of the Center's CMS data displayed for the Center.

Source: Medicare FFS Claims
 * CY 2018 data are current as of report date

Figure 2— ASC-2: Patient Fall Rates, per 1,000 Claims



In addition to the CMS comparative data, a quarterly benchmarking report is also used to compare the Center performance to national ASC Quality Collaboration measure rates as well as other multispecialty centers within AMSURG. An example of this benchmarking rate is shown below. It is noted that the Center has had an increase in the number of hospital transfers during 2018, and the resulting rate of transfers is above the ASC Quality Collaboration rate. This comparison precipitates a focused review of the transfers in order to develop any corrective actions which are indicated by that review.

2314-001 Rockville Maryland Multispecialty
 Current Quarter: 2018

| Quality Measures | Center Performance | | | | Quality Benchmark | | | |
|--------------------|--------------------|--------|--------|--------|-------------------|--------|--------|---------|
| | 3Q17 | 4Q17 | 1Q18 | 2Q18 | 2017 | 2018 | Multi | ASC QC* |
| Burns | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.018 | 0.019 |
| Falls | 0.000 | 0.000 | 1.131 | 0.000 | 0.000 | 0.526 | 0.133 | 0.119 |
| Hospital Transfers | 0.000 | 1.072 | 2.262 | 1.965 | 0.516 | 2.103 | 1.013 | 0.976 |
| Wrongs | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.052 | 0.023 |
| Infections | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.269 | 0.182 |
| Medication Error | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.210 | 0.250 |
| Event Reporting | 6,945 | 11,790 | 12,443 | 15,717 | 9,288 | 14,194 | 11,655 | |

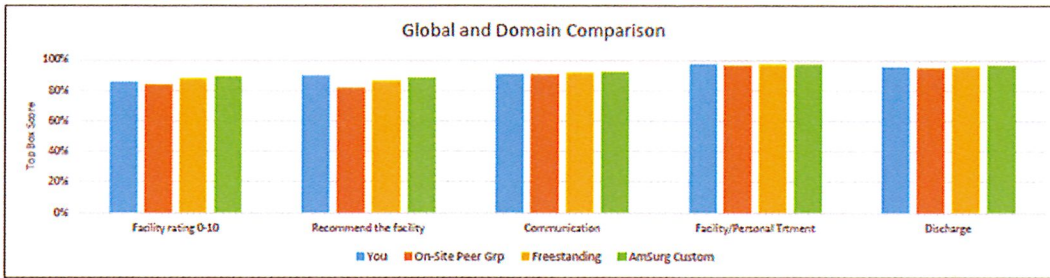
| OAS CAHPS | 3Q17 | 4Q17 | 1Q18 | 2Q18 | 2017 | 2018 | Amsurg | freestanding |
|---|---------|------|------|------|------|------|--------|--------------|
| Overall Patient Satisfaction OASCAHPS - Top Box | No Data | 75% | 71% | 85% | 75% | 81% | 89% | 85% |

Count of Center Reported Events and Volume

2Q18

| Count of Center Reported Events | | | | | | | 2Q18 Case Volumes | | | |
|---------------------------------|------|------|------|------|------|------|-------------------|-------------|----------|--|
| Quality Measure | 3Q17 | 4Q17 | 1Q18 | 2Q18 | 2017 | 2018 | Total | Colonoscopy | Cataract | |
| Burns | 0 | 0 | 0 | 0 | 0 | 0 | 1,018 | 0 | 0 | |
| Falls | 0 | 0 | 1 | 0 | 0 | 1 | 68,735 | 14,368 | 10,782 | |
| Hospital Transfers | 0 | 1 | 2 | 2 | 1 | 4 | 363,656 | 225,522 | 44,175 | |
| Wrongs | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| Infections | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| Medication Error | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| Event Reporting | 7 | 11 | 11 | 16 | 18 | 27 | | | | |

In addition to mandatory CMS quality measures, the Center is also participating voluntarily in the OAS-CAHPS patient survey. Benchmark comparisons to the freestanding database maintained by Press Ganey (survey vendor) are also provided for this data.



