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***STATE HEALTH PLAN  
FOR FACILITIES AND SERVICES:  
GENERAL SURGICAL SERVICES***

***COMAR 10.24.11***

*Effective  
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**State Health Plan for Facilities and Services:  
General Surgical Services**

**.01 Incorporation by Reference.** This Chapter is incorporated by reference into the Code of Maryland Regulations.

**.02 Introduction.**

**A. Purposes of the State Health Plan for Facilities and Services.**

The Maryland Health Care Commission has prepared this General Surgical Services Chapter ("Chapter") of the State Health Plan for Facilities and Services ("State Health Plan") to help meet the current and future health system needs of all Maryland residents.

The State Health Plan serves two purposes:

(1) It establishes health care policy to guide the Commission's actions. Maryland law requires that all State agencies and departments involved in regulating, funding, or planning for the health care industry carry out their responsibilities in a manner consistent with the State Health Plan and available fiscal resources; and

(2) It is the foundation for the Commission's decisions in its regulatory programs. These programs ensure that appropriate changes in services for health care facilities are appropriate and consistent with the Commission's policies. The State Health Plan contains policies, methodologies, standards, and criteria that the Commission uses in making Certificate of Need ("CON") decisions.

**B. Legal Authority of the State Health Plan.**

The State Health Plan is adopted under Maryland's health planning law, Maryland Code Annotated, Health-General §19-118. This Chapter partially fulfills the Commission's responsibility to adopt a State Health Plan at least every five years and to review and amend the Plan as necessary. Health General §19-118(a)(2) provides that the State Health Plan shall include:

- (1) The methodologies, standards, and criteria for CON review; and
- (2) Priority for conversion of acute capacity to alternative uses where appropriate.

**C. Organizational Setting of the Commission.**

The Commission is an independent agency located within the Department of Health and Mental Hygiene for budgetary purposes. The purposes of the Commission, as enumerated at Health-General §19-103(c), include responsibilities to:

(1) Develop health care cost containment strategies to help provide access to appropriate quality health care services for all Marylanders, after consulting with the Health Services Cost Review Commission; and

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(2) Promote the development of a health regulatory system that provides, for all Marylanders, financial and geographic access to quality health care services at a reasonable cost by advocating policies and systems to promote the efficient delivery of and improved access to health care services, and enhancing the strengths of the current health care service delivery and regulatory system.

The Commission has sole authority to prepare and adopt the State Health Plan and to issue Certificate of Need decisions and exemptions based on the State Health Plan. Health General §19-118(e) provides that the Secretary of Health and Mental Hygiene shall make annual recommendations to the Commission on the State Health Plan and permits the Secretary to review and comment on the specifications used in its development. However, Health-General §19-110(a) clarifies that the Secretary does not have power to disapprove or modify any determinations the Commission makes regarding or based upon the State Health Plan. The Commission pursues effective coordination of its health planning functions with the Secretary, with State health-related agencies, and with the Health Services Cost Review Commission in order to assure an integrated, effective health care policy for the State. The Commission also consults the Maryland Insurance Administration as appropriate.

### **D. Plan Content and Applicability.**

In general, a CON is required for:

- (1) The building, development, or establishment of a health care facility;
- (2) The relocation of an existing or previously approved health care facility;
- (3) A change in the bed capacity of a health care facility;
- (4) Certain changes in the type or scope of any "health care service" offered by a health care facility; and
- (5) A capital expenditure by a health care facility that exceeds the current applicable threshold for capital expenditures.

This Chapter of the State Health Plan supersedes and replaces the previously adopted State Health Plan for Facilities and Services: Ambulatory Surgical Services, COMAR 10.24.11, and is applicable to all matters regarding CON review of surgical facilities and services except for open heart surgery and organ transplantation, addressed respectively in COMAR 10.24.17 and 10.24.15.

This Chapter of the State Health Plan is applicable, in whole or in part, to the review of projects requiring CON approval, including:

- (1) The building, development, or establishment of a hospital providing surgical services;
- (2) The building, development, or establishment of an ambulatory surgical facility;
- (3) The relocation of an existing or previously approved hospital providing surgical services;
- (4) The relocation of an existing ambulatory surgical facility;
- (5) A changes in the type or scope of any health care service offered by a health care facility that involves the expansion of surgical capacity that is used in whole or in part for ambulatory surgery, other

than procedure rooms, in any setting owned or controlled by a hospital, if the building or expansion would increase the surgical capacity of the State's health care system; and

(6) The addition of an operating room, other than a procedure room, to an existing ambulatory surgical facility or to a physician outpatient surgery center with surgical capacity other than procedure rooms.

