

UPDATED APRIL 2024

AMBULATORY SURGICAL FACILITY

APPLICATION FOR CERTIFICATE OF NEED (CON)

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 Review Criteria listed at COMAR 10.24.01.08G. The first Review Criteria requires the Applicant to respond to all applicable standards in the State Health Plan chapter, COMAR 10.24.11.

- **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 four (4) hard copies of the application to:

Health Care 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. 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.

PDFs, Microsoft Word files, and spreadsheets should be submitted to mhcc.confilings@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.

PART I - PROJECT IDENTIFICATION AND GENERAL INFORMATION

1. FACILITY

Name of Facility: _____

Address:

Street City Zip County

2. NAME OF OWNER

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 and any related parent entities. Attach a chart that completely delineates this ownership structure.

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): _____

Address:

Street				
	City	Zip	State	County
Telephone:				

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	<input type="checkbox"/>	
B.	Corporation		
	(1) Non-profit	<input type="checkbox"/>	
	(2) For-profit	<input type="checkbox"/>	
	(3) Close	<input type="checkbox"/>	State & Date of Incorporation <input type="text"/>
C.	Partnership		
	General	<input type="checkbox"/>	
	Limited	<input type="checkbox"/>	
	Limited Liability Partnership	<input type="checkbox"/>	
	Limited Liability Limited Partnership	<input type="checkbox"/>	
	Other (Specify):		
D.	Limited Liability Company	<input type="checkbox"/>	
E.	Other (Specify):		

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

A. Lead or primary contact:

Name and Title:

Company Name _____

Mailing Address:

Street _____ City _____ State _____ Zip _____

Telephone:

E-mail Address (required):

Fax:

**If company name
is different than
applicant briefly
describe the
relationship**

B. Additional or alternate contact:

Name and Title: _____

Company Name _____

Mailing Address: _____

Street _____ City _____ State _____ Zip _____

Telephone: _____

E-mail Address (required): _____

Fax:

**If company name
is different than
applicant briefly
describe the
relationship**

7. NAME OF THE OWNER OF THE REAL PROPERTY and Improvements (if different from the licensee or proposed licensee)

Legal Name of the Owner of the Real Property _____

Address:

Street _____ City _____ State _____ Zip _____

Telephone: _____

8. If a management company or companies is or will be involved in the clinical or financial management of the facility or will provide oversight of any construction or renovations proposed as part of this APPLICATION, identify each company or individual that will provide the services and describe the services that will be provided. Identify any ownership relationship between the management company and the owner of the facility, bed rights, and/or the real property or any related entity.

Name of Management Company _____

Address:

Street

City

State

Zip

County

Telephone: _____

***Please provide a chart showing the breakdown of ownership that includes the owners of the real property, and operations. Please include the management company if applicable.**

9. 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 hospital making a capital expenditure, as defined in Health-General Article, §19-120(k), Annotated Code of Maryland, and in this chapter, that exceeds the hospital capital threshold, including a capital expenditure:
 - (a) For the relocation of an existing health care facility owned or controlled by a merged asset system, except as provided in Regulation .03E of this chapter; and
 - (b) By a relocated health care facility to permit the facility to offer a new health care service for which CON is otherwise required.

10. 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

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.

11. CURRENT CAPACITY AND PROPOSED CHANGES

Unit Description	Currently Licensed/ Certified	Units to be Added or Reduced	Total Units if Project is Approved
Operating Rooms			
Procedure Rooms			

12. 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.

13. 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: _____
- (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: _____
Please provide a copy of the option to lease as an attachment.
- (5) Other: _____
Explain and provide legal documents as an attachment.

14. PROJECT IMPLEMENTATION SCHEDULE (COMAR 10.24.01.12A)

In completing this section, please note applicable obligation deadlines set forth in Commission regulations, COMAR 10.24.01.12. Ensure that the information presented reflects information presented in Application Item 10 (Project Description).

Project Implementation Schedule

An application for a CON or other Commission approval shall propose a schedule for implementation of the project in accordance with COMAR 10.24.01.12A(1) that specifies the estimated time for, at a minimum, the following project implementation steps: Obligation of Capital Expenditure, Beginning Construction, Complete Construction and Full Operation.