| Rockville Maryland Multispecialty 2 | Your Top Box Score | | | | On-Site Peer Grp N=1,278 | Freestanding N=761 | AmSurg Custom N=206 |
|-------------------------------------|--------------------|---------------------------|--------------------------|---|-----------------------------|-----------------------|------------------------|
| Composite Question | Current n | Previous % Feb18-Apr18 | Current % May18-Jul18 | | Percentile Rank | Percentile Rank | Percentile Rank |
| Facility rating 0-10 | 117 | 82.0% | 85.5% | ▲ | 58 | 29 | 20 |
| Recommend the facility | 118 | 82.6% | 89.6% | ▲ | 90 | 74 | 61 |
| Communication | 118 | 89.2% | 90.6% | ▲ | 47 | 31 | 28 |
| Provided needed info re procedure | 118 | 91.9% | 95.6% | ▲ | 91 | 83 | 70 |
| Instructions good re preparation | 118 | 94.4% | 98.3% | ▲ | 96 | 93 | 89 |
| Procedure info easy to understand | 117 | 92.5% | 94.9% | ▲ | 78 | 58 | 42 |
| Anesthesia info easy to understand | 81 | 89.3% | 86.4% | ▼ | 5 | 4 | 5 |
| Anes side effect easy to understand | 81 | 77.7% | 77.6% | ▲ | 17 | 15 | 20 |
| Facility/Personal Trtment | 118 | 95.0% | 97.3% | ▲ | 66 | 50 | 47 |
| Check-in run smoothly | 118 | 91.3% | 97.5% | ▲ | 85 | 74 | 66 |
| Facility clean | 118 | 95.0% | 97.5% | ▲ | 42 | 27 | 25 |
| Clerks and receptionists helpful | 118 | 96.3% | 94.1% | ▼ | 23 | 20 | 22 |
| Clerks and reception courteous | 117 | 98.8% | 97.4% | ▼ | 44 | 40 | 44 |
| Staff treat w/ courtesy, respect | 117 | 95.7% | 98.3% | ▲ | 64 | 46 | 45 |
| Staff ensure you were comfortable | 117 | 93.2% | 99.1% | ▲ | 92 | 87 | 82 |
| Discharge | 118 | 95.2% | 95.4% | ▲ | 59 | 32 | 20 |
| Written discharge instructions | 118 | 99.4% | 98.3% | ▼ | 74 | 52 | 50 |
| Instructions regarding recovery | 118 | 88.6% | 89.6% | ▲ | 82 | 63 | 51 |
| Information re subsequent pain | 105 | 95.3% | 93.3% | ▼ | 29 | 15 | 12 |
| Information re subsequent nausea | 82 | 97.3% | 95.1% | ▼ | 23 | 14 | 6 |
| Information re subsequent bleeding | 112 | 91.4% | 95.5% | ▲ | 25 | 12 | 3 |
| Info on response to infection | 99 | 99.3% | 100.0% | ▲ | 99 | 99 | 99 |

In summary, the Center undertakes active monitoring and benchmark comparisons as a component of its Quality Improvement efforts. Numerous sources of benchmarking data are used to assist in assessment of performance and the need for focused improvement efforts.

Standard .05(A) (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.

Response: See Transfer Agreement at **Attachment 13** which complies with Department of Health regulations implementing the requirements of Health-General Article §19-308.2.

The Transfer Agreement includes the following:

- i) Notification to the receiving hospital before the transfer and confirmation by that hospital that the patient meets that hospital's admissions criteria relating to appropriate bed, physician, and other services necessary to treat the patient;

Paragraph 1

- ii) The use of medically appropriate life-support measures that a reasonable and prudent physician exercising ordinary care would use to stabilize the patient before transfer and to sustain the patient during the transfer;

Paragraph 5

- iii) The provision of appropriate personnel and equipment that a reasonable and prudent physician exercising ordinary care would use for the transfer;

Paragraph 5

- iv) The transfer of all necessary records for continuing the care for the patient.

