

Title 10 MARYLAND DEPARTMENT OF HEALTH

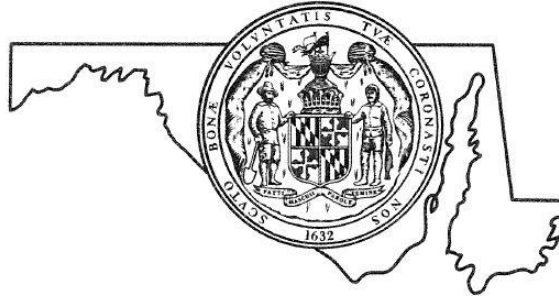
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Chapter 11 State Health Plan for Facilities and Services: General Surgical Services

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.01 Incorporation by Reference.

The State Health Plan for Facilities and Services: General Surgical Services, Chapter 10.24.11, is incorporated by reference.



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STATE HEALTH PLAN FOR FACILITIES AND SERVICES:

GENERAL SURGICAL SERVICES

Proposed Permanent Regulations

COMAR 10.24.11

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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 (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 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 decisions on applications for Certificates of Need (CONs), Certificates of Conformance, and Certificates of Ongoing Performance.

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 (Health-General) §§19-114 – 19-130. This Chapter partially fulfills the Commission's responsibility to adopt a State Health Plan annually. Health General §19-118(a)(2) provides that the State Health Plan shall:

- (i) Be consistent with the Maryland All Payer Model Contract;
- (ii) Include methodologies, standards, and criteria for CON review; and
- (iii) Prioritize 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 for budgetary purposes. The purposes of the Commission, as enumerated in Health-General §19-103(c), include responsibilities to:

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(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 (HSCRC); and

(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 based on the State Health Plan. Health General §19-118(e) provides that the Secretary of Health 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 to assure an integrated, effective health care policy for the State. The Commission also consults the Maryland Insurance Administration as appropriate.

D. Chapter Content and Applicability.

This Chapter supersedes and replaces the previously adopted State Health Plan for Facilities and Services: General Surgical Services, COMAR 10.24.11, and is applicable to all matters regarding CON review of surgical facilities and services except for cardiac surgery and organ transplantation, addressed respectively in COMAR 10.24.17 and 10.24.15. This Chapter also applies, in whole or in part, to certain projects that require exemption from CON review and to requests for determinations of coverage by CON review.

(1) This Chapter applies, in whole or in part, to the review of projects requiring CON approval, including:

(a) The building, development, or establishment of a hospital providing surgical services;

(b) The addition of one or more operating rooms (OR) (whether inpatient, outpatient, or mixed use) in a hospital.

(c) The addition of one or more operating rooms in a freestanding medical facility;

(d) The building, development, establishment, or expansion of an ambulatory surgical facility with three or more operating rooms;

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(e) The addition of one or more operating rooms to an ambulatory surgery center (ASC) that has only procedure rooms (ASC-P), one operating room (ASC-1) or two operating rooms (ASC-2) that would bring the total operating rooms to three or more, thereby establishing an ambulatory surgical facility;

(f) A change in the type or scope of any health care service offered by a health care facility that involves general surgical facilities and services and is determined to require a certificate of need;

(g) The relocation of an existing hospital providing surgical services;

(h) The relocation of an existing ambulatory surgical facility; and

(i) A hospital project that exceeds the threshold for capital expenditures, as adjusted for inflation, as defined in Health-General §19-120(a), if the project involves surgical facilities and services.

(2) A hospital proposing a project to which the standards of this 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 in this Chapter and in COMAR 10.24.10, the Acute Care Hospital 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.

A. Regulatory Environment.

Almost all venues for outpatient surgery require licensure by the Maryland Department of Health, either as a hospital or as a freestanding ambulatory surgical facility,¹ as a prerequisite for Medicare participation by the hospital or center itself. A facility that will not be participating in Medicare is not required to be licensed by the Maryland Department of Health and a facility that does not seek reimbursement from third party payors as an ambulatory surgical facility, such as a physician's office that bills only for professional services or a cosmetic surgical center² that directly bills patients for the full charges, is not a freestanding ambulatory surgical facility, as defined in the Maryland Department of Health's regulations regarding licensure of freestanding ambulatory surgical facilities.