In developing the schedule, please note that COMAR 10.24.01.12C requires a holder to obligate at least 51 percent of the approved capital expenditure for a project involving building construction, renovation, or both, as documented by a binding construction contract or equipment purchase order, within the following specified time periods:

- (a) An approved new hospital has up to 36 months;
- (b) A project involving an approved new non-hospital health care facility or involving a building addition or replacement of building space of a health care facility has up to 24 months;
- (c) A project limited to renovation of existing building space of a health care facility has up to 18 months; and
- (d) A project that does not involve construction or renovation shall document that the approved project is complete and operational within 18 months.

In a multiphase plan of construction with more than one construction contract approved for an existing health care facility, a holder has:

- (a) Up to 12 months after approval to obligate 51 percent of the capital expenditure for the first phase of construction; and
- (b) Up to 12 months after completion of the immediately preceding phase of construction to obligate 51 percent of the capital expenditure for any subsequent approved phase.

15. 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 bathrooms, 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.

16. 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.

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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.).

**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.
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2. Are the applicant, owners, or the responsible persons listed in response to Part 1, questions 2, 3, 4, 7, and 8 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.
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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.
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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.
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5. Have the applicant, owners or responsible individuals listed in response to Part 1, questions 2, 3, 4, 7, and 8, 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).
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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.

Date

Signature of Owner or Board-designated Official

Position/Title

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 10.24.01.08G(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 from COMAR 10.24.11: State Health Plan for Facilities and Services: General Surgical Services.¹

Please provide a direct, concise response explaining the project's consistency with each standard. In cases where demonstrating compliance with a standard requires the provision of specific documentation, please include the documentation as a part of 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 covered by COMAR 10.24.11: State Health Plan for Facilities and Services: General Surgical Services 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 and Network Participation.

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

(a) Each ambulatory surgery center, ambulatory surgical facility, and 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) Each ambulatory surgery center, ambulatory surgical facility, and general

¹Copies of all applicable State Health Plan chapter are available on the Commission's web site at <https://mhcc.maryland.gov/mhcc/pages/home/regulations/regulations.aspx>

hospital shall provide to the public, upon inquiry or as required by applicable regulations, the names of the health carrier networks in which it currently participates.

(c) Each ambulatory surgery center, ambulatory surgical facility, and general hospital shall provide to the public, upon inquiry, the names of the health carrier networks in which each surgeon and other health care practitioner that provides services at the facility currently participates.

(d) 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.

(e) Providing a patient with an estimate of out-of-pocket charges prior to arrival for surgery shall be a condition of any CON issued by the Commission.

Standard .05(A) (2) Information Regarding Procedure Volume.

Each hospital, ambulatory surgical facility, and ambulatory surgery center shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the location. A hospital, ambulatory surgical facility, or ASC shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.

Standard .05(A) (3) Charity Care and Financial Assistance Policy. (See ADDENDUM A: ADDRESSING THE CHARITY CARE STANDARD, attached.)

Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care and financial assistance regarding free and reduced-cost care to uninsured, underinsured, or indigent patients and shall provide ambulatory surgical services on a charitable basis to qualified persons consistent with the policy. The policy shall include, as applicable below, at a minimum:

(a) Determination of Eligibility for Charity Care or Financial Assistance. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital or ambulatory surgical facility shall make a determination of probable eligibility and notify the patient of that determination.

(b) Notice of Charity Care Policy and Financial Assistance Policy. Public notice and information regarding the hospital or ambulatory surgical facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population 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. This notice shall include general information about who qualifies and how to obtain a copy of the policy or may include a posted copy of the policy. 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.

(c) **Criteria for Eligibility.** A hospital shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. 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 ambulatory surgical facilities described in these regulations. An ambulatory surgical facility, at a minimum, shall include the following eligibility criteria in its charity care policies:

(i) 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 charges; and

(ii) 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.

(d) 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.

(e) A hospital shall be able to demonstrate that its historic level of charity care or its projected level of charity care is appropriate to the needs of its actual or projected service area population. This demonstration shall include an analysis of the socio-economic conditions of the hospital's actual or projected service area population, a comparison of those conditions with those of Maryland's overall socio-economic indicators, and a comparative analysis of charity care provision by the applicant hospital and other hospitals in Maryland. The socio-economic indicators evaluated shall include median income and type of insurance by zip code area, when available. The analysis provided may also include an analysis of the social determinants of care affecting use of health care facilities and services and the health status of the actual or projected hospital service area population.

(f) An applicant submitting a proposal to establish or expand an ambulatory surgical facility 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 ambulatory surgical facilities 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;

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

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

(g) 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 ambulatory surgical facilities, measured as a percentage of total ambulatory surgical facility 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;

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

(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.