Paragraph 6

The Center has procedures for emergency transfer to a hospital that meet or exceed the minimum requirements in COMAR 10.05.05.09.

See Attachment 14

These procedures include the following:

- (1) Having a written transfer agreement with a local Medicare participating hospital or requiring all physicians, dentists, or podiatrists performing surgery in the freestanding ambulatory surgical facility to have admitting privileges at such a hospital;

See Attachment 13

- (2) Having a mechanism for notifying the hospital of a pending emergency case;

Procedure: "The receiving hospital is notified of the transfer and necessary information is provided. Documentation is provided on the Hospital Transfer for...";

- (3) Having a mechanism for arranging appropriate transportation to the hospital; and

Procedure: "The mode of information as ordered by the physician is contacted. 911 is an acceptable means of transport in emergency situations. In non-emergent transfer situations private transfer or transfer by contracted ambulance service is acceptable as ordered by the physician."

- (4) The manner in which a facility sends a copy of the patient's medical record to the hospital.

Procedure: "Copies of the appropriate patient chart items are sent with the patient."

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.

Standard .05B (1) Service Area.

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

Response: See Attachment 15

Standard .05B (2) Need - Minimum Utilization for Establishment of a New or Replacement Facility. NOT APPLICABLE

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

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

(b) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the initiation of surgical services at the proposed facility, consistent with Regulation .07 of this chapter.

(c) An applicant proposing the establishment or replacement of a hospital shall submit a needs assessment that includes the following:

(i) Historic trends in the use of surgical facilities for inpatient and outpatient surgical procedures by the new or replacement hospital's likely service area population;

(ii) The operating room time required for surgical cases projected at the proposed new or replacement hospital by surgical specialty or operating room category; and

(iii) In the case of a replacement hospital project involving relocation to a new site, an analysis of how surgical case volume is likely to change as a result of changes in the surgical practitioners using the hospital.

(d) An applicant proposing the establishment of a new ambulatory surgical facility shall submit a needs assessment that includes the following:

(i) Historic trends in the use of surgical facilities for outpatient surgical procedures by the proposed facility's likely service area population;

(ii) The operating room time required for surgical cases projected at the proposed facility by surgical specialty or, if approved by Commission staff, another set of categories; and

(iii) Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.

Standard .05B (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.

Response: The Center is in compliance with this standard because it can demonstrate that its existing OR was utilized optimally over the past 12 months and that the expanded two-OR capacity is likely to be used at optimal capacity within three years. The Center has long ago outgrown its single OR and has been working through days that flow well into the evening and adding weekends not typically open in order to accommodate the increasing number of cases and increasing level of case acuity. In 2017, as a single specialty center, the Center already was operating at 120% of optimal capacity with only 3,816 cases. 2018 will close at 130% optimal capacity with 2,170 OR hours and nearly 4,000 total cases even though new specialties were not added until halfway through the calendar year. In 2019 the Center is on track to easily demonstrate the need for 1.7 ORs, performing a projected 4,419 cases requiring a minimum of 166,475 surgical minutes; no amount of weekends, overtime or late night days will be able to keep up with the volume. Compared to the single specialty center that opened in 2001 the Center now will provide services to a total of 4 specialties including OB/Gynecology, Urology, Colorectal and General Surgery. While confident that each patient does and will continue to receive safe and efficient patient care, the Center is appropriately concerned about the impact on "customer satisfaction" of increasingly growing volumes. Extending the day certainly meets

the needs of the number of cases but frequently inconveniences and sometimes even causes discomfort to the patients and their respective families.

The Center hosts a rather large number of surgeons (60) for a single OR facility yet the Center has continued to grow as a result of the level of confidence the Center instills in both its physicians and patients. The Center projects demand for operating room time in 2020 equivalent to 1.8 operating rooms operating at optimal capacity. The Center projects demand equivalent to optimal use of two rooms by 2021. The Center would like the ability to continue to meet the needs of the community and better its service by affording both physician and patient a reasonable day and hour for surgery. As we the Center has demonstrated with its historical volume as well as future projections based both on trend and addition of specialties there is a need for a second OR.