¹ Note that the term "freestanding ambulatory surgical facility," defined at COMAR 10.05.05.01, is a general licensure category in Maryland Department of Health regulations that includes both an ambulatory surgical facility, a CON-regulated, statutorily-defined health care facility that contains three or more operating rooms, as well as an ambulatory surgical center, which may have only procedure rooms or procedure rooms and up to two operating rooms that is issued a determination of coverage by Commission staff.

² Cosmetic surgical facilities, defined in regulations at COMAR 10.12.03.01, require licensure by the Maryland Department of Health under COMAR 10.12.03.02.

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Beginning in the 1990s and until the law changed effective October 1, 2019, a Certificate of Need was required to establish an ambulatory surgical facility with two or more operating rooms (ORs) or to add one or more ORs to an ambulatory surgical facility. Any person could establish a surgery center with only one OR and any number of non-sterile procedure rooms or a surgery center with only non-sterile procedure rooms, by obtaining a determination of coverage from Commission staff. As would be expected, given that regulatory environment, almost all development of freestanding facilities that offer surgical services in the last 20 years has been concentrated in developing centers that do not require Commission approval.

Beginning in 2014, Commission regulations adopted the term “physician outpatient surgery center” or “POSC,” to distinguish the many outpatient surgical centers with only one OR or no ORs that fell below the threshold of CON regulation from the smaller in number “ambulatory surgical facilities,” which, at that time, had two or more ORs. Effective October 1, 2019, Maryland law changed the definition of an ambulatory surgical facility subject to CON regulation to a center, service, office, or facility with three or more ORs. Thus, effectively, a POSC became a center with no more than two operating rooms. Additionally, limitations on the development of ORs by hospitals in non-hospital settings were removed from statute, allowing the same scope of regulation for hospital and non-hospital project sponsors. In conjunction with these changes to the scope of CON regulation, the term “POSC” has been replaced in this Chapter by the term “ambulatory surgery center” or “ASC,” with subcategories to denote an ASC with only procedure rooms (ASC-P), an ASC with one OR (ASC-1), and an ASC with two ORs (ASC-2).

Previously, the Chapter had been revised to align with changes in the Facilities Guideline Institute’s Guidelines for Design and Construction of Outpatient Facilities or the Facilities Guideline Institute’s Guidelines for Design and Construction of Hospitals, as applicable (FGI Guidelines), including with respect to definitions for operating room and procedure room. The definition of procedure room in the 2014 and 2018 FGI Guidelines provides that local anesthesia and minimal or moderate sedation may be administered in a procedure room and does not explicitly allow for general anesthesia. However, based on the change in Maryland statute, Maryland’s regulations for surgical facilities permit general anesthesia in a procedure room in limited situations, as described in this Chapter. The FGI Guidelines continue to be updated approximately every four years and are relied upon by Commission staff for reviewing architectural floor plans as part of reviewing determinations of coverage for ambulatory surgery centers.

Effective October 1, 2020, Maryland law changed to explicitly allow use of general anesthesia, for certain types of procedures and in limited situations, in non-sterile procedure rooms. The law specifically states that neither open procedures that enter the thorax, abdomen, pelvis, cranium, or spine nor procedures that routinely require induction of deep sedation or general anesthesia for the entirety of the surgical procedure may be performed in procedure rooms. The definition for procedure room included in these regulations adds necessary specificity to promote patient safety and is consistent with the evolving approach of the Facilities Guideline Institute for outpatient surgical facilities.

For regulated facilities, there are no explicit limits placed on the addition of ORs within a geographic area, as is the case for hospital bed capacity. In general, if a facility can credibly project an ability to use additional OR capacity consistent with codified assumptions concerning what

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constitutes “full” and “optimal” use of OR capacity, the Commission may approve the requested expansion. The exception to this approach, that historically has only rarely occurred, is when a proposed ambulatory surgical facility would shift cases from existing hospital OR capacity. The statutory changes in 2019 and 2020 reflect a preference for regulatory policies that facilitate the ability to safely perform outpatient surgery in the least expensive setting.

B. Delivery System.

Based on the most recent information reported to the Commission and to the Health Services Cost Review Commission,³ hospitals have experienced a shrinking volume of inpatient and outpatient surgery cases over the period 2010 through 2019, with outpatient surgical case volume down 16% and inpatient surgical volume down 26% in 2019 compared to 2010.⁴ In CY 2019, it is estimated that 55% of all the outpatient surgical cases were performed in Maryland hospitals, and 45% of outpatient surgical cases were performed in an ASC or ambulatory surgical facility.