This Chapter of the State Health Plan is applicable, in whole or in part, to the review of a health care facility project that exceeds the threshold for capital expenditures, as adjusted for inflation, as provided in Health General §19-120(k), if the capital expenditure involves surgical facilities and services.

A hospital proposing a project for which the standards of this State Health Plan chapter are applicable, because the project involves either an expansion of surgical capacity or an expenditure for surgical services, shall address all standards applicable to its proposed project found in the Acute Care Chapter of the State Health Plan, COMAR 10.24.10. The hospital shall also address all applicable standards in this General Surgical Services Chapter of the State Health Plan. A hospital is not required to address standards in this Chapter that are completely addressed in its responses to the standards in COMAR 10.24.10.

### .03 Issues and Policies

#### *Growth in Surgery: Hospital and Non-Hospital Settings*

In Maryland, total reported surgical case volume for both inpatient and ambulatory surgeries increased 54.0 percent between CY2000 and CY2010. For this period, the average annual percentage of hospital discharges that had inpatient surgery remained similar, about 27 percent. In CY2010, inpatient surgical cases accounted for 27.7 percent of total hospital discharges from Maryland's general acute care hospitals. Outpatient hospital surgery cases increased 36.6 percent between CY2000 and CY2010, and non-hospital outpatient surgery cases increased 96.9 percent during the same period.

The growth rate of ambulatory surgery cases has been large in the past 10-15 years, especially in non-hospital settings. One national survey shows a 300 percent increase in ambulatory surgery cases at freestanding (non-hospital) settings for ambulatory surgery between 1996 and 2006, while the number of hospital-based ambulatory surgery cases saw little change.<sup>1</sup> This growth has been facilitated by a rapid increase in the number of ambulatory surgical facilities ("ASFs") and physician outpatient surgery centers ("POSCs"). While ASFs and POSCs both provide surgical services, in this Chapter the term "physician outpatient surgery center" refers to a non-hospital center with no more than one sterile operating room engaged in the provision of surgical services that, prior to its establishment, obtained a determination of coverage from the Commission in accordance with this Chapter and COMAR 10.24.01.

In Maryland, between 2000 and 2010, the number of ASFs and POSCs increased from 254 to 335, an increase of 32 percent.<sup>2</sup> The majority of freestanding settings for ambulatory surgery in Maryland are POSCs (77.6 percent in 2010). Nearly all freestanding settings for ambulatory surgery in Maryland are licensed by the Department of Health and Mental Hygiene as "freestanding ambulatory surgical facilities" and certified for Medicare participation as Ambulatory Surgical Centers. A facility or center that does not seek reimbursement from payors as an ambulatory surgical facility, e.g., a cosmetic surgical center that

<sup>1</sup> Cullen, KA, Hall, MJ, and Golosinskiy, A. "Ambulatory Surgery in the United States, 2006." National Health Statistics Reports. January 28, 2009.

<sup>2</sup> Maryland Health Care Commission. "Maryland Ambulatory Surgery Provider Directory" (2000 and 2010).

bills only surgical patients for the full charges associated with their surgery, does not fall within the definition of “ambulatory surgical facility” in CON law.

The supply of operating rooms at ASFs and POSCs in Maryland exceeds the demand for these rooms, as measured by the operating room capacity assumptions that have been used by MHCC in recent years. This is explained to some extent by the ease with which a one OR POSC may be established, as provided in Maryland law. Nevertheless, utilization of operating room and procedure room capacity increased in the last decade. Between CY2001 and CY2010, the average annual number of cases per operating room increased from 436.1 to 623.4. The utilization of procedure rooms also improved over this time period. Between CY2001 and CY2010, the average number of cases per procedure room increased from 738.1 to 878.7. As shown in Table 1, there has been a fairly consistent increase in the utilization of both operating and procedure rooms during this period, as measured by the number of cases per room.

**Table 1: Utilization of Operating and Procedure Rooms in ASFs and POSCs in CY2001-CY2010**

Year	OR Cases Per OR	PR Cases Per PR
2001	436.1	738.1
2002	465.9	768.2
2003	465.0	766.3
2004	505.1	772.0
2005	538.6	825.9
2006	535.6	803.3
2007	521.2	877.1
2008	555.9	954.9
2009	647.0	904.4
2010	623.4	878.7

Source: MHCC Staff analysis of data from the annual survey of ASFs and POSCs.

