

Robert E. Moffit, Ph.D.
CHAIR



Ben Steffen
EXECUTIVE DIRECTOR

MARYLAND HEALTH CARE COMMISSION
4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

STATE HEALTH PLAN FOR FACILITIES AND SERVICES:

GENERAL SURGICAL SERVICES

COMAR 10.24.11

Proposed Permanent Regulation

Written Public Comments
Accepted Until 4:30 pm on November 28, 2017
Send To: Eileen Fleck
Chief, Acute Care Policy and Planning
[*Eileen.Fleck@maryland.gov*](mailto:Eileen.Fleck@maryland.gov)
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215-2299
Fax Number (410) 358-1311

TOLL FREE
1-877-245-1762

TDD FOR DISABLED
MARYLAND RELAY SERVICE
1-800-735-2258

This page intentionally left blank

TABLE OF CONTENTS

	<u>Page</u>
.01 Incorporation by Reference	1
.02 Introduction.....	1
A. Purposes of the State Health Plan for Facilities and Services	1
B. Legal Authority of the State Health Plan	1
C. Organizational Setting of the Commission.....	1
D. Chapter Content and Applicability.....	2
.03 Issues and Policies	3
.04 Procedural Rules.....	8
A. Determination of Coverage.....	8
B. Design Requirements: Physician Outpatient Surgery Centers.....	10
C. Effective Date.....	10
.05 Standards	10
A. General Standards	10
B. Project Review Standards	14
.06 Exemption from Certificate of Need Review for Establishment of an Ambulatory Surgical Facility.....	19
A. Applicability	19
B. General and Project Review Standards.....	19
C. Transferability and Procedural Requirements.....	21
.07 Operating Room Capacity and Needs Assessment	22
A. Assumptions Regarding Operating Room Capacity	22
B. Assessing the Need for Operating Rooms.....	23
C. Operating Room Inventory Assumptions.....	25
D. Data Sources.....	25
.08 Definitions.....	26

This page intentionally left blank

**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 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 it 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 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

(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 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. 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 is also applicable, in whole or in part, to certain projects that require exemption from CON review.

(1) This Chapter is applicable, 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 building, development, or establishment of an ambulatory surgical facility with two or more operating rooms, unless an applicant qualifies for and receives an exemption from CON review;

(c) The addition of an operating room to an existing physician outpatient surgery center with an operating room; unless an applicant qualifies for and receives an exemption from CON review;

(d) A change in the type or scope of any health care service offered by a health care facility that involves the establishment or 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;

(e) The relocation of an existing or previously approved hospital providing surgical services;

(f) The relocation of an existing ambulatory surgical facility;

(g) A health care facility project that exceeds the threshold for capital expenditures, as adjusted for inflation, that is provided in Health-General §19-120(k), if the capital expenditure involves surgical facilities and services; and

(h) A health maintenance organization or a health care facility that either controls, directly or indirectly, or is controlled by a health maintenance organization that seeks to develop, operate, or participates in the building, developing, operating, or establishing of an ambulatory surgical facility or center, as defined in Health General §19-114(b).

(2) This Chapter is applicable, in whole or in part, to a request for an exemption from CON review by:

(a) A general hospital seeking to convert to a freestanding medical facility, pursuant to COMAR 10.24.19.04C when such conversion involves the establishment of ambulatory surgical capacity;

(b) A general hospital seeking to relocate surgical capacity from a hospital to establish an ambulatory surgical facility; and

(c) The office of one or more health care practitioners or a group practice, as defined in §1-301 of the Health Occupations Article, seeking to establish an ambulatory surgical facility with two operating rooms.

(3) 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 the Acute Care Chapter of the State Health Plan, COMAR 10.24.10. 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, the total number of outpatient surgical cases in operating rooms at hospitals decreased by 2.9% between CY 2010 and CY 2015, while the total number of inpatient surgical cases decreased by 15.5%. In contrast to the decline in surgical case volume at hospitals, outpatient

surgeries at physician outpatient surgery centers (“POSCs”) and ambulatory surgical facilities (“ASFs”) in operating rooms increased by 7.5 % during the same period, even though the number of ASFs and POSCs decreased slightly over this period, from 334 to 323. 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.

Operationally, both ASFs and POSCs are licensed in Maryland as “freestanding ambulatory surgical facilities” and certified by Medicare as “ambulatory surgical centers.” In CY 2015, there were 47 general hospitals in Maryland providing both inpatient and outpatient surgery, in a total of 596 operating rooms. There were 41 ASFs, with 110 operating rooms and 282 POSCs, with 164 operating rooms. Both hospital and non-hospital surgery settings perform some invasive procedures in non-sterile procedure rooms when the procedure does not require a sterile room (e.g., minor surgical procedures and some types of endoscopy). The supply of these non-sterile procedure rooms is not regulated by MHCC. In CY 2015, 113 POSCs, about 40% of the total, only included non-sterile procedure rooms and only performed procedures in these non-sterile rooms.