After substantial growth in the 1990s and the first decade of the current century, the results from the Commission’s annual surveys of FASFs suggest that the number of FASFs stabilized over the last ten years, within the range of 320 to 340 facilities. In 2008, there were 47 hospitals operating in Maryland. As of May 2021, there are 45 hospitals in Maryland, and this number is expected to fall to 42 within the next three years because three hospitals will convert to freestanding medical facilities.

The ease with which an ASC may be established in Maryland appears to have produced a high ratio of smaller surgery centers per population, as compared to other states. However, the actual utilization of the surgical capacity in ASCs and ambulatory surgical facilities and the efficient utilization of this capacity influences whether these settings are more cost-effective for outpatient surgery compared to hospitals. The growth that has occurred throughout the nation in non-hospital settings for outpatient surgery and the shift in volume of 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 ultimate financial impact on hospitals.⁵ Concern over the financial viability of hospitals may be a factor influencing many states to maintain tighter limitations than Maryland on development of non-hospital surgical facilities. The State’s system of all-payer hospital rate regulation reduces the risk that the loss of lucrative surgical lines of business will threaten a hospital’s financial viability, but the potential underutilization of hospital surgical capacity or a reduction in efficiency for hospitals as a result of a shift in outpatient surgical cases will be monitored by MHCC and HSCRC.

³ The discussion of the delivery system in this section is based on analysis of information collected on the Commission’s annual FASF Survey and analysis of hospital data obtained from the HSCRC for calendar years 2010 through 2019.

⁴ MHCC staff analysis of HSCRC discharge abstract data and outpatient data for CY 2010 through CY 2019.

⁵ Kehayes, K. and Hartzell, S. “Increasing surgery migration puts pressure on hospitals to develop an ASC plan.” *Becker’s ASC Review*, August 18, 2020. <https://www.beckersasc.com/cardiology/increasing-surgery-migration-puts-pressure-to-hospitals-to-develop-an-asc-plan.html?tmpl=component&print=1&layout=default>. Accessed April 22, 2021.

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C. Potential Impact of New Regulatory Policies.

Payors typically pay ASCs and ambulatory surgical facilities at substantially lower rates than a hospital for the same surgical procedure, given the higher overhead expenses usually involved in building and operating a hospital. Therefore, to the extent that surgical cases may be performed safely and appropriately in a non-hospital setting and will result in cost savings to the health care system, regulatory policy should seek to make such settings sufficiently available and accessible for appropriate patients. This was the Commission's primary motivation in seeking changes to the law in 2019, raising the outpatient surgical center size that requires CON approval from two or more operating rooms to three or more operating rooms and putting hospitals on the same footing as other persons in establishing and expanding ASCs and ambulatory surgical facilities.

The pattern of development of non-hospital surgical centers in Maryland produced by the earlier law, in place for nearly 30 years, has been a proliferation of surgical centers with no more than one operating room. At a macro level, the large proportion of small surgical centers may be a less efficient delivery system than a system that allows surgical centers with two operating rooms to be developed more easily. Whether the change in policy results in a reduction in one-OR surgical centers and the extent to which the loss of economies of scale achieved by hospitals with larger multiple operating room suites is replaced by efficient larger ambulatory surgical facilities remains to be determined. Historically, data reported by ASCs and ambulatory surgical facilities in Maryland show that, on average, facilities with more operating rooms tend to perform at a higher volume of cases per operating room.

Given the wide distribution of ASCs and ambulatory surgical facilities, it is unlikely that geographic access to services will be negatively affected by allowing ASCs with two operating rooms to be more easily developed. However, to the extent that these changes in regulatory policy accelerate the shift in outpatient surgery from hospitals to ambulatory surgical facilities, access for persons who benefit from hospitals' charity care policies may find outpatient surgery to be less financially accessible. Hospitals provide greater financial support for the indigent population because hospitals' budgets account for charity care and sliding scale financial assistance.

D. Policy Statements.

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, are developed and operated in a cost-effective manner, and, at a systems level, produce a delivery system that provides surgical services at a reasonable cost. The standards developed to meet these goals will guide decisions on CON applications, determinations of coverage, and requests for an exemption from CON review. These goals are reflected in the following seven policy statements.

Policy 1: Surgical services should be provided in settings where patient safety will be assured by adherence to licensure and accreditation requirements for safety standards.