Note: Only ASFs and POSCs with at least one case for a given category were included in the averages calculated.

The rapid growth in ASFs and POSCs and the shift in outpatient surgery from hospitals to non-hospital settings, especially classes of surgery for which higher levels of reimbursement can be obtained, has raised concerns about the financial impact on hospitals.<sup>3</sup> Concern over the financial viability of hospitals has driven CON regulation of surgical facilities in many states; however, this concern has been muted in Maryland by the system of all-payer hospital rate regulation, which reduces the risk that the loss of lucrative surgical lines of business will threaten a hospital’s financial viability.

#### *Settings for Ambulatory Surgery and Cost-Effectiveness*

One of the major benefits perceived in performing ambulatory surgery in non-hospital settings is the potential for lower costs. Payers are typically able to reimburse ASFs and POSCs less than a hospital

<sup>3</sup> Paquette IM, Smink D, Finlayson, SR. “Outpatient Cholecystectomy at Hospitals Versus Freestanding Ambulatory Surgical Centers” *Journal of the American College of Surgeons*, 2008 Feb:206 (2):301-5.

for the same surgical procedure,<sup>4</sup> given the higher overhead expenses usually involved in building and operating hospital-based facilities. Therefore, to the extent that surgical cases may be performed safely and appropriately in a non-hospital setting, regulatory policy should seek to make such settings sufficiently available and accessible for appropriate patients.

The pattern of development of non-hospital surgical centers produced by the legislative decision not to require a CON for a center with no more than one operating room has led to a very high proportion of POSCs among all surgical settings in Maryland and raises concerns with respect to the efficient use of resources. A smaller number of ambulatory surgical facilities with multiple operating rooms would be expected to realize savings through economies of scale, and could meet the demand for surgical services without significantly reducing geographic access to services. Data reported by ASFs and POSCs in Maryland show that, on average, facilities with more operating rooms have more cases per operating room. In CY2010, the average number of cases per operating room was substantially higher for ASFs with three to six operating rooms (776.9) compared to POSCs with one operating room (560.4). Similarly, the average number of surgical minutes per operating room was higher at ASFs with three to six operating rooms (41,064) compared to POSCs with one operating room (35,768).

### *Settings for Ambulatory Surgery and Safety*

Promoting the efficient use of resources may be a reason to encourage the development of non-hospital surgical facilities with more operating rooms. Studies have shown that surgical outcomes are better for many types of surgery when performed by a surgeon who performs a high volume of a particular type of surgery or at a location where a high volume of a particular type of surgery is performed.<sup>5</sup>

There have been several studies comparing the safety of performing various surgical procedures in different settings (licensed outpatient surgical facilities, physician offices, and hospitals). These studies generally have concluded that the type of ambulatory surgery being examined in the study could be performed very safely in alternative settings, and office-based surgery for appropriate patients is as safe as surgery in a licensed outpatient facility.<sup>6</sup>

### *Policies*

The chief goals of CON regulation of surgical facilities and services are to assure that surgical facilities meet established design standards, for safe and effective operation, and are developed and operated in a cost-effective manner. These goals will guide decisions on requests for determination of coverage for POSCs and decisions on CON applications. These goals are reflected in the following seven policy statements regarding the Maryland CON program.

<sup>4</sup> United States Government Accountability Office. "Payment for Ambulatory Surgical Centers Should Be Based on the Hospital Outpatient System." November 2006. <<http://www.gao.gov/new.items/d0786.pdf>>.

<sup>5</sup> Borowski DW, Bradburn DM, Mills SJ, Bharathan B, Wilson RG, Ratcliffe AA, Kelly SB "Volume-outcome analysis of colorectal cancer-related outcomes." *British Journal of Surgery Society Ltd.* 2010 Sep;97(9):1416-1430. Murphy MM, Ng SC, Simons JP, Csikesz NG, Shah SA, Tseng JF. "Predictors of Major Complications After Laparoscopic Cholecystectomy: Surgeon, Hospital, or Patient?" *Journal of the American College of Surgeons.* 2010 Jul;211(1):73-80. Wilson A, Marlow NE, Maddern GJ, Barraclough B, Collier NA, Dickinson IC, Fawcett J, Graham JC. "Radical Prostatectomy: a Systematic Review of the Impact of Hospital and Surgeon Volume on Patient Outcome." *ANZ Journal of Surgery.* 2010 Jan;80(1-2):24-9.

