

| STANDARD  | GUIDANCE FOR SATISFYING STANDARD   |
|---|--|
| <p><b>A. General Standards.</b><br/> <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 or an exemption from Certificate of Need review for a project covered by this Chapter shall address and document its compliance with each of the following general standards as part of its application.</b></p>  |  |
| <p><b>(1) Information Regarding Charges.</b><br/>           Information regarding charges for surgical services shall be available to the public.</p> <p>(a) A physician outpatient surgery center, ambulatory surgical facility, or a general hospital shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.</p> <p>(b) The Commission shall consider complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration when evaluating an applicant’s compliance with this standard in addition to evaluating other sources of information.</p> <p>(c) Making this information available shall be a condition of any CON issued by the Commission.</p> | <p>Describe how this information is made available.</p> <p>Document the communications vehicle(s).</p> <p>Applicant should speak to, and staff should verify, complaint proceedings involving the applicant.</p>   |
| <p><b>(2) Information Regarding Procedure Volume.</b><br/>           A hospital, physician outpatient surgery center, or ASF shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the location where an individual has inquired. A hospital, POSC, or ASF shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.</p>   | <p>Applicant should provide volume information for its 10 most frequently performed procedures performed for the last 12 months.</p>   |
| <p><b>(3) Charity Care Policy.</b><br/>           (a) Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care that ensures access to services regardless of an individual's ability to pay and shall provide ambulatory surgical services on a charitable basis to qualified indigent persons consistent with this policy. The policy shall have the following provisions:</p>   | <p>Provide a copy of the policy</p>  |
| <p>(i) Determination of Eligibility for Charity Care. Within two business days following a patient's request for charity care services, application for medical assistance, or both, the facility shall make a determination of probable eligibility.</p>   | <p>Quote the specific language from the policy that describes the determination <i>of probable eligibility</i> 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 <i>of probable eligibility</i> (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 policy must include the more easily navigated determination of probable eligibility.</i></p> |
| <p>(ii) Notice of Charity Care Policy. Public notice and information regarding the facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population and in a format understandable by the service area population. Notices regarding the facility's charity care policy shall be posted in the registration area and business office of the facility. Prior to a patient's arrival for surgery, the facility shall address any financial concerns of the patient, and individual notice regarding the facility's charity care policy shall be provided.</p>  | <p>Quote the specific language from the policy that describes the method of implementing, and provide a sample for each communications vehicle(s).</p>  |
| <p>(iii) Criteria for Eligibility. A hospital shall comply with applicable State statutes and Health Services Cost Review Commission ("HSCRC") regulations regarding financial assistance policies and charity care eligibility.</p> <p>An ASF, at a minimum, shall include the following eligibility criteria in its charity care policies.</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• At a minimum, persons with family income above 100 percent of the federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands.</li> </ul> | <p>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>  |