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- Policy 2: Surgical services, both inpatient and outpatient, should be provided in the most cost-effective manner for the health care delivery system that is consistent with safely and appropriately meeting the health care needs of patients.**
- Policy 3: The efficient use of resources for performing surgical services should be promoted.**
- Policy 4: A provider of surgical services should participate in utilization review or a peer review program for surgical services.**
- Policy 5: Surgical services, both inpatient and outpatient, in all settings, should be geographically and financially accessible.**
- 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 should 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 and participation in quality performance initiatives.**

.04 Procedural Rules.

A. Determination of Coverage.

As provided in Maryland law effective October 1, 2019, a Certificate of Need is not required for any center, service, office, facility, or office of one or more health care practitioners, a group practice, or a non-rate regulated center owned by a hospital if the center does not have more than two operating rooms. Rather, a request for a determination of coverage must be obtained. A determination of coverage must also be obtained by an ASC seeking to add new procedure rooms or operating rooms that result in a total of no more than two ORs, or to make any changes in the information that resulted in Commission staff's issuance of an initial determination of coverage for the ASC. For establishment of a new ASC, this notice shall include all the information described in the following list. For a change in a principal owner or in majority ownership of an ASC, the notice may be limited to an affirmation that no changes are occurring in the physical facilities, physicians or other health care practitioners, staff, or surgical specialties provided at the ASC and that changes are limited to ownership. Notice regarding establishment of a new ASC or changes to the information provided in the initial determination of coverage, including changes in ownership, shall be consistent with the notification requirements in COMAR 10.24.01.

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(1) The name and address of the proposed ASC-P, ASC-1, or ASC-2 at which surgical services will be provided.

(2) The name and address of the person or organization seeking to provide or expand ambulatory surgical services, including street address, phone number, and e-mail address, where the Commission should direct correspondence and requests for additional information.

(3) The date anticipated for initiation of surgical services, and if applicable, other services by the proposed ASC or alteration or expansion of an existing ASC.

(4) The number of sterile operating rooms and the number of non-sterile procedure rooms proposed for the ASC.

(5) A statement attesting that the ASC intends to meet the quality of care and patient safety requirements for State licensure and Medicare certification, including all requirements for life and fire safety, infection control, quality assessment and improvement, patient transfer, credentialing, medical record-keeping, and the provision of an estimate of out-of-pocket charges to each patient prior to arrival for surgery. An existing ASC shall provide documentation of State licensure and Medicare certification and certify that it is meeting each of the requirements in this subsection, including the provision of an estimate of out-of-pocket charges for each patient prior to arrival for surgery.

(6) A statement attesting that the ASC will provide volume information on specific types of surgeries over the most recent 12-month period available upon inquiry by prospective patients.

(7) The names of all persons, corporate entities, or other organizations with an ownership interest in the proposed ASC and percentage of ownership, and the officers, directors, partners, and owners of those entities or organizations.

(8) The names and locations of any other ambulatory surgical facilities, or offices with ambulatory surgical capacity, in which individuals, entities, or organizations listed in response to Item 7 have an interest or other economic relationship, as an officer, director, partner, member, or owner.

(9) A list of any other ASCs or ambulatory surgical facilities at the same address as the proposed new or expanded ambulatory surgical capacity.

(10) A list of any contractual relationships to provide ambulatory surgical services between the ASC proposed to be established or expanded, with other health care facilities, or with health care providers who are not owners or employees of the entity, and who exercise only medical practice privileges at the location.

(11) The names and specialties of physicians, podiatrists, or other qualified health care practitioners who will perform surgical or other services at the proposed ASC, or who currently

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provide services, in the case of an existing ASC seeking to expand surgical capacity, as well as the general types of surgical procedures performed by these practitioners.

(12) The specific procedures that will be performed in any sterile operating room and the types of anesthesia that will be used in the sterile operating room, and the specific procedures that will be performed in any non-sterile procedure room and the types of anesthesia that will be used in each non-sterile procedure room.

(13) An architectural drawing of the entire ASC, showing the functions, dimensions, fixed equipment, and with each room and area clearly labeled. For each connecting corridor, the drawing shall indicate whether the corridor is restricted or non-restricted and sterile or non-sterile.

(14) A detailed description of the physical characteristics of the operating room and any procedure rooms, including the features that determine sterility or non-sterility of the rooms, 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. Label the sterile corridor, if any.