<sup>6</sup> Coldiron BM, Healy C, Bene NI. "Office Surgery Incidents: What Seven Years of Florida Data Show Us." *Dermatologic Surgery.* 2008 Mar;34(3):285-91; Hancox, J.G., Venkat AP, Coldiron B, Feldman SR, Williford PM. "The Safety of Office-Based Surgery: Review of Recent Literature from Several Disciplines." *Archives of Dermatology.* 2004 Nov;140(11):1379-82.

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- Policy 1:** Surgical services will be provided in settings where patient safety will be assured.
- Policy 2:** Surgical services will be provided in the most cost-effective manner possible consistent with appropriately meeting the health care needs of patients.
- Policy 3:** The efficient use of resources for performing surgical services will be promoted; under-utilization of surgical capacity will be discouraged.
- Policy 4:** A provider of surgical services should participate in utilization review or peer review programs for surgical services.
- Policy 5:** Surgical services, both inpatient and outpatient, in all settings, should be geographically accessible and should be accessible regardless of a patient's ability to pay.
- Policy 6:** A provider of surgical services should consider smart and sustainable growth policies as well as green design principles in facility or center design choices.
- Policy 7:** A provider of surgical services will continuously and systematically work to improve the quality and safety of patient care. This includes planning and implementing electronic health record systems that contribute to infection control, patient safety, and quality improvement.

**.04 Procedural Rules**

**A. Determination of Coverage.**

A request for a determination of coverage by Certificate of Need for a POSC shall provide the following information, in addition to the information requested in COMAR 10.24.01.05(A):

- (1) The date anticipated for initiation of surgical services by the proposed center or for completion of changes proposed to an existing center;
  - (2) The type of anesthesia to be used in the operating room (general, conscious sedation, or local), and in each procedure room;
  - (3) A detailed description of the physical characteristics of the operating room and each procedure room, including the features that determine sterility or non-sterility of each room, air handling system specifications, in-line gases, types of surgical equipment, lighting, flooring, the presence of a sink in the room, and other relevant facts;
  - (4) The estimated total cost of constructing or fitting out existing space to create the center or change an existing center, and the identification of the sources of cost estimates;
  - (5) The number of recovery beds or chairs that will be provided at the proposed center.
  - (6) The location of recovery beds or chairs shall be clearly labeled on the architectural drawing;
- and

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(7) The request for determination of coverage shall be accompanied by the following statement, signed by the physician(s) responsible for operation of the proposed center.

“In the proposed physician outpatient surgery center, no more than one room will be used as a sterile operating room, in which surgical procedures are performed. I hereby declare and affirm under the penalties of perjury that the information I have given in this request for determination of (non)-coverage under Certificate of Need law is true and correct to the best of my knowledge and belief.”

(8) The percentage ownership of each owner shall be provided in the initial request and the Commission shall be notified of any subsequent changes in owners or ownership shares.

**B. Design Requirements: Physician Outpatient Surgery Centers.**

(1) The Commission will review floor plans submitted by a proposed or existing POSC seeking a determination of coverage to assure consistency with the current Facility Guidelines Institute, Guidelines for Design and Construction of Health Care Facilities (“FGI Guidelines”), Sections 3.7 or, as applicable, 3.9. Essential requirements in the current FGI Guidelines for POSCs that shall be met in any proposed POSC floor plan are the following:

- (a) A Class B or C operating room shall be located in a restricted area; and
- (b) The clean and soiled work areas shall be physically separated.

(2) Design or equipment features of a proposed POSC at variance with the current FGI Guidelines shall be justified in a determination of coverage request. Commission staff may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, in determining whether the proposed variance is acceptable.

(3) A procedure room that falls within the design and use parameters of a Class A room, as defined by the FGI Guidelines, may be included within a POSC and will not be classified as an operating room for purposes of determining whether a surgical center requires Certificate of Need review and approval, if the procedure room:

- (a) Is not accessed directly from a restricted area of the facility;
- (b) Is equipped and ventilated separately from any Class B or Class C operating room proposed for development at the POSC; and
- (c) Will be used exclusively for minor procedures in which patients are given only analgesic agents that are appropriate for a Class A room as defined in Section .07.