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 or other accreditation organization recognized by the Centers for Medicare and Medicaid and the Maryland Department of Health as acceptable for obtaining Medicare certification and Maryland licensure.

(c) An existing ambulatory surgical facility or ASC 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 Services 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 ASC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland.

(d) An applicant seeking to establish an ambulatory surgical facility shall:

(i) Demonstrate that the proposed facility will meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment;

(ii) Agree that, within two years of initiating service at the facility, it will obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities or another accreditation organization recognized by the Centers for Medicare and Medicaid Services as acceptable for obtaining Medicare certification and approved by the State of Maryland; and

(iii) Acknowledge in writing that, if the facility fails to obtain the accreditation in subparagraph (ii) on a timely basis, it shall voluntarily suspend operation of the facility.

(e) An applicant or a related entity that currently or previously has operated or owned one or more ASCs or ambulatory surgical facilities in or outside of Maryland, in the five years prior to the applicant's filing of an application to establish an ambulatory surgical facility, shall provide details regarding the quality of care provided at each such ASC or ambulatory surgical facility including information on licensure, accreditation, performance metrics, and other relevant information.

Standard .05(A) (5) Transfer Agreements.

(a) Each hospital shall have arrangements for transfer of surgical patients to another hospital that comply with the requirements of Health-General Article §19-308.2.

(b) Each ambulatory surgical facility shall have a process for assuring the emergency transfer of surgical patients to a hospital that complies with the requirements of COMAR 10.05.05.09.

B. Project Review Standards.

The standards in this regulation govern reviews of Certificate of Need applications involving surgical facilities and services. An applicant for a Certificate of Need shall demonstrate consistency with all applicable review standards.

Standard .05B (1) Service Area.

An applicant proposing to establish a new hospital providing surgical services or an 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.

Standard .05B (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 .06 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 .06 of this Chapter.

(c) An applicant proposing to establish or replace 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 the relocation.

(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 .06 of this Chapter;

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

(c) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity, consistent with Regulation .06 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.

Standard .05B (4) Design Requirements.

Floor plans submitted by an applicant must be consistent with the current FGI Guidelines:

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

(b) An ambulatory surgical facility shall meet the requirements in current Section 3.7 of the FGI Guidelines.

(c) Design features of a hospital or ambulatory surgical facility 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.

Standard .05B (5) Support Services.

Each applicant seeking to establish or expand an ambulatory surgical facility shall provide or agree to provide laboratory, radiology, and pathology services as needed, either directly or through contractual agreements, in compliance with COMAR 10.05.05.

Standard .05B (6) Patient Safety.

The design of proposed 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.

Standard .05B (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 adjustment of the hospital's global budget revenue authorized for 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 25% 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 hospital or ambulatory surgical facility will generate excess revenues over total expenses for the specific services affected by the project (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.

Standard .05B (9) Impact. (See addendum B: providing individual physician volume data.)

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

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

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

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

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

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

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

Other Criteria:

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 a need for the proposed project.

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.

(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 Recent Years (Actual)		Current Year Projected	Projected Years (ending with first full year at full utilization)			
	20__	20__		20__	20__	20__	20__
CY or FY (Circle)	20__	20__	20__	20__	20__	20__	20__
a. Number of operating rooms (ORs)							
• Total Procedures in ORs							
• Total Cases in ORs							
• Total Surgical Minutes in ORs**							
b. Number of Procedure							

Rooms (PRs)							
● Total Procedures in PRs							
● Total Cases in PRs							
● Total Minutes in PRs**							

**Do not include turnover time.

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

CY or FY (Circle)	Projected Years (Ending with first full year at full utilization)			
	20__	20__	20__	20__
a. Number of operating rooms (ORs)				
● Total Procedures in ORs				
● Total Cases in ORs				
● Total Surgical Minutes in ORs**				
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). Alternatives to the Project. The Commission shall consider the alternative approaches to meeting the need identified for the project that were considered by the applicant in planning the project and the basis for the applicant’s choice of the project among considered alternatives. In a comparative review of applications within the same review cycle, the Commission shall compare the costs and the likely effectiveness of alternative projects in meeting identified needs, improving the availability and accessibility of care, and improving the quality of care.

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.

10.24.01.08G(3)(d). Project Financial Feasibility and Facility or Program Viability. The Commission shall consider the availability of resources necessary to implement the project and the availability of revenue sources and demand for the proposed services adequate to ensure ongoing viability and sustainability of the facility to be established or modified or the service to be introduced or expanded.