(15) The estimated total cost of constructing or fitting out the area associated with the provision of the ambulatory surgical procedures, and an identification of the sources of the estimates.

(16) The number of recovery beds or chairs provided for the proposed or existing center, which should also be clearly labeled on the architectural drawing.

(17) A request for determination of coverage, or notification of proposed changes to an existing ASC, must be accompanied by the following statement, signed by the principal owner of the proposed or existing center:

In the proposed ASC, no more than the requested number of sterile operating rooms will be used as sterile operating rooms, 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 a determination of coverage under Certificate of Need law is true and correct to the best of my knowledge and belief.

An ASC-P seeking to add not more than two operating rooms or an ASC-1 proposing to add a second operating room and not changing any other aspects of its operation previously disclosed in a request for a determination of coverage may obtain a new determination of coverage by providing an architectural drawing of the entire ASC, as proposed, showing the functions, dimensions, fixed equipment, and with each room and area clearly labeled. For each connecting corridor, the drawing shall indicate whether the corridor is restricted or non-restricted and sterile or non-sterile. Additionally, an attestation shall be provided attesting that no other changes in the center or its operational characteristics or staffing is planned.

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B. Design Requirements: ASC-P, ASC-1, and ASC-2.

(1) Commission staff will review floor plans submitted by a proposed or existing ASC seeking a determination of coverage to assure consistency with the applicable current FGI Guidelines. Essential requirements in the current FGI Guidelines that shall be met in any proposed ASC-1 or ASC-2 floor plan include the following:

- (a) Operating rooms 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 ASC at variance with the current FGI Guidelines shall be justified in the 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 diagnostic and treatment area that falls within the design and use parameters of a procedure room, as defined in the FGI Guidelines, may be included within an ASC and will not be classified as an operating room for purposes of determining whether an ASC 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 sterile operating room proposed for development at the ASC; and
- (c) Will be used exclusively for procedures that are appropriate for a procedure room as defined in Regulation .07B(30) of this Chapter.

C. Effective Date.

(1) A letter of intent or 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 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.

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(1) Information Regarding Charges and Network Participation.

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

(a) Each ambulatory surgery center, ambulatory surgical facility, and hospital shall provide to the public, upon inquiry or as required by applicable regulations or law, information concerning charges for the full range of surgical services provided.

(b) Each ambulatory surgery center, ambulatory surgical facility, and general hospital shall provide to the public, upon inquiry or as required by applicable regulations, the names of the health carrier networks in which it currently participates.

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

(d) The Commission shall consider complaints to the Consumer Protection Division in the Office of the Attorney General of Maryland or to the Maryland Insurance Administration when evaluating an applicant's compliance with this standard in addition to evaluating other sources of information.

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

(2) Information Regarding Procedure Volume.

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

(3) Charity Care and Financial Assistance Policy.

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

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

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(b) Notice of Charity Care and Financial Assistance Policy. Public notice and information regarding the hospital or ambulatory surgical facility's charity care policy shall be disseminated, on an annual basis, through methods designed to best reach the facility's service area population in a format understandable by the service area population. Notices regarding the facility's charity care policy shall be posted in the registration area and business office of the facility. This notice shall include general information about who qualifies and how to obtain a copy of the policy or may include a posted copy of the policy. Prior to a patient's arrival for surgery, the facility shall address any financial concerns of the patient, and individual notice regarding the facility's charity care policy shall be provided.

(c) Criteria for Eligibility. A hospital shall comply with applicable State statutes and HSCRC regulations regarding financial assistance policies and charity care eligibility. A health maintenance organization, acting as both the insurer and provider of health care services for members, shall have a financial assistance policy for its members that is consistent with the minimum eligibility criteria for charity care required of ambulatory surgical facilities described in these regulations. An ambulatory surgical facility, at a minimum, shall include the following eligibility criteria in its charity care policies:

(i) Persons with family income below 100 percent of the current federal poverty guideline who have no health insurance coverage and are not eligible for any public program providing coverage for medical expenses shall be eligible for services free of charge; and

(ii) Persons with family income above 100 percent of the federal poverty guideline but below 200 percent of the federal poverty guideline shall be eligible for services at a discounted charge, based on a sliding scale of discounts for family income bands.