**C. Effective Date**

(1) An application submitted after the effective date of these regulations is subject to the provisions of this chapter; and

(2) A request for a determination of coverage that is submitted after the effective date of these regulations is subject to the provisions of this chapter.

**.05 Standards****A. General Standards.**

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

**(1) Information Regarding Charges.**

Information regarding charges for surgical services shall be available to the public. A hospital or an ambulatory surgical facility 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.

**(2) Charity Care Policy.**

(a) Each hospital and ambulatory surgical facility shall have a written policy for the provision of charity care that ensures access to services regardless of an individual's ability to pay and shall provide ambulatory surgical services on a charitable basis to qualified indigent persons consistent with this policy. The policy shall have the following provisions:

(i) **Determination of Eligibility for Charity Care.** Within two business days following a patient's request for charity care services, application for medical assistance, or both, the facility shall make a determination of probable eligibility.

(ii) **Notice of Charity Care Policy.** Public notice and information regarding the facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population and in a format understandable by the service area population. Notices regarding the surgical 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, facilities should address any financial concerns of patients, and individual notice regarding the facility's charity care policy shall be provided.

(iii) **Criteria for Eligibility.** Hospitals shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. ASFs, at a minimum, must include the following eligibility criteria in charity care policies. Persons with family income below 100 percent of the current federal poverty guideline who have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services free of charge. At a minimum, persons with family income above 100 percent of the federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands. A health maintenance organization, acting as both the insurer and provider of health care services for members, shall have a financial assistance policy for its members that is consistent with the minimum eligibility criteria for charity care required of ASFs described in these regulations.

(b) A hospital with a level of charity care, defined as the percentage of total operating expenses that falls within the bottom quartile of all hospitals, as reported in the most recent Health Service Cost Review Commission Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

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

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

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

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

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

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

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

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

**(3) 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 and Mental Hygiene.

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

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

(i) In compliance with the conditions of participation of the Medicare and Medicaid programs; and

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(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.

(d) A person proposing the development of an ambulatory surgical facility shall demonstrate that the proposed facility will:

(i) Meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment.

(ii) Obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities within two years of initiating service at the facility or voluntarily suspend operation of the facility.

**(4) Transfer Agreements.**

(a) Each ASF and hospital shall have written transfer and referral agreements with hospitals capable of managing cases that exceed the capabilities of the ASF or hospital.

(b) Written transfer agreements between hospitals shall comply with the Department of Health and Mental Hygiene regulations implementing the requirements of Health-General Article §19-308.2.

(c) Each ASF shall have procedures for emergency transfer to a hospital that meet or exceed the minimum requirements in COMAR 10.05.05.09.

**B. Project Review Standards.**

The standards in this section 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.

**(1) Service Area.**

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

**(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 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

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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.

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

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

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

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

(b) 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.

**(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. 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.

(b) An ASF shall meet the requirements in Section 3.7 of the FGI Guidelines.

(c) Design features of a hospital or ASF that are at variance with the current FGI Guidelines shall be justified. The Commission may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.

(5) **Support Services.**

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

(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;

(7) **Construction Costs.**

The cost of constructing surgical facilities shall be reasonable and consistent with current industry cost experience.

(a) Hospital projects.

(i) The projected cost per square foot of a hospital construction or renovation project that includes surgical facilities shall be compared to the benchmark cost of good quality Class A hospital construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors.

(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any rate increase proposed by the hospital related to the capital cost of the project shall not include:

1. The amount of the projected construction cost and associated capitalized construction cost that exceeds the Marshall Valuation Service® benchmark; and

2. Those portions of the contingency allowance, inflation allowance, and capitalized construction interest expenditure that are based on the excess construction cost.

(b) **Ambulatory Surgical Facilities.**

(i) The projected cost per square foot of 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.

(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.

(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 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) 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.

**.06 OPERATING ROOM CAPACITY AND NEEDS ASSESSMENT**

**A. Assumptions Regarding Operating Room Capacity.**

**(1) Room-Specific Assumptions.**

Full and optimal operating room capacity will vary depending on the range and type of surgical procedures for which the operating room is used. Four categories of operating room are recognized in this State Health Plan chapter: Dedicated Inpatient Operating Rooms (hospital only); Mixed-Use Operating Rooms (hospital only); Dedicated Outpatient Operating Rooms; and Special Purpose Operating Rooms.

