

**Review Guide – COMAR 10.24.11 – General Surgical Services Standards**

STANDARD	GUIDANCE FOR SATISFYING STANDARD
<p><b>COMAR 10.24.11.05A General Standards.</b></p> <p><b>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 this Chapter shall address and document its compliance with each of the following general standards as part of its application.</b></p>	
<p><b><u>COMAR 10.24.11.05A(1) - Information Regarding Charges and Network Participation.</u></b></p> <p>Information regarding charges for surgical services shall be available to the public.</p> <p>(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.</p> <p>(b) Each ambulatory surgery center, ambulatory surgical facility, and general 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.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p>	<p>Describe how this information is made available. Provide a copy of the document and/or communications vehicle(s). Affirm that this information will be provided.</p> <p>Same as (a).</p> <p>Same as (a).</p> <p>List any complaints to the Consumer Protection Division, provide information on any determinations and actions taken to correct any deficiencies.</p> <p>Provide commitment.</p>
<p><b><u>COMAR 10.24.11.05A(2) - Information Regarding Procedure Volume.</u></b></p> <p>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</p>	<p>Provide volume information for its 10 most frequently performed procedures by surgical specialty for the last 12 months. Affirm that this list will be updated annually.</p>

<p>surgical facility, or ASC shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.</p>	
<p><b><u>COMAR 10.24.11.05A(3) - Charity Care and Financial Assistance Policy.</u></b></p> <p>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 facility's policy.</p>
<p><i>(a) Determination of Eligibility for Charity Care or Financial Assistance.</i> 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>Identify the specific language from 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 <i>of probable eligibility</i> and give a citation to the location within the policy.</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 for making a final determination.</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><i>Note that requiring a completed application with documentation for determination of probable eligibility for charity care does not comply with this standard, which is intended to ensure that a procedure is in place to inform a potential charity care/reduced fee 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 1) a probable determination to be communicated within two days based on an abridged set of information, followed by 2) a final determination based on a completed application with the required documentation is permissible. But the policy must include the more easily navigated determination of probable eligibility.</i></p>
<p><i>(b) Notice of Charity Care and Financial Assistance Policy.</i> 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</p>	<p>Identify the specific language from the policy that describes the method of implementing and provide a sample of the language used for each communications vehicle(s).</p>

<p>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>	
<p><i>(c) Criteria for Eligibility.</i> 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"> <li>(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 charge; and</li> <li>(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.</li> </ul>	<p>Identify the specific language from the policy that describes the provisions for the sliding fee scale and time payment plans and provide a citation to the location within the policy where the language can be found. Your criteria shall include, at a minimum, the eligibility criteria listed in this Standard.</p>
<p><i>(d)</i> 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.</p>	<p>If the applicant's charity care level falls within the bottom quartile of all hospitals, offer a complete explanation describing why the hospital's level of charity care is appropriate to the needs of its service area population.</p>
<p><i>(e)</i> 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><i>(f)</i> 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 COMAR 10.24.11 13 of charity care provided by ambulatory surgical facilities in the most recent year reported, measured</p>	<p>Provide commitment.</p>

<p>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:  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;  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 the Commission, the applicant shall demonstrate that its historic level of charity care was appropriate to the needs of its service area population.</p>	<p>If the facility has not met the expected level of charity care, describe why its historic levels are appropriate.</p>
<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:</p> <p>(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment; and</p> <p>(ii) It has a specific plan for achieving the level of charitable care provision to which it is committed.</p> <p>(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.</p>	

**COMAR 10.24.11.05A(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.	Provide a copy of license with documentation from OHCQ (letter or email) that the current license is “in good standing.”
(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.	Provide a copy of accreditation certificate.
(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;	Provide a copy of documentation from CMS
(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	Provide a copy of documentation from appropriate body.
(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.	An applicant should demonstrate that it is enrolled in the AMBULATORY SURGERY CENTER QUALITY REPORTING program, and that it has submitted its data.  <a href="https://www.qualityreportingcenter.com/asc/resources/">https://www.qualityreportingcenter.com/asc/resources/</a>  <a href="https://www.qualityreportingcenter.com/asc/">https://www.qualityreportingcenter.com/asc/</a>
(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;	Provide a description of the process of licensure and the steps you will take to obtain licensure in Maryland in order to demonstrate your understanding of the process.
(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	Make the commitment.
(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.	Provide acknowledgement.