Some surgery in Maryland occurs in non-licensed settings. A facility or center that does not seek reimbursement from third party payors as an ambulatory surgical facility, such as a physician’s office that only bills for professional services or a cosmetic surgical center that directly bills patients for the full charges associated with their surgery and does not bill third party payors for the services of the facility, does not fall within the definition of “ambulatory surgical facility” in CON law or in regulations regarding licensure of freestanding ambulatory surgical facilities.

In Maryland, between CY 2010 and CY 2015, the use rate of outpatient surgery performed in operating rooms in all settings, declined from an estimated 95 to 91 surgical cases per thousand population. During this same period, the use rate of inpatient surgery decreased more sharply, from 30 to 24 cases per thousand population. If both operating room and procedure room cases are combined, the overall rate of invasive procedures in non-hospital settings, both ASFs and POSCs, increased from 103 to 109 cases per thousand population over this same period.

In terms of case volume, the utilization of hospital operating rooms declined between CY 2010 and CY 2015, from 921 cases per room in CY 2010 to 823 cases per room in CY 2015. In contrast, operating rooms in the non-hospital setting have increased their throughput, with the average annual number of cases per operating room rising from 632 in CY 2010 to 746 cases per room in CY 2015. The utilization of procedure rooms also increased over this time period in non-hospital settings. Between CY 2010 and CY 2015, the reported average annual number of cases per procedure room increased from 886 to 961. 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, in non-hospital settings.

**Table 1: Utilization of Operating and Procedure Rooms in ASFs and POSCs
CY 2006 - CY 2015**

Year	Average Cases Per OR	Average Cases Per PR
2006	535	803
2007	521	877
2008	555	954
2009	647	904
2010	632	886
2011	649	900
2012	667	930
2013	680	946
2014	683	931
2015	746	961

Source: MHCC staff analysis of data from the annual survey of ASFs and POSCs, CY 2006 through CY 2015. Note: Only ASFs and POSCs with at least one case for a given category were included in the averages calculated.

Private payors, including both insurance plans and individuals, are the largest primary source of payment, by case volume, for all hospital surgery performed in operating rooms, accounting for 46% of all cases, followed by Medicare (34%) and Medicaid (15%). For inpatient surgery, Medicare has surpassed private payors in the last five years, as the largest source of payment, accounting for 45% of all inpatient cases, followed by private payors (36%) and Medicaid (14%). In non-hospital settings, private payors accounted for approximately 45% of revenue in CY 2015, followed by Medicare at 27%. Medicaid is a much less frequent source of payment for surgery in non-hospital settings, accounting for only 4% of total revenue in CY 2015. However, it should be noted that Medicaid has been steadily increasing as a proportion of all payment sources for non-hospital surgical centers. In 2005, Medicaid accounted for only 1% of total reported revenue by these providers. Additionally, as with hospitals, the proportion of revenue from Medicare for non-hospital surgical settings has been increasing while the proportion of total revenue from private payors and other sources (non-Medicare or Medicaid) has been declining.

Information on actual hours of operating room use in Maryland hospitals and non-hospital surgical settings is difficult to accurately derive from available information sources. The indications are that this measure of capacity use shows that Maryland has a more than adequate supply of operating rooms, based on the capacity assumption of the Chapter (1,632 hours per OR per year for dedicated outpatient ORs in the non-hospital setting and 1,900 hours per year per OR in the hospital setting for mixed-use, general purpose ORs, which account for the vast majority of rooms in service.)

The ease with which a POSC may be established, as provided in Maryland law, has a significant influence on this measure of operating room efficiency. 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.¹ Concern over the financial viability of hospitals has been a factor influencing many states to maintain tighter limitations than Maryland on development of non-hospital surgical facilities. However, 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.

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 and charges. Payors typically reimburse ASFs and POSCs less than a hospital for the same surgical procedure,² 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, 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 some savings through economies of scale and could probably meet the demand for surgical services without inappropriately affecting geographic access to services. Data reported by ASFs and POSCs in Maryland show that, on average, facilities with more operating rooms tend to be perform a higher volume of cases per operating room. In CY 2015, the average number of cases per operating room was substantially higher for ASFs with three to six operating rooms, 860 cases, compared to POSCs with one operating room, 674 cases.

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 multiple 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.³

¹ 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.

² 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>>.

³ [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](#), [Barracough 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.

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 that office-based surgery for appropriate patients is as safe as surgery in a licensed outpatient facility.⁴

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 a determination of coverage for a POSC, requests for an exemption from CON review, and decisions on a CON application. These goals are reflected in the following seven policy statements regarding the Maryland CON program.

- 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.**

⁴ [Coldiron BM, Healy C, Bene NJ](#). "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.

.04 Procedural Rules.