**(a) Dedicated Inpatient Operating Room or Mixed-Use Operating Room:**

(i) Has full capacity use of 2,375 hours per year, which includes the time during which surgical procedures are being performed and room turnaround time between surgical cases; and

(ii) Has an optimal capacity of 80 percent of full capacity, which is 1,900 hours per year, which includes the time during which surgical procedures are being performed and room turnaround time between surgical cases.

**(b) Dedicated Outpatient Operating Room:**

(i) Expected to be used for a minimum 255 days per year, 8 hours per day;

(ii) Has full capacity use of 2,040 hours per year, which includes the time during which surgical procedures are being performed and room turnaround time between surgical cases; and

(iii) Has optimal capacity of 80 percent of full capacity, which is 1,632 hours per year, which includes the time during which surgical procedures are being performed and room turnaround time between surgical cases.

**(c) Special Purpose Operating Room.**

Optimal capacity for a special purpose operating room is best determined on a case-by-case basis, using information provided by an applicant regarding the population and/or facility need for each such operating room, the documented demand for each such operating room, and any unique operational requirements related to the special purpose for which the operating room will be used.

(2) General Assumptions.

(a) When reliable information on average room turnaround time is not available from an applicant, it is assumed that an average room turnaround time of 25 minutes can be achieved.

(b) These operating room capacity assumptions and the operating room inventory rules in .06D of this Chapter will be used in determining the need for operating room capacity implied by an observed volume of operating room minutes, an estimate of historic operating room minutes, or a forecast of operating room minutes.

(c) An applicant that proposes an alternative to these assumptions as a more appropriate basis for determining the need for operating room capacity in the review of its project shall fully explain and justify the basis for the alternative assumptions.

(d) In utilizing these operating room capacity assumptions to determine the need for operating room capacity, any fractional need for operating rooms will be rounded up to the nearest whole number.

**B. Assessing the Need for Operating Rooms.**

(1) An applicant for a CON to establish a new surgical facility or to add operating rooms at an existing facility shall include an assessment of need for operating room capacity as part of the response to Project Review Standards .05B(2) or .05B(3). This assessment shall include information on the historic number of operating room cases for one of the following:

(a) The likely service area of the new facility; or

(b) The defined service area of an existing facility for at least the past five years, unless the facility has been operating for fewer than five years, in which case all available historic data on operating room use for the facility shall be presented.

(2) The operating room capacity assumptions in .06A of this Chapter and the operating room inventory rules in .06D of this Chapter shall be used in the needs assessment.

(a) Data for calendar years or fiscal years may be presented, as long as the time period used is identified and consistent across facilities.

(b) Data shall include the number of cases and the number of operating room minutes separately for each type of operating room listed in .06(A)(1), as applicable.

(c) If only estimates of the cases and minutes by type of operating room are available, then a full explanation of the basis for the assumptions used shall be presented.

(3) Projections of future demand for operating rooms shall be consistent with recently observed trends in the demand for operating rooms in the likely service area of a new facility or, in the case of expansion projects, recently observed trends in demand for operating rooms in the existing facility and in the existing facility's service area, including:

(a) The observed trend in case volume and the observed trend in average time per case and room turnaround time;

(b) Projections that assume a change in recently observed trends in the demand for operating room services in the service area or in existing facilities shall be fully explained, and the basis for each such assumption shall be explicit and described in detail; and

(c) Projections of case volume shall account for changes in the population for the demographic group expected to be served by the applicant facility. Assumptions used in assessing the impact of population changes on demand for facilities and services shall be explicit and described in detail.

**C. Assessing Impact.**

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):

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

(2) A minimum of two years of historic 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

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

(4) Impact on an affected hospital.

(a) If the 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 of the operating room capacity at a hospital, then the applicant shall include, as part of the 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; and

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

**D. Operating Room Inventory Assumptions.**

(1) Unstaffed operating rooms are available for the delivery of surgical services, and are included in the inventory and in the measure of capacity.

(2) Obstetric delivery rooms, including rooms designated solely for cesarean sections, are not available for ambulatory surgery.

(3) Procedure rooms or treatment rooms used only for "minor" surgery or "closed" procedures that can be safely performed in a non-sterile room are not part of a facility's operating room inventory or operating room capacity.

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(4) A needs assessment that employs operating room inventory rules that deviate from these assumptions shall provide an explicit and detailed explanation of each basis supporting the deviation.