Standard .05B (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.

Response: The Center meets the requirements in current Section 3.7 of the FGI guidelines. **See Attachment 2.**

Standard .05B (5) Support Services.

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

Response: The Center does not directly provide laboratory, radiology, or pathology services. Various outside providers are used for laboratory and pathology services on an as needed basis based on the patient's insurance and clinical needs.

Standard .05B (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.

Response: The Center has taken patient safety into consideration with the design of this Project, working closely with the architect and engineers to ensure compliance with all standards and FGI Guidelines. The Center already had in place proper ventilation, air exchange and finishes. The Center will install a waste gas line for the addition of the anesthesia machine to eliminate the potential of anesthetic gases escaping into room air. Additional safety elements include a doorway that opens into the restricted corridor to increase infection control precautions and simulate the traffic pattern of the existing OR therefore lessening the need for additional staff training and adjustment.

Standard .05B (7) Construction Costs. NOT APPLICABLE

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.

Standard .05B (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.

Response: Utilization projections were based on historical utilization trends, the transition from single to multi-specialty, adding physicians, and certain cases moving from hospital ORs with higher levels of acuity. The Center based its revenue estimates on the utilization projections and current charges and rates of reimbursement. Expenses are based on current staffing and other overall expenses. The Center has historically generated an excess of revenues over expenses and projects a continued profitable operation after the addition of a second OR. Therefore the Project and the center are consistent with this standard.

Standard .05B (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.

Not applicable because the Project is not establishing a new ambulatory surgical 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.

Response: The Project anticipates a minimal if any impact on surgical case volume at general hospitals. The only cases anticipated to be performed at the Center which are currently performed at hospitals are certain hysterectomies when payors in certain instances are requiring they be performed in an outpatient setting.

Standard .05B (10) Preference in Comparative Reviews. NOT APPLICABLE

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.

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. To be discussed after numbers produced

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.

[(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

The 2016 and 2017 OR minutes were analyzed and the total Surgical Minutes in OR/s was calculated using total OR minutes plus 25 minute per case for turnover yielding 102,460 and 114,445 minutes for 2016 and 2017 respectively. The OR needed @ Optimal Capacity was calculated as follows for 2016: $(102,460/60)/1,632 = 1.0$ OR.

The 2018 OR minutes were analyzed through September and then annualized

The 2019 thru 2021 OR minutes were projected based on OR case growth with the main driver being 300 General Surgery cases added in 2019 with starting General Surgery (Dr. Kravitz and Dr. Starin)

| CY or FY (Circle) | Two Most Actual Ended Recent Years | | Current Year Projected | Projected Years (ending with first full year at full utilization) | | |
|--------------------------------------|------------------------------------|------------|------------------------|---|------------|------------|
| | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
| a. Number of operating rooms (ORs) | 1 | 1 | 1 | 2 | 2 | 2 |
| • Total Procedures in ORs | 2,502 | 2,568 | 2,763 | 3,565 | 3,832 | 4,100 |
| • Total Cases in ORs | 1,251 | 1,284 | 1,382 | 1,782 | 1,916 | 2,050 |
| • Total Surgical Minutes in ORs** | 102,460 | 114,455 | 130,199 | 166,475 | 178,961 | 191,488 |
| ORs needed @ Optimal Capacity | 1.0 | 1.2 | 1.3 | 1.7 | 1.8 | 2.0 |
| b. Number of Procedure Rooms (PRs) | 3 | 3 | 5 | 5 | 5 | 5 |
| • Total Procedures in PRs | 2,359 | 2,532 | 2,585 | 2,637 | 2,690 | 2,744 |
| • Total Cases in PRs | 2,359 | 2,532 | 2,585 | 2,637 | 2,690 | 2,744 |
| • Total Minutes in PRs** | 40,320 | 48,420 | 64,884 | 139,763 | 142,558 | 145,410 |