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

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

(f) An applicant submitting a proposal to establish or expand an ambulatory surgical facility for which third party reimbursement is available, shall commit to provide charitable surgical services to indigent patients that are equivalent to at least the average amount

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of charity care provided by ambulatory surgical facilities in the most recent year reported, measured as a percentage of total operating expenses. The applicant shall demonstrate that:

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

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

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

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

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

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

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

(4) Quality of Care.

A facility providing surgical services shall provide high quality care.

(a) An existing hospital or ambulatory surgical facility shall document that it is licensed, in good standing, by the Maryland Department of Health.

(b) A hospital shall document that it is accredited by the Joint Commission or other accreditation organization recognized by the Centers for Medicare and Medicaid and the Maryland Department of Health as acceptable for obtaining Medicare certification and Maryland licensure.

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- (c) An existing ambulatory surgical facility or ASC shall document that it is:
 - (i) In compliance with the conditions of participation of the Medicare and Medicaid programs;
 - (ii) Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation organization recognized by the Centers for Medicare and Medicaid Services as acceptable for obtaining Medicare certification; and
 - (iii) A provider of quality services, as demonstrated by its performance on publicly reported performance measures, including quality measures adopted by the Centers for Medicare and Medicaid Services. The applicant shall explain how its ambulatory surgical facility or each ASC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland.
- (d) An applicant seeking to establish an ambulatory surgical facility shall:
 - (i) Demonstrate that the proposed facility will meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment;
 - (ii) Agree that, within two years of initiating service at the facility, it will obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities or another accreditation organization recognized by the Centers for Medicare and Medicaid Services as acceptable for obtaining Medicare certification and approved by the State of Maryland; and
 - (iii) Acknowledge in writing that, if the facility fails to obtain the accreditation in subparagraph (ii) on a timely basis, it shall voluntarily suspend operation of the facility.
- (e) An applicant or a related entity that currently or previously has operated or owned one or more ASCs or ambulatory surgical facilities in or outside of Maryland in the five years prior to the applicant's filing of an application to establish an ambulatory surgical facility, shall provide details regarding the quality of care provided at each such ASC or ambulatory surgical facility including information on licensure, accreditation, performance metrics, and other relevant information.

(5) Transfer Agreements.

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

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

B. Project Review Standards.

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

(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.

(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:

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- (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, consistent with Regulation .06 of this Chapter. The needs assessment shall include the following:

(i) Historic and projected trends in the demand for specific types of surgery among the population in the proposed service area;

(ii) Operating room time required for surgical cases historically provided at the facility by surgical specialty or operating room category; and

(iii) Projected cases to be performed in each proposed additional operating room.

(4) Design Requirements.

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

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

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

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

(5) Support Services.

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

(6) Patient Safety.

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

(a) Document the manner in which the planning of the project took patient safety into account; and

(b) Provide an analysis of patient safety features included in the design of proposed new, replacement, or renovated surgical facilities.

(7) Construction Costs.

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

(a) Hospital projects.

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

(ii) If the projected cost per square foot exceeds the Marshall Valuation Service® benchmark cost, any adjustment of the hospital's global budget revenue authorized for the hospital related to the capital cost of the project shall not include:

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

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

(b) Ambulatory Surgical Facilities.

(i) The projected cost per square foot of new construction shall be compared to the benchmark cost of good quality Class A construction given in the Marshall Valuation Service® guide, updated using Marshall Valuation Service® update multipliers, and adjusted as shown in the Marshall Valuation Service® guide as necessary for site terrain, number of building levels, geographic locality, and other listed factors. This standard does not apply to the costs of renovation or the fitting out of shell space.

(ii) If the projected cost per square foot of new construction exceeds the Marshall Valuation Service® benchmark cost by 25% or more, then the applicant's project shall not be approved unless the applicant demonstrates the reasonableness of the construction costs. Additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility may be provided to support an applicant's analysis of the reasonableness of the construction costs.

(8) Financial Feasibility.

A surgical facility project shall be financially feasible. Financial projections filed as part of an application that includes the establishment or expansion of surgical facilities and services shall be accompanied by a statement containing each assumption used to develop the projections.

(a) An applicant shall document that:

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

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

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

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

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(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 other practitioner;

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

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

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

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

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

.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 Chapter: dedicated inpatient general purpose operating rooms (hospital only); mixed-use general purpose operating rooms (hospital only); dedicated outpatient general purpose operating rooms; and special purpose operating rooms.