**E. Data Sources.**

The following information sources are recognized as standard and accepted sources of information for use in an application reviewed under this Chapter. An applicant that uses other sources of data in a need or impact assessment shall demonstrate the reasonableness and reliability of each such data source.

(1) Operating Room Inventory.

(a) The Maryland Health Care Commission's Maryland Ambulatory Surgery Directory and additional data collected in the annual survey;

(b) The Health Services Cost Review Commission's most recent Operating Room Survey within the Accounting and Budget Manual Reporting System for Hospitals collected under COMAR 10.37.01.03; and

(c) Commission action on Certificate of Need applications or exemptions from Certificate of Need involving surgical facilities or services.

(2) Population.

(a) Current Maryland Department of Planning population estimates and projections; and

(b) Current U.S. Bureau of the Census population estimates and projections.

(3) Utilization of Surgical Facilities.

(a) The Maryland Health Care Commission's Uniform Hospital Discharge Abstract Data Set obtained pursuant to COMAR 10.24.02.02 "Collection and Reporting of Hospital Data";

(b) Special surveys conducted by Commission staff to obtain data necessary for planning or for CON regulation;

(c) The Health Services Cost Review Commission's most recent Outpatient Data Set obtained under COMAR 10.37.04.01 "Collection and Submission of Data"; and

(d) The Maryland Health Care Commission's Maryland Ambulatory Surgery Provider Directory and the additional data collected in the annual survey used to create the Directory.

**.07 DEFINITIONS.**

A. In this Chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Ambulatory surgery" means surgery requiring a period of post-operative observation but not requiring overnight hospitalization. This includes procedures involving any cutting instrument, procedures involving microscopic or endoscopic surgery, and procedures involving the use of a laser for

the removal or repair of an organ or other tissue. For purposes of this Chapter, ambulatory surgery is synonymous with outpatient surgery.

(2) "Ambulatory Surgical Facility" or "ASF" means a health care facility that:

- (a) Has two or more "Class B" or "Class C" operating rooms;
- (b) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization;
- (c) Seeks reimbursement from payors as an ambulatory surgical facility, as defined in Health-General Article §19-3B-01, Annotated Code of Maryland; and
- (d) Is physically separate from any hospital.

(3) "Charity care" means:

- (a) Free or discounted health and health-related services provided to persons who cannot afford to pay;
- (b) Care to uninsured, low-income patients who are not expected to pay all or part of a bill, or who are able to pay only a portion using an income-related fee schedule; or
- (c) The unreimbursed cost to a health care facility for providing free or discounted care to persons who cannot afford to pay and who are not eligible for public programs. Charity care results from a facility's policy to provide health care services free of charge or discounted to individuals who meet certain financial criteria. Generally, a bill must be generated and recorded and the patient must meet the organization's criteria for charity care, and demonstrate an inability to pay. Charity care does not include bad debt.

(4) "Class A operating room" means an operating room in which minor surgical procedures are performed under only topical, local, regional anesthesia, or minimal intravenous sedation, except as noted. Minimal intravenous sedation is a drug-induced state during which a patient responds normally to verbal commands, and the patient's airway reflexes, ventilator functions, and cardiovascular functions are unaffected. Spinal and epidural routes are appropriate only if those methods are used exclusively for closed pain management procedures and not in preparation for open surgical procedures. A deeper level of intravenous sedation in a Class A operating room is only appropriate for a minor procedure, such as an endoscopy, that is minimally invasive. A Class A operating room may be accessed from a semi-restricted corridor or an unrestricted corridor.

(5) "Class B operating room" means an operating room in which minor or major surgical procedures may be performed in conjunction with oral, parenteral, or intravenous sedation or under analgesic or dissociative drugs. Procedures that use spinal, epidural axillary, and stellate ganglion blocks; regional blocks (e.g. interscalene) and supraclavicular, infraclavicular, and intravenous regional anesthesia are appropriately performed in a Class B operating room. A Class B room shall be located within the restricted area of a surgical facility or POSC.

(6) "Class C operating room" means an operating room in which major surgical procedures that require general or regional block anesthesia and support of vital bodily functions may be performed. A Class C room shall be located within the restricted area of a surgical facility or POSC.

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(7) "Commission" means the Maryland Health Care Commission or, as appropriate, the staff of the Maryland Health Care Commission.

(8) "Dedicated inpatient operating room" means an operating room that is used exclusively for inpatient surgery, located at a hospital.