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

| | Projected Years (beginning with first full year at full utilization) | | |
|------------------------------------|---|---------|---------|
| | 2019 | 2020 | 2021 |
| CY or FY (Circle) | 2019 | 2020 | 2021 |
| a. Number of operating rooms (ORs) | 1 | 1 | 1 |
| • Total Procedures in ORs | 1,470 | 1,737 | 2,006 |
| • Total Cases in ORs | 735 | 869 | 1,003 |
| • Total Surgical Minutes in ORs** | 68,647 | 81,133 | 93,660 |
| ORs needed @ Optimal Capacity | 0.7 | 0.8 | 1.0 |
| b. Number of Procedure Rooms (PRs) | 5 | 5 | 5 |
| • Total Procedures in PRs | 2,637 | 2,690 | 2,744 |
| • Total Cases in PRs | 2,637 | 2,690 | 2,744 |
| • Total Minutes in PRs** | 139,763 | 142,558 | 145,410 |

*Do not include turnover time

Response: The Center is in compliance with this standard because it can demonstrate that its existing OR was utilized optimally over the past 12 months and that the expanded two-OR capacity is likely to be used at optimal capacity within three years. The Center has long ago outgrown its single OR and has been working through days that flow well into the evening and adding weekends not typically open in order to accommodate the increasing number of cases and increasing level of case acuity. In 2017, as a single specialty center, the Center already was operating at 120% of optimal capacity with only 3,816 cases. 2018 will close at 130% optimal capacity with 2,170 OR hours and nearly 4,000 total cases even though new specialties were not added until halfway through the calendar year. In 2019 the Center is on track to easily demonstrate the need for 1.7 ORs, performing a projected 4,419 cases requiring a minimum of 166,475 surgical minutes; no amount of weekends, overtime or late night days will be able to keep up with the volume. Compared to the single specialty center that opened in 2001 the Center now will provide service to a total of 4 specialties including OB/Gynecology, Urology, Colorectal and General Surgery. While confident that each patient does and will continue to receive safe and efficient patient care, the Center is appropriately concerned about the impact on “customer satisfaction” of increasingly growing volumes. Extending the day certainly meets the needs of the number of cases but frequently inconveniences and sometimes even causes discomfort to the patient and their respective families.

The Center hosts a rather large number of surgeons (60) for a single OR facility yet the Center has continued to grow through the level of confidence the Center instills in both its physicians and patients. The Center would like the ability to continue to meet the needs of the community

and better its service by affording both physician and patient a reasonable day and hour for surgery. As we the Center has demonstrated with its historical volume as well as future projections based both on trend and addition of specialties there is a need for a second OR.

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.

Response: The alternative to adding an additional operating room is the current adjusted operations at the Center as described below. This adjustment has resulted in staffing issues, as well as patient and physician dissatisfaction and this is not sustainable over the long term. These adjustments also negatively impact the Center's ability to serve the general surgical patients.

The Center has adjusted its operations to accommodate the increase in demand for OR time. These initiatives included:

- Moving all appropriate eligible cases to the procedure room to open up time in the operating room;
- Expanding routine hours into the evening and night and opening Saturdays. Current standard for "operating room hours is 0700-1530, the Center has had to allow cases to be posted at 0600 and extend beyond 2100 at times due to the unpredictable high acuity case volume.
- The Center has hired additional PRN staff to supplement the FT staff to try and prevent overtime burnout.
- The Center has offered premium pay to FT staff to encourage them to volunteer for the late or weekend hours that are above and beyond their FT work week.

The addition of high acuity cases (hysterectomies, laparoscopic myomectomies, etc.) has resulted in decreased patient and physician satisfaction. Due to the nature of the cases, often the OR time scheduled differs greatly from the OR time needed. These cases are preferably performed in the morning because of the long recovery time and therefore all subsequent cases

in the operating room for the day are affected by the case/s going over schedule. This affects in countless ways both the patient (childcare, ride coordination, NPO status, etc.) and the physicians scheduled to follow these cases, i.e. office schedule, hospital rounds, call schedule.