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(a) A dedicated inpatient general purpose operating room or mixed-use general purpose 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 and includes the time during which surgical procedures are being performed and room turnaround time between surgical cases.

(b) A dedicated outpatient general purpose operating room:

(i) Is expected to be used for a minimum 255 days per year, eight 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 and includes the time during which surgical procedures are being performed and room turnaround time between surgical cases, unless an applicant demonstrates that a different optimal capacity standard is applicable based on:

1. The ability of the ambulatory surgical facility or the hospital to maintain patient safety and quality of care at the proposed optimal capacity standard; and

2. An analysis of the cost-per-case of operating at a range of utilization levels that includes the applicant's proposed optimal capacity standard, the standard described in §A(1)(b)(iii) of this regulation, and utilization levels between these two standards, and that explains the basis of each assumption used in the analysis; or

3. An analysis of the benefits and costs for patients served by each surgeon operating at a proposed ambulatory surgical facility and the benefits and costs for each surgeon when the ambulatory surgical facility operates at the utilization level described in §A(1)(b)(iii) of this regulation and at the applicant's proposed optimal capacity standard; and the cost per case at both the applicant's proposed optimal capacity standard and the standard described in §A(1)(b)(iii) of this regulation, as well as the cost per case at utilization levels between these two standards; all assumptions used in these analyses shall be explained.

(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:

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- (i) The population or facility need for each special purpose operating room or both;
- (ii) The documented demand for each special purpose operating room; and
- (iii) 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 assumptions in §§C and D of this regulation 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, and 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 each basis for its alternative assumptions.

B. Assessing the Need for Operating Rooms.

(1) An applicant for a CON to establish a new ambulatory surgical facility through the addition of one or more operating rooms to an ASC-2, or the addition of two or more operating rooms to an ASC-1 shall include an assessment of need for operating room capacity as part of the response to project review standards in Regulation .05B(2) or .05B(3) of this Chapter. In addition to addressing those standards, the applicant's assessment shall include information on the historic number of operating room cases for:

- (a) The likely service area of the new ambulatory surgical facility; or
- (b) The defined service area of an existing ambulatory surgical facility, ASC-1, or ASC-2 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) A hospital with at least three operating rooms that proposes to establish an ambulatory surgical facility through a request for exemption in conjunction with the conversion of the hospital to a freestanding medical facility shall demonstrate that proposed surgical capacity is needed consistent with the operating room capacity assumptions in §A of this regulation and the

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operating room inventory assumptions in §C of this regulation; the applicant is not required to demonstrate that its existing OR capacity is currently utilized at or above optimal capacity.

(3) The operating room capacity assumptions in §A of this regulation and the operating room inventory assumptions in §C of this regulation shall be used in the needs assessment for additional operating rooms.

(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 subsection A(1) of this regulation, as applicable.

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

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

D. 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.

Sources for operating room inventory include:

(a) The Commission's annual survey of ambulatory surgical facilities and ASCs;

(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 actions on Certificate of Need applications and requests for exemptions from Certificate of Need that involve surgical facilities or services.

(2) Population.

Sources of information on population are:

(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.

Sources of information on utilization of surgical facilities are:

(a) The 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 or at the direction of Commission staff to obtain data necessary for planning or for CON regulation;

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(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 Commission's website for quality reporting and any additional data collected in the annual survey used to update the website.

.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 surgery center" or "ASC" means any center, service, office, facility, or office of one or more health care practitioners, a group practice, or a non-rate-regulated center owned by a hospital that has no more than two operating rooms, 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. Subcategories of ASCs include: an ASC-P, which has only procedure rooms; an ASC-1, which has one operating room; and an ASC-2, which has two operating rooms.

(3) "Ambulatory surgical facility" means a health care facility that:

- (a) Has three or more operating rooms;
- (b) Operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization and
- (c) Seeks reimbursement from payors as an ambulatory surgical facility.

(4) "Charity care" means:

- (a) Free or discounted health and health-related services provided to persons who cannot afford to pay;
- (b) Care to uninsured, underinsured, or 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 sliding fee schedule; or

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(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, the patient must demonstrate an inability to pay. Charity care does not include bad debt.

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

(6) "Dedicated inpatient operating room" means a sterile operating room that is used exclusively for inpatient surgery and is located at a hospital.

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

(8) "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 or in applicable chapters of the State Health Plan

(9) "FGI Guidelines" refers to the Facilities Guideline Institute's Guidelines for Design and Construction of Outpatient Facilities or the Facilities Guideline Institute's Guidelines for Design and Construction of Hospitals, as applicable.