|   |   |
|---|---|
| <p>A health maintenance organization, acting as both the insurer and provider of health care services for members, shall have a financial assistance policy for its members that is consistent with the minimum eligibility criteria for charity care required of ASFs described in these regulations.</p>  |   |
| <p>(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent HSCRC Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.</p>   | <p>Offer a complete explanation describing why its level of charity care is appropriate to the needs of its service area population.</p>  |
| <p>(c) A proposal to establish or expand an ASF for which third party reimbursement is available, shall commit to provide charitable surgical services to indigent patients that are equivalent to at least the average amount of charity care provided by ASFs in the most recent year reported, measured as a percentage of total operating expenses. The applicant shall demonstrate that:</p>   |   |
| <p>(i) Its track record in the provision of charitable health care facility services supports the credibility of its commitment; and</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.</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> <ul style="list-style-type: none"> <li>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;</li> <li>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.</li> </ul> |
| <p>(iii) If an existing ASF has not met the expected level of charity care for the two most recent years reported to MHCC, the applicant shall demonstrate that its historic level of charity care was appropriate to the needs of the service area population.</p>   |   |
| <p>(d) A health maintenance organization, acting as both the insurer and provider of health care services for members, if applying for a Certificate of Need for a surgical facility project, shall make a commitment to provide charitable services to indigent patients. Charitable services may be surgical or non-surgical and may include charitable programs that subsidize health plan coverage. At a minimum, the amount of charitable services provided as a percentage of total operating expenses for the health maintenance organization will be equivalent to the average amount of charity care provided statewide by ASFs, measured as a percentage of total ASF expenses, in the most recent year reported. The applicant shall demonstrate that:</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> |  |
| <p><b>(4) Quality of Care.</b><br/>A facility providing surgical services shall provide high quality care.</p>  |  |
| <p>(a) An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health.</p>   | <p>Copy of license with documentation from OHCQ (letter or email) that the current license is "in good standing."</p>  |
| <p>(b) A hospital shall document that it is accredited by the Joint Commission.</p>   | <p>Copy of accreditation certificate.</p>  |
| <p>(c) An existing ambulatory surgical facility or POSC shall document that it is:</p>  |  |
| <p>(i) In compliance with the conditions of participation of the Medicare and Medicaid programs;</p>  | <p>Documentation from CMS</p>  |
| <p>(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</p>  | <p>Documentation from appropriate body.</p>  |
| <p>(iii) A provider of quality services, as demonstrated by its performance on publicly reported performance measures, including quality measures adopted by the Centers for Medicare and Medicaid Services. The applicant shall explain how its ambulatory surgical facility or each POSC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland.</p>   | <p>An applicant should demonstrate that it is enrolled in the AMBULATORY SURGERY CENTER QUALITY REPORTING program, and that it has submitted its data.</p> <p><a href="https://www.qualityreportingcenter.com/asc/resources/">https://www.qualityreportingcenter.com/asc/resources/</a></p> <p><a href="https://www.qualityreportingcenter.com/asc/">https://www.qualityreportingcenter.com/asc/</a></p> |
| <p>(d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will:</p>   |  |
| <p>(i) Meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment; and</p>  |  |
| <p>(ii) Obtain accreditation by the Joint Commission, the Accreditation Association</p>   | <p>Make the commitment.</p>  |

|   |  |
|---|--|
| <p>for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility</p>   |  |
| <p>(e) An applicant or a related entity that currently or previously has operated or owned a POSC or ambulatory surgical facility, in Maryland or outside of Maryland, in the five years prior to the applicant's filing of a request for exemption request to establish an ASF, shall address the quality of care provided at each location through the provision of information on licensure, accreditation, performance metrics, and other relevant information.</p> |  |
| <p><b>(5) Transfer Agreements.</b></p> <p>(a) Each ASF shall have written transfer and referral agreements with hospitals capable of managing cases that exceed the capabilities of the ASF.</p>  | <p>Submit a copy of the transfer agreement(s).</p>   |
| <p>(b) Written transfer agreements between hospitals shall comply with Department of Health regulations implementing the requirements of Health-General Article §19-308.2.</p>  | <p>Enumerate these regulations and demonstrate compliance with them.</p> <p>§19-308.2 says:</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>(c) Each ASF shall have procedures for emergency transfer to a hospital that meet or exceed the minimum requirements in COMAR 10.05.05.09.</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 10.05.05.08:</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> <p>(2) Having a mechanism for notifying the hospital of a pending emergency case;</p>   |