Serving GYN surgeons over the years has been successful because of the large percentage of their cases being able to be performed in the procedure rooms. Now that the Center has chosen to expand the specialties served, the Center is finding it more difficult to accommodate its demand. While the Center has been able to take a small volume from the new general surgery practice, the Center is unable to offer the general surgery practice the ability to do laparoscopic cases requiring time in the OR. A second OR would allow the Center to better serve the general surgery practice eliminating the need to schedule patients based on type of anesthesia needed.

The Center has been approached this year by both urology and pain management specialties that are being denied payment by certain third party payers when their procedures are performed in the hospital because of the high cost of these procedures when performed in a hospital. The difficulty scheduling urology and pain management due to lack of operating time or an uncertain scheduled start time is another example of the restrictions of a single OR.

The goals of having a second operating room are;

- Reduce overtime and unnecessary additional overhead with extended hours and days
- Prevent staff burnout
- Increase patient satisfaction by keeping to schedule more closely
- Increase efficiency (the ability to "bounce" room to room when necessary)
- Reduce physician and physician office frustrations with lack of time to schedule larger cases
- Increase volume to meet demand by creating more OR time for high acuity cases and building physician confidence in a schedule that can run more on time
- Allow for cases that are being forced out of the hospital setting due to payer restrictions
- Create open OR time to both accommodate the internal growth and allow for new growth

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.

See Attachment 16

- 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.

See Attachment 17

- 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.

See Attachment 18

- 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).

Response: The Project will be in compliance with the applicable performance requirements found at COMAR 10.24.01.12B.(2). The renovation design has been completed and there are no further State and local land use, environmental, and design approvals required.

TABLE 3: REVENUES AND EXPENSES - ENTIRE FACILITY (including proposed project)