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

- Identify the performance requirements applicable to the proposed project (Part 1, Question 14, “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(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.
- s).

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

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

CY or FY (Circle)	Two Most Recent Years Actual		Current Year Projected	Projected Years (ending with first full year at full utilization)			
	20__	20__	20__	20__	20__	20__	20__
1. Revenue							
a. Inpatient services							
b. Outpatient services							
c. Gross Patient Service Revenue							
d. Allowance for Bad Debt							
e. Contractual Allowance							
f. Charity Care							
g. Net Patient Services Revenue							
h. Other Operating Revenues (Specify)							
i. Net Operating Revenue							

Table 3 Cont.	Two Most Recent Years Actual		Current Year Projected	Projected Years (ending with first full year at full utilization)			
	20__	20__	20__	20__	20__	20__	
2. Expenses							
a. Salaries, Wages, and Professional Fees, (including fringe benefits)							
b. Contractual Services							
c. Interest on Current Debt							
d. Interest on Project Debt							
e. Current Depreciation							
f. Project Depreciation							
g. Current Amortization							
h. Project Amortization							
i. Supplies							
j. Other Expenses (Specify)							
k. Total Operating Expenses							
3. Income							
a. Income from Operation							
b. Non-Operating Income							
c. Subtotal							
d. Income Taxes							
e. Net Income (Loss)							
4. Patient Mix:							
A. Percent of Total Revenue							
1. Medicare							
2. Medicaid							
3. Blue Cross							
4. Commercial Insurance							
5. Self-Pay							
6. Other (Specify)							
7. TOTAL	100%	100%	100%	100%	100%	100%	100%

Table 3 Cont.	Two Most Recent Years Actual		Current Year Projected	Projected Years (ending with first full year at full utilization)			
	20__	20__	20__	20__	20__	20__	20__
B. Percent of Patient Days/Visits/Procedures (as applicable)							
1. Medicare							
2. Medicaid							
3. Commercial Insurance							
4. Self-Pay							
5. Other (Specify)							
6. TOTAL	100%	100%	100%	100%	100%	100%	100%

TABLE 4: REVENUES AND EXPENSES - PROPOSED PROJECT

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

CY or FY (Circle)	Projected Years (Ending with first full year at full utilization)			
	20__	20__	20__	20__
1. Revenues				
a. Inpatient Services				
b. Outpatient Services				
c. Gross Patient Services Revenue				
d. Allowance for Bad Debt				
e. Contractual Allowance				
f. Charity Care				
g. Net Patient Care Service Revenues				
h. Total Net Operating Revenue				
2. Expenses				
a. Salaries, Wages, and Professional Fees, (including fringe benefits)				
b. Contractual Services				
c. Interest on Current Debt				
d. Interest on Project Debt				
e. Current Depreciation				
f. Project Depreciation				
g. Current Amortization				
h. Project Amortization				
i. Supplies				
j. Other Expenses (Specify)				
k. Total Operating Expenses				

Table 4 Cont. CY or FY (Circle)	Projected Years (Ending with first full year at full utilization)			
	20__	20__	20__	20__
3. Income				
a. Income from Operation				
b. Non-Operating Income				
c. Subtotal				
d. Income Taxes				
e. Net Income (Loss)				
4. Patient Mix:				
A. Percent of Total Revenue				
1. Medicare				
2. Medicaid				
3. Commercial Insurance				
4. Self-Pay				
5. Other (Specify)				
6. TOTAL	100%	100%	100%	100%
B. Percent of Patient Days/Visits/Procedures (as applicable)				
1. Medicare				
2. Medicaid				
3. Commercial Insurance				
4. Self-Pay				
5. Other (Specify)				
6. TOTAL	100%	100%	100%	100%

10.24.01.08G(3)(e). Compliance with Terms and Conditions of Previous Certificates of Need. An applicant shall demonstrate compliance with all terms and conditions of each previous CON granted to the applicant.

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.

10.24.01.08G(3)(f). Project Impact. The Commission shall consider the impact of the proposed project on the costs and charges of existing providers of the facilities and services included in the project and on access to those facilities and services in the service area of the project.

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.

10.24.01.08G(3)(g) Health Equity. The Commission shall consider how a proposed project will address health care disparities in availability, accessibility, and quality of care among different populations within the service area. The Commission shall consider how social determinants of health within the service area of the proposed project create disparities in the delivery of health care.