|   |   |
|---|---|
|   | <p>(3) Having a mechanism for arranging appropriate transportation to the hospital; and</p> <p>(4) The manner in which a facility sends a copy of the patient's medical record to the hospital.</p>   |
| <p><b>B. Project Review Standards.</b><br/> <b>The standards in this regulation govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate consistency with all applicable review standards, unless an applicant is eligible for an exemption covered in Regulation .06. of this chapter.</b></p>  |   |
| <p><b><u>(1)Service Area.</u></b></p> <p>An applicant proposing to establish a new hospital providing surgical services or a new ambulatory surgical facility shall identify its projected service area. An applicant proposing to expand the number of operating rooms at an existing hospital or ambulatory surgical facility shall document its existing service area, based on the origin of patients served.</p>   | <p>Provide a list of zip codes (based on patient origin if an existing facility that is expanding).</p>   |
| <p><b><u>(2) Need - Minimum Utilization for Establishment of a New or Replacement Facility.</u></b></p> <p>An applicant proposing to establish or replace a hospital or ambulatory surgical facility shall demonstrate the need for the number of operating rooms proposed for the facility. This need demonstration shall utilize the operating room capacity assumptions and other guidance included in Regulation .06 of this Chapter. This needs assessment shall demonstrate 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.</p> |   |
| <p>(a) An applicant proposing the establishment or replacement of a hospital shall submit a needs assessment that includes the following:</p>   |   |
| <p>(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;</p>  |   |
| <p>(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</p>   |   |
| <p>(iii) In the case of a replacement hospital project involving relocation to a new site, an analysis of how surgical case volume is likely to change as a result of changes in the surgical practitioners using the hospital.</p>   |   |
| <p>(b) An applicant proposing the establishment of a new ambulatory surgical facility shall submit a needs assessment that includes the following:</p>  |   |
| <p>(i) Historic trends in the use of surgical facilities for outpatient surgical procedures by the proposed facility's likely service area population;</p>  |   |
| <p>(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</p>  |   |
| <p><b>(iii) Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.</b></p>  | <p><b>Document each MD's current caseload; expected caseload at the proposed facility; and where these cases will transfer from.</b><br/> <b>Would need to produce signed statements of intent to bring cases there and provide documented projections of volume.</b></p> |

**(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;   | Compare utilization to operating room capacity assumptions and other guidance included at Regulation .07 of this Chapter |
| (b) Demonstrate that its existing operating rooms were utilized at optimal capacity in the most recent 12-month period for which data has been reported to the Health Services Cost Review Commission or to the Maryland Health Care Commission; and                           |  |
| (c) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity. The needs assessment shall include the following: |  |
| (i) Historic trends in the use of surgical facilities at the existing facility;  |  |
| (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.  |  |

**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 Section 2.2 of the FGI Guidelines.  | Provide attestation from architect. |
| (b) An ASF shall meet the requirements in Section 3.7 of the FGI Guidelines.  | Provide attestation from architect. |
| (c) Design features of a hospital or ASF that are at variance with the current FGI Guidelines shall be justified. The Commission may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable. | Provide justification/rationale.    |

**5 Support Services.**

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

If via contractual agreement, provide the name and address of provider.

**6 Patient Safety.**

The design of surgical facilities or changes to existing surgical facilities shall include features that enhance and improve patient safety. An applicant shall:

|  |  |
|--|--|
| (a) Document the manner in which the planning of the project took patient safety into account; and |  |
| (b) Provide an analysis of patient safety features included in the design of                       |  |

|   |   |
|---|---|
| proposed new, replacement, or renovated surgical facilities.  |   |
| <p><b><u>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 rate increase proposed by 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) Ambulatory Surgical Facilities.</p>  |   |
| <p>(i) The projected cost per square foot of an ambulatory surgical facility construction or renovation project 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.</p> <p>(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost by 15% or more, then the applicant's project shall not be approved unless the applicant demonstrates the reasonableness of the construction costs. Additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility may be provided to support an applicant's analysis of the reasonableness of the construction costs.</p>  | <p>Provide an MVS analysis.</p>   |
| <p><b><u>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>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> |



(a) An applicant shall document that:

(i) Utilization projections are consistent with observed historic trends in use of the applicable service(s) by the likely service area population of the facility;

(ii) Revenue estimates are consistent with utilization projections and are based on current charge levels, rates of reimbursement, contractual adjustments and discounts, bad debt, and charity care provision, as experienced by the applicant facility or, if a new facility, the recent experience of similar facilities;

(iii) Staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant facility, or, if a new facility, the recent experience of similar facilities; and

(iv) The facility will generate excess revenues over total expenses (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years of initiating operations.

(b) A project that does not generate excess revenues over total expenses even if utilization forecasts are achieved for the services affected by the project may be approved upon demonstration that overall facility financial performance will be positive and that the services will benefit the facility's primary service area population.

## **9 Impact**

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

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

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

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

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

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

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

**10 Preference in Comparative Reviews.**

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