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

| | Two Most Recent Years (Actual) | | Current Year Projected | Projected Years (ending at least two years after project completion and full occupancy) Add columns if needed in order to document that the hospital will generate excess. | | |
|--|--------------------------------|----------------------|------------------------|---|----------------------|----------------------|
| | CY 2016 | CY 2017 | CY 2018 | 2019 | 2020 | 2021 |
| Indicate CY or FY | | | | | | |
| 1. REVENUE | | | | | | |
| a. Inpatient Services | | | | | | |
| b. Outpatient Services | \$ 54,940,738 | \$ 62,168,475 | \$ 55,831,315 | \$ 64,643,003 | \$ 67,369,769 | \$ 70,118,481 |
| Gross Patient Service Revenues | \$ 54,940,738 | \$ 62,168,475 | \$ 55,831,315 | \$ 64,643,003 | \$ 67,369,769 | \$ 70,118,481 |
| c. Allowance For Bad Debt | \$ 109,881 | \$ 125,735 | \$ 112,918 | \$ 130,740 | \$ 136,255 | \$ 141,814 |
| d. Contractual Allowance | \$ 48,489,512 | \$ 54,446,388 | \$ 48,796,145 | \$ 56,613,549 | \$ 59,001,617 | \$ 61,408,906 |
| e. Charity Care | \$ 780,240 | \$ 983,328 | \$ 983,328 | \$ 1,022,468 | \$ 1,065,598 | \$ 1,109,074 |
| Net Patient Services Revenue | \$ 5,561,105 | \$ 6,613,024 | \$ 5,938,924 | \$ 6,876,246 | \$ 7,166,299 | \$ 7,458,687 |
| f. Other Operating Revenues (Specify/add rows if needed) | | | | | | |
| NET OPERATING REVENUE | \$ 5,561,105 | \$ 6,613,024 | \$ 5,938,924 | \$ 6,876,246 | \$ 7,166,299 | \$ 7,458,687 |
| 2. EXPENSES | | | | | | |
| a. Salaries & Wages (including benefits) | \$ 950,457 | \$ 1,050,410 | \$ 1,084,073 | \$ 1,284,073 | \$ 1,309,754 | \$ 1,335,950 |
| b. Contractual Services | \$ 626,459 | \$ 530,887 | \$ 431,383 | \$ 431,383 | \$ 431,383 | \$ 431,383 |
| c. Interest on Current Debt | \$ 4,734 | \$ 15,225 | \$ 77,003 | \$ 61,896 | \$ 47,439 | \$ 32,205 |
| d. Interest on Project Debt | \$ - | \$ - | \$ - | \$ - | \$ - | \$ - |
| e. Current Depreciation | \$ 58,913 | \$ 15,550 | \$ 174,709 | \$ 206,000 | \$ 206,000 | \$ 206,000 |
| f. Project Depreciation | \$ - | \$ - | \$ - | \$ 12,857 | \$ 12,857 | \$ 12,857 |
| g. Current Amortization | \$ - | \$ - | \$ - | \$ - | \$ - | \$ - |
| h. Project Amortization | \$ - | \$ - | \$ - | \$ - | \$ - | \$ - |
| i. Supplies | \$ 962,930 | \$ 1,070,241 | \$ 1,125,892 | \$ 1,268,376 | \$ 1,321,879 | \$ 1,375,812 |
| j. Other Expenses - Rent | \$ 120,081 | \$ 203,153 | \$ 242,597 | \$ 243,319 | \$ 243,319 | \$ 243,319 |
| j. Other Expenses - Banking Fees | \$ 30,946 | \$ 32,105 | \$ 28,716 | \$ 28,716 | \$ 28,716 | \$ 28,716 |
| j. Other Expenses - Insurance, Licenses and taxes | \$ 101,645 | \$ 35,692 | \$ 35,627 | \$ 35,627 | \$ 35,627 | \$ 35,627 |
| j. Other Expenses - Travel | \$ 15,964 | \$ 32,272 | \$ 34,865 | \$ 34,865 | \$ 34,865 | \$ 34,865 |
| j. Other Expenses - Loss on Disposition of Equipment | \$ 2,419 | \$ - | \$ 701 | \$ - | \$ - | \$ - |
| TOTAL OPERATING EXPENSES | \$ 2,874,548 | \$ 2,985,535 | \$ 3,235,566 | \$ 3,607,113 | \$ 3,671,840 | \$ 3,736,734 |
| 3. INCOME | | | | | | |
| a. Income From Operation | \$ 2,686,557 | \$ 3,627,489 | \$ 2,703,358 | \$ 3,269,133 | \$ 3,494,460 | \$ 3,721,953 |
| b. Non-Operating Income | \$ 50 | \$ 3,132 | \$ 7,617 | | | |
| SUBTOTAL | \$ 2,686,607 | \$ 3,630,621 | \$ 2,710,975 | \$ 3,269,133 | \$ 3,494,460 | \$ 3,721,953 |
| c. Income Taxes | | | | | | |
| NET INCOME (LOSS) | \$ 2,686,607 | \$ 3,630,621 | \$ 2,710,975 | \$ 3,269,133 | \$ 3,494,460 | \$ 3,721,953 |
| 4. PATIENT MIX | | | | | | |
| a. Percent of Total Revenue | | | | | | |
| 1) Medicare | 1.4% | 1.0% | 1.1% | 1.1% | 1.1% | 1.1% |
| 2) Medicaid | 5.6% | 6.9% | 1.4% | 1.4% | 1.4% | 1.4% |
| 3) Blue Cross | 28.2% | 26.2% | 29.2% | 29.2% | 29.2% | 29.2% |
| 4) Commercial Insurance | 57.3% | 56.4% | 54.5% | 54.5% | 54.5% | 54.5% |
| 5) Self-pay | 7.5% | 8.4% | 13.7% | 13.7% | 13.7% | 13.7% |
| 6) Other | 0.1% | 1.1% | 0.1% | 0.1% | 0.1% | 0.1% |
| TOTAL | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