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

(11) "Green design principles" means the design principles outlined in the LEED® for Healthcare Rating System.

(12) "Health Carrier" means an insurer, non-profit health service plan, health maintenance organization, managed care organization, dental plan organization, employer, third party administrator, or any other entity that contracts to provide health care items or services to enrollees of the health carrier.

(13) "Health Carrier Network" means a health carrier's providers and facilities that contract directly or indirectly through a subcontracting entity with the health carrier to provide health care items or services to the carrier's enrollees.

(14) "Health care practitioner" means a person who is licensed, certified, or otherwise authorized under the Health Occupations Article to provide medical services in the ordinary course of business or practice of a profession.

(15) "Hospital" in this Chapter means a nonfederal facility in Maryland with one or more inpatient beds licensed for acute general care.

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(16) “ICD-9-CM or ICD-10-CM procedure codes” mean the codes of medical and surgical procedures classified according to the *International Classification of Diseases, 9th or 10th edition, Clinical Manual*.

(17) “Inpatient surgery” means surgery that requires a period of post-operative observation and admission of the patient for overnight hospitalization.

(18) “Invasive procedure” is a procedure with high infection risk that penetrates the protective surfaces of a patient’s body, including skin and mucous membranes and generally requires entry into a body cavity or may involve insertion of an indwelling foreign body. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin are not included in this definition.

(19) “Jurisdiction” means any of the 23 Maryland counties or Baltimore City.

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

(21) “Minor surgery” means a surgical procedure that is not invasive and involves little risk to the life of the patient and does not routinely require general anesthesia and support of bodily functions.

(22) “Mixed-use operating room” means a sterile operating room that is used for both inpatient and outpatient surgical procedures, located at a hospital.

(23) “Operating room” or “OR” means a sterile room in the surgical suite that meets the requirements of a restricted area and is designated and equipped for performing surgical operations or other invasive procedures that require an aseptic field. Any form of anesthesia may be administered in an OR.

(24) “Operating room inventory” means the number of existing operating rooms approved through CON or a determination of coverage.

(25) “Operating room minutes” means 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.

(26) “Optimal capacity,” unless otherwise specified in this Chapter, means 80 percent of full capacity.

(27) “Outpatient operating room” means a sterile operating room that is used for outpatient surgical procedures located in an ambulatory surgical facility, ASC-1, ASC-2, hospital, or freestanding medical facility.

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(28) “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.

(29) “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.

(30) “Procedure room” means a non-sterile room in which minor surgical procedures are performed, including endoscopy and endoscopic procedures requiring deep sedation. Procedure rooms shall only be accessed from a semi-restricted corridor or an unrestricted corridor. Procedure rooms shall not be used for open surgical procedures that enter the thorax, abdomen, pelvis, cranium, or spine, for procedures that routinely require induction of deep sedation or general anesthesia for the entirety of the surgical procedure, or for procedures that require a sterile environment. Deep sedation or general anesthesia may be induced if warranted by changes in a patient’s clinical situation and the room is equipped to safely conduct the required level of anesthesia. An anesthesia practitioner is not precluded from providing the highest level of anesthesia support that may be required to safely treat patients undergoing procedures that are appropriate for the non-sterile environment of a procedure room, whether located in a hospital, a freestanding medical facility, an ambulatory surgical facility, or an ambulatory surgery center.

(31) “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.

(32) “Service area” means the area comprised of the postal zip code areas for a hospital, ambulatory surgical facility, or ambulatory surgery center, from which the first 85 percent of cases originated during the most recent 12-month period.

(33) “Smart and sustainable growth policies” means the policies articulated in §5-7A01 of the State Finance and Procurement Article.

(34) “Special-purpose operating room” means a sterile operating room that is dedicated for a specific purpose or surgical specialty such as a caesarian-section operating room and in which space, equipment, or other factors limit its use to a narrow range of surgical procedures.

(35) “Surgery” means a surgical operation for 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 one or more parts of the body affected, the complexity of the operation, and the expected recovery time.

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(36) “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 turnaround time.

(37) “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 ICD-10 procedure codes in the *International Classification of Diseases, 10th edition*.

(38) “Treatment room” means a non-sterile room in which only minor surgical procedures are performed. It is synonymous with the term “procedure room.”