(9) "Dedicated outpatient operating room" means an operating room that is used exclusively for ambulatory surgery, located at a hospital or ambulatory surgical facility.

(10) "Exemption" means the Commission authorization for a project that follows the process for exemption from Certificate of Need review, found at COMAR 10.24.01.04.

(11) "Full capacity" means the operating room capacity assumed for each specific type of operating room, as described in Regulation .06A.

(12) "Green design principles" means the design principles outlined in the LEED® for Healthcare Rating System of the ROC Report.

(13) "Hospital" means a nonfederal facility in Maryland with one or more beds licensed for acute general or special care, as defined in Health-General Article §19-301(f), Annotated Code of Maryland.

(14) "ICD-9-CM procedure codes" mean the codes of medical and surgical procedures classified according to the *International Classification of Diseases, 9th edition, Clinical Manual*.

(15) "Inpatient Surgery" means surgery that requires a period of post-operative observation and admission of the patient for overnight hospitalization.

(16) "Inventory" means the number of existing, CON-approved, and CON-excluded operating rooms.

(17) "Jurisdiction" means any of the 23 Maryland counties or Baltimore City.

(18) "Major surgery" means a surgical procedure that requires general or regional anesthesia and support of vital bodily functions. It also refers to a surgical procedure that is invasive and performed in conjunction with oral, parenteral, or intravenous sedation, or under analgesic or dissociative drugs.

(19) "Minor surgery" means a surgical procedure that involves little risk to the life of the patient and does not require general anesthesia and support of bodily functions.

(20) "Mixed-use operating room" means an operating room that is used for both inpatient and outpatient surgical procedures, located at a hospital.

(22) "Operating room minutes" mean the length of time, expressed in minutes, during which an operating room is used for surgical procedures, measured from the beginning to the end of the application of anesthesia.

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- (23) "Optimal capacity" means 80 percent of full capacity.
- (24) "Outpatient operating room" means an operating room that is used for outpatient surgical procedures located in a POSC, hospital, or other health care facility.
- (25) "Outpatient surgery" means surgery requiring a period of post-operative observation but not requiring overnight hospitalization. This includes procedures involving microscopic or endoscopic surgery, and procedures involving the use of a laser for the removal or repair of an organ or other tissue. For purposes of this Chapter, ambulatory surgery is synonymous with outpatient surgery.
- (26) "Person" includes an individual, receiver, trustee, guardian, executor, administrator, fiduciary, or representative of any kind, and any partnership, firm, association, limited liability company, limited liability partnership, public or private corporation, or other entity.
- (27) "Physician Outpatient Surgery Center" or "POSC" means any center, service, office, facility, or office of one or more health care practitioners that has no more than one Class B or Class C operating room, that operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization, and that seeks reimbursement from payors for the provision of ambulatory surgical services.
- (28) "Procedure room" means an operating room in which only minor surgical procedures are performed and includes a Class A operating room.
- (29) "Restricted area" means a designated space with limited access that has physical barriers or security controls and protocols that delineate requirements for use, monitoring, maintenance, and surgical attire and hair covering. Masks are required in a restricted area where open sterile supplies are located or scrubbed persons may be present.
- (30) "Service area" means the area comprised of the postal zip code areas for a hospital, ambulatory surgical facility, or physician outpatient surgery center, from which the first 85 percent of cases originated during the most recent 12-month period.
- (31) "Smart and sustainable growth policies" means the policies articulated in §5-7A-01 of the State Finance and Procurement Article.
- (32) "Special-purpose operating room" means a Class B or C operating room that is dedicated for a specific purpose or surgical specialty and in which space, equipment, or other factors limit its use to a narrow range of surgical procedures.
- (33) "Surgery" means the treatment or diagnosis of disease, injury, or other disorders by direct physical intervention, usually with an incision made by instruments. Surgery can be major or minor, depending on the part(s) of the body affected, the complexity of the operation, and the expected recovery time.
- (34) "Surgical capacity" means the volume of surgery, expressed as the number of cases that can be accommodated in an operating room in a year, taking into account the time for surgery, operating room preparation, and operating room clean up.

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(35) "Surgical cases" means the number of patients who undergo one or more surgical procedures identified by ICD-9-CM procedure codes 01.0 through 86.99 or the corresponding codes in the future International Classification of Diseases, 10th edition.

(36) "Treatment room" means an operating room in which only minor surgical procedures are performed. It is synonymous with the term "procedure room."