TABLE 4: REVENUES AND EXPENSES - PROPOSED PROJECT

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

| | Projected Years (ending at least two years after project completion and full occupancy) Add columns if needed in order to document that the hospital will generate excess | | |
|--|--|----------------------|----------------------|
| Indicate CY or FY | 2019 | 2020 | 2021 |
| 1. REVENUE | | | |
| a. Inpatient Services | | | |
| b. Outpatient Services | \$ 10,757,135 | \$ 12,708,670 | \$ 14,667,524 |
| Gross Patient Service Revenues | \$ 10,757,135 | \$ 12,708,670 | \$ 14,667,524 |
| c. Allowance For Bad Debt | \$ 21,756 | \$ 25,703 | \$ 29,665 |
| d. Contractual Allowance | \$ 9,420,967 | \$ 11,130,097 | \$ 12,845,638 |
| e. Charity Care | \$ 170,147 | \$ 201,015 | \$ 231,998 |
| Net Patient Services Revenue | \$ 1,144,265 | \$ 1,351,855 | \$ 1,560,223 |
| f. Other Operating Revenues (Specify/add rows if needed) | | | |
| NET OPERATING REVENUE | \$ 1,144,265 | \$ 1,351,855 | \$ 1,560,223 |
| 2. EXPENSES | | | |
| a. Salaries & Wages (including benefits) | \$ 200,000 | \$ 204,000 | \$ 208,080 |
| b. Contractual Services | \$ - | \$ - | \$ - |
| c. Interest on Current Debt | \$ - | \$ - | \$ - |
| d. Interest on Project Debt | | | |
| e. Current Depreciation | \$ - | \$ - | \$ - |
| f. Project Depreciation | \$ 12,857 | \$ 12,857 | \$ 12,857 |
| g. Current Amortization | | | |
| h. Project Amortization | | | |
| i. Supplies | \$ 211,068 | \$ 249,360 | \$ 287,795 |
| j. Other Expenses - Rent | \$ - | \$ - | \$ - |
| j. Other Expenses - Banking Fees | \$ - | \$ - | \$ - |
| j. Other Expenses - Insurance, Licenses and taxes | \$ - | \$ - | \$ - |
| j. Other Expenses - Travel | \$ - | \$ - | \$ - |
| j. Other Expenses - Loss on Disposition of Equipment | \$ - | \$ - | \$ - |
| TOTAL OPERATING EXPENSES | \$ 423,926 | \$ 466,217 | \$ 508,732 |
| 3. INCOME | | | |
| a. Income From Operation | \$ 720,339 | \$ 885,637 | \$ 1,051,491 |
| b. Non-Operating Income | | | |
| SUBTOTAL | \$ 720,339 | \$ 885,637 | \$ 1,051,491 |
| c. Income Taxes | | | |
| NET INCOME (LOSS) | \$ 720,339 | \$ 885,637 | \$ 1,051,491 |
| 4. PATIENT MIX | | | |
| a. Percent of Total Revenue | | | |
| 1) Medicare | 1.1% | 1.1% | 1.1% |
| 2) Medicaid | 1.4% | 1.4% | 1.4% |
| 3) Blue Cross | 29.2% | 29.2% | 29.2% |
| 4) Commercial Insurance | 54.5% | 54.5% | 54.5% |
| 5) Self-pay | 13.7% | 13.7% | 13.7% |
| 6) Other | 0.1% | 0.1% | 0.1% |
| TOTAL | 100.0% | 100.0% | 100.0% |

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.

Response: Not applicable.

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.

Response: The Center's surgical case volume growth and its projected future growth are likely to require operating room hours consistent with operation of two operating rooms at optimal capacity use. Much of this growth is the result of becoming multi-specialty and high satisfaction with the services provided at the Center.

As explained herein, the Center now is being forced to operate at very extended hours. Therefore, with the addition of an operating room, the Project will have a positive impact on patient access to services offered by the Center and on the cost to the health care delivery system as higher acuity cases are being moved from the hospital to an outpatient surgery center. The Project will not have a negative impact on other providers.