<p>(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.</p>	
<p><b><u>COMAR 10.24.11.05A(5) - Transfer Agreements.</u></b></p>	<p>Submit a copy of the transfer agreement(s).</p>
<p>(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.</p>	<p>Describe how the facility's transfer policy complies with Health-General Article §19-308.2 below:</p> <p>(a) (1) Subsection (b)(1) of this section is not intended to preempt the requirements of § 10-625 of this article.</p> <p>(2) The Department shall adopt guidelines, after consultation with the Maryland Hospital Association, Inc., governing the transfer of patients between hospitals to ensure that transfers of patients between hospitals are accomplished in a medically appropriate manner and in accordance with the health care policies of the State that, at a minimum, require:</p> <p>(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;</p> <p>(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;</p> <p>(iii) The provision of appropriate personnel and equipment that a reasonable and prudent physician exercising ordinary care would use for the transfer; and</p> <p>(iv) The transfer of all necessary records for continuing the care for the patient.</p>
<p>(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.</p>	<p>The applicant should list the requirements and demonstrate how the transfer agreement addresses each of these requirements.</p> <p>The transfer agreement should specify the procedures as laid out in COMAR 10.05.05.09:</p> <p>A. The freestanding ambulatory surgical facility shall have an effective procedure for the transfer of patients to a hospital when care beyond the capabilities of the facility is required.</p> <p>B. Procedures for emergency transfer to a hospital shall include, at a minimum:</p> <p>(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;</p>

- (2) Having a mechanism for notifying the hospital of a pending emergency case;
- (3) Having a mechanism for arranging appropriate transportation to the hospital; and
- (4) The manner in which a facility sends a copy of the patient's medical record to the hospital.

**COMAR 10.24.11.05B 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.**

**COMAR 10.24.11.05B(1) - Service Area.**

An applicant proposing to establish a 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.

Provide a list of zip codes (based on patient origin if an existing facility that is expanding).

**COMAR 10.24.11.05B(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:

(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;	Cite the data source.
(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	Cite the data source.
(iii) Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.	Document each physician's current caseload, expected caseload at the proposed facility, and the referral source where these cases will transfer from. Would need to produce signed statements of intent to bring cases there and provide documented projections of volume.
<b><u>COMAR 10.24.11.05B(3) – Need – Minimum Utilization for Expansion of An Existing Facility.</u></b>	
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;	Compare utilization to 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;	Cite the data source.
(ii) Operating room time required for surgical cases historically provided at the facility by surgical specialty or operating room category; and	Cite the data source.
(iii) Projected cases to be performed in each proposed additional operating room.	Document each MD's current caseload; expected caseload at the proposed facility; and the source where these cases will transfer from. Would need to produce signed statements of intent to bring cases there and provide documented projections of volume.
<b><u>COMAR 10.24.11.05B(4) Design Requirements.</u></b>	
Floor plans submitted by an applicant must be consistent with the current FGI Guidelines.	
(a) A hospital shall meet the requirements in Section 2.2 of the FGI Guidelines.	Provide attestation from architect.
(b) An ambulatory surgical facility shall meet the requirements in current Section 2.7 of the FGI Guidelines.	Provide attestation from architect.
(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	Provide justification/rationale.



<p>Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.</p>	
<p><b><u>COMAR 10.24.11.05B(5) - Support Services.</u></b></p> <p>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.</p>	<p>If via contractual agreement, provide the name and address of provider.</p>
<p><b><u>COMAR 10.24.11.05B(6) – Patient Safety.</u></b></p> <p>The design of proposed surgical facilities or changes to existing surgical facilities shall include features that enhance and improve patient safety. An applicant shall:</p>	
<p>(a) Document the manner in which the planning of the project took patient safety into account; and</p>	
<p>(b) Provide an analysis of patient safety features included in the design of proposed new, replacement, or renovated surgical facilities.</p>	
<p><b><u>COMAR 10.24.11.05B(7) - Construction Costs.</u></b></p> <p>The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.</p>	
<p>(a) Hospital projects.</p> <p>(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.</p> <p>(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:</p> <ol style="list-style-type: none"> <li>(1) The amount of the projected construction cost and associated capitalized construction cost that exceeds the Marshall Valuation Service® benchmark; and</li> <li>(2) Those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.</li> </ol>	<p>Provide an MVS analysis.</p>

<p><b>(b) Ambulatory Surgical Facilities.</b></p> <p>(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.</p> <p>(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.</p>	<p>Provide an MVS analysis.</p>
<p><b><u>COMAR 10.24.11.05B(8) – Financial Feasibility.</u></b></p> <p>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.</p> <p>(a) An applicant shall document that:</p> <p>(i) Utilization projections are consistent with observed historic trends in use of each applicable service by the likely service area population of the facility;</p> <p>(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;</p> <p>(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</p> <p>(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</p>	<p>Provide the data and assumptions necessary for staff to evaluate consistency with each subpart of this standard. <i>The response(s) should be placed under each subpart.</i></p>

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.

**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 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.