INSTRUCTIONS: In evaluating proposed projects for health equity, the Commission will scrutinize the project’s impact on health care disparities and social determinants within the service area. Health equity involves the fair distribution of resources and opportunities, ensuring individuals, regardless of background, have the chance to achieve their highest level of health. It further encompasses addressing disparities and systemic barriers that affect different populations.

With health equity in mind, the applicant shall identify the specific medically underserved area(s)/group(s)² within the designated service area and outline how the proposed project will address the unique health needs and quality of care for each identified group.

Applicants are expected to furnish a detailed overview of their organization’s expertise and experience in health care access and service delivery. Emphasis should be placed on highlighting any relevant background that underscores the organization’s commitment to equitable health care. This encompasses efforts to integrate implicit bias and cultural competency training within the health facility and among current staff members.

Please provide a comprehensive account of how the applicant planned with the community during the preparations for this project and how it will continue to engage with the community. Include a description of any specific initiatives and programs aimed at improving community well-being that are relevant to the proposed project. If applicable, the applicant should acknowledge any unintended barriers caused by the project that may have been identified through community discourse and propose proactive solutions to mitigate and rectify potential issues.

10.24.01.08G(3)(h) Character and Competence. The Commission shall assess the character and competence of an applicant based upon experience and past performance, including any records of violation in operating a health care service or facility.

INSTRUCTIONS: In evaluating proposed projects for Character/Competence, the Commission will review the information provided in response to Part III of the application and look for a detailed narrative response highlighting any past issues and how any issues have now been corrected or addressed. If there have not been any past issues, please include in your narrative any history that has been a positive reflection of character/competence. The response should include, at minimum:

- Names/addresses of all owners and individuals responsible for the proposed project and its implementation. This includes any person with 5% or more ownership interest in the facility
- For each individual identified disclose any involvement in the ownership, development, or management of another health care facility

² According to HRSA, medically underserved populations and areas are identified as those which lack access to primary care services. These groups may face economic, cultural, or language barriers to health care. Some examples include: People experiencing homelessness, people who are low-income, people who are eligible for Medicaid, Native Americans and other historically disadvantaged populations of color, migrant farm workers, etc. (<https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation#mups>)

- For each individual and facility identified disclose if any license has been suspended or revoked, or been subject to any disciplinary action (such as a ban on admissions) in the last 5 years
- For each individual and facility identified disclose inquiries in the last from 10 years from any federal (CMS) or state authority (OHCQ), or other regulatory body regarding possible non-compliance with any state, or federal 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
- Disclose if any owners and individuals responsible for the project have identified above have 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

ADDENDUM A: GUIDANCE FOR CHARITY CARE AND FINANCIAL ASSISTANCE POLICY STANDARD

<p>(3) Charity Care Policy. Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care and financial assistance regarding free and reduced-cost care to uninsured, underinsured, or indigent patients and shall provide ambulatory surgical services on a charitable basis to qualified persons consistent with the policy. The policy shall include, as applicable below, at a minimum:</p>	<p>Provide a copy of the policy</p>
<p>(a) Determination of Eligibility for Charity Care or Financial Assistance. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the hospital or ambulatory surgical facility shall make a determination of probable eligibility and notify the patient of that determination.</p>	<p>Quote the specific language from the policy that describes the determination <u>of probable eligibility</u> within 2 business days (as well as a citation to the location within the policy).</p> <p>Provide a copy of your policy regarding a determination of probable eligibility within two business days of request for charity/reduced fee care or application for Medicaid</p> <p>Quote the specific language from the policy that describes the determination <u>of probable eligibility</u> (and give a citation to the location within the policy).</p> <p>Provide copies of any application and/or other forms involved in the process for making a determination of probable eligibility within two business days.</p> <p>Provide a copy of your procedures, if any, and other documents that detail your process for making a determination of probable eligibility and your procedures, if any, for making a final determination.</p> <p><i>Note that requiring a completed application with documentation does not comply with this standard, which is intended to ensure that a procedure is in place to inform a potential charity/reduced fee care recipient of his/her probable eligibility within two business days of initial inquiry or application for Medicaid based on a simple and expeditious process.</i></p> <p><i>A two-step process that allows for a probable determination to be communicated within two days based on an abridged set of information, followed by a final determination based on a completed application with the required documentation is permissible. But the</i></p>

	<i>policy must include the more easily navigated determination of probable eligibility.</i>
<p>(b) Notice of Charity Care Policy and Financial Assistance Policy. Public notice and information regarding the hospital or ambulatory surgical facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population 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. This notice shall include general information about who qualifies and how to obtain a copy of the policy or may include a posted copy of the policy. 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.</p>	Quote the specific language from the policy that describes the method of implementation, and provide a sample for each communication vehicle(s).
<p>(c) Criteria for Eligibility. A hospital shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. 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 ambulatory surgical facilities described in these regulations. An ambulatory surgical facility, at a minimum, shall include the following eligibility criteria in its charity care policies:</p> <ul style="list-style-type: none"> (j) 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 charges; and (iii) 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. 	Quote the specific language from the policy that describes the provisions for the sliding fee scale and time payment plans...also provide a citation to the location within the policy where the language can be found.
<p>(d) 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</p>	Offer a complete explanation describing why its level of charity care is appropriate to the needs of its service area population.

the needs of its service area population.	
<p>(e) A hospital shall be able to demonstrate that its historic level of charity care or its projected level of charity care is appropriate to the needs of its actual or projected service area population. This demonstration shall include an analysis of the socio-economic conditions of the hospital's actual or projected service area population, a comparison of those conditions with those of Maryland's overall socio-economic indicators, and a comparative analysis of charity care provision by the applicant hospital and other hospitals in Maryland. The socio-economic indicators evaluated shall include median income and type of insurance by zip code area, when available. The analysis provided may also include an analysis of the social determinants of care affecting use of health care facilities and services and the health status of the actual or projected hospital service area population.</p>	<p>Submit an analysis that compares the socio-economic conditions of the hospital's actual or projected service area population with the socio-economic conditions in Maryland overall, and include a comparison of charity care provided by the applicant hospital and other hospitals in Maryland.</p> <p>The analysis shall include median income and type of insurance by zip code area, when available, and any social determinants of care affecting the use of health care facilities and services and the health status of the actual or projected hospital service area population.</p>
<p>(f) An applicant submitting a proposal to establish or expand an ambulatory surgical facility 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 ambulatory surgical facilities in the most recent year reported, measured as a percentage of total operating expenses. The applicant shall demonstrate that:</p>	
<p>(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment;</p>	<p>Provide data on history of charity care provision.</p>
<p>(ii) It has a specific plan for achieving the level of charitable care provision to which it is committed. and</p>	<p>Describe the plan to meet the charity care commitment. An "ideal" response for demonstrating a serious <i>"specific plan for achieving the level of charitable care provision to which it is committed"</i> would:</p> <p>a) name the specific social service organizations/agencies that an applicant has contacted or plans to contact to inform them of the availability of charity care, and;</p> <p>b) incorporate a real-time reporting mechanism that will alert management regarding its progress toward its charity care commitment, and a statement of what actions will then be taken.</p>
<p>(iii) If an existing ambulatory surgical facility has not met the expected level of charity care for the two most recent years reported to Commission, the applicant shall demonstrate that its historic level of charity care was appropriate to the needs of the service area population.</p>	

(g) 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 ambulatory surgical facilities, measured as a percentage of total ambulatory surgical facility 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;
- (ii) It has a specific plan for achieving the level of charitable care provision to which it is committed; and
- (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.

Please see the response in Paragraph (f)(i) – (iii) above.

ADDENDUM B: PROVIDING INDIVIDUAL PHYSICIAN VOLUME DATA

Volume projections – ambulatory surgery facility applications

This forms package has been prepared to assist CON applicants for Ambulatory Surgical Facilities in providing information required for the CON review (see below). Each potentially involved physician should be asked to complete an individual submission, and the project sponsor (applicant) should aggregate that data (final table in this package). The information requested in this form will enable the applicant to comply with the regulations (listed immediately below) that prescribe data an applicant must provide.

The State Health Plan: General Surgical Services
Excerpted from COMAR 10.24.11. 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 other practitioner;

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

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

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

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

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

Note: duplicate and/or expand these forms as needed to accommodate providers.



Individual Physician’s Submission (provide this form for each physician who will do procedures at the proposed facility)

Physician Name	Surgical Volume Latest 2 complete years				Projections						Facility(s) from which these cases will be migrating	
	Year ____		Year ____		Year 1		Year 2		Year 3			
	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes	Cases	Minutes		

5 most frequently performed surgeries, two most recent years		
Surgical Procedure*	Yr1	Yr2

* List in descending order based on the cumulative 2 year volume

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

Signature _____

Print Name: _____