A. Determination of Coverage.

As provided in COMAR 10.24.01.05A, a Certificate of Need is not required for any center, service, office, facility, or office of one or more health care practitioners or a group practice, as defined in Health Occupations Article, Title 1, Annotated Code of Maryland, if the entity does not have more than one operating room. COMAR 10.24.01.05A also provides that at least 45 days before seeking to establish a new operating room or rooms, or making any change in the information provided for initial determination of coverage by Certificate of Need, a person shall provide notice to the Commission. This notice shall include the following information:

(1) The name and address of the proposed POSC 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 POSC or alteration or expansion of an existing POSC.

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

(5) A statement attesting that the POSC 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 estimates of out-of-pocket charges for patients. Existing POSCs must provide documentation of State licensure and Medicare certification.

(6) A statement attesting that the POSC 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 POSC 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 POSCs 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 POSC 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 POSC, or who currently provide services, in the case of an existing POSC 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 POSC, 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 or surgical facility, which should also be clearly labeled on the architectural drawing.

(17) The request for determination of coverage, or notification of changes proposed to an existing POSC, must be accompanied by the following statement, signed by each physician responsible for operation of the proposed center or facility:

In the proposed POSC, no more than one room will be used as a sterile operating room, in which surgical procedures are performed and a facility fee could be charged. I hereby declare and affirm under the penalties of perjury that the information I have given in this request for determination of coverage under Certificate of Need law is true and correct to the best of my knowledge and belief.

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 Hospitals and Outpatient 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 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 POSC 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 fall within the design and use parameters of a procedure room, as defined in the FGI Guidelines, may be included within a POSC and will not be classified as an operating room for purposes of determining whether a POSC 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 POSC; and
- (c) Will be used exclusively for minor procedures in which patients are given only analgesic agents that are appropriate for a procedure room as defined in Regulation .08B(26) of this chapter.

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 reflect Commission expectations for the delivery of surgical services by all health care facilities in Maryland, as defined in Health-General §19-114(d).

Each applicant that seeks a Certificate of Need for a project or an exemption from Certificate of Need review for a project covered by this Chapter shall address and document its compliance with each of the following general standards as part of its application.

(1) Information Regarding Charges.

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

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

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

(c) Making this information available shall be a condition of any CON issued by the Commission.

(2) Information Regarding Procedure Volume.

A hospital, physician outpatient surgery center, or ASF shall provide to the public upon inquiry information concerning the volume of specific surgical procedures performed at the location where an individual has inquired. A hospital, POSC, or ASF shall provide the requested information on surgical procedure volume for the most recent 12 months available, updated at least annually.

(3) 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 facility's charity care policy shall be posted in the registration area and business office of the facility. Prior to a patient's arrival for surgery, the facility shall address any financial concerns of the patient, and individual notice regarding the facility's charity care policy shall be provided.

(iii) **Criteria for Eligibility.** A hospital shall comply with applicable State statutes and Health Services Cost Review Commission (“HSCRC”) regulations regarding financial assistance policies and charity care eligibility. An ASF, at a minimum, shall include the following eligibility criteria in its 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 HSCRC Community Benefit Report, shall demonstrate that its level of charity care is appropriate to the needs of its service area population.

(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 its 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 make a commitment to provide charitable services to indigent patients. Charitable services may be surgical or non-surgical and may include charitable programs that subsidize health plan coverage. At a minimum, the amount of charitable services provided as a percentage of total operating expenses for the health maintenance organization will be equivalent to the average amount of charity care provided statewide by ASFs, measured as a percentage of total ASF expenses, in the most recent year reported. The applicant shall demonstrate that:

(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.

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

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

(ii) Accredited by the Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, or another accreditation agency recognized by the Centers for Medicare and Medicaid 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 POSC, as applicable, compares on these quality measures to other facilities that provide the same type of specialized services in Maryland.

(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; and

(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.

(e) An applicant or a related entity that currently or previously has operated or owned a POSC or ambulatory surgical facility, in Maryland or outside of Maryland, in the five years prior to the applicant's filing of a request for exemption request to establish an ASF, shall address the quality of care provided at each location through the provision of information on licensure, accreditation, performance metrics, and other relevant information.

(5) Transfer Agreements.

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

(b) Written transfer agreements between hospitals shall comply with Department of Health 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 regulation govern reviews of Certificate of Need applications and requests for exemption from Certificate of Need review involving surgical facilities and services. An applicant for a Certificate of Need or an exemption from Certificate of Need shall demonstrate consistency with all applicable review standards, unless an applicant is eligible for an exemption covered in Regulation .06. of this chapter.

(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:

(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 .07 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 .07 of this chapter.

(c) 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.

(d) An applicant proposing the establishment of a new ambulatory surgical facility shall submit a needs assessment that includes the following:

(i) Historic trends in the use of surgical facilities for outpatient surgical procedures by the proposed facility's likely service area population;

(ii) The operating room time required for surgical cases projected at the proposed facility by surgical specialty or, if approved by Commission staff, another set of categories; and

(iii) Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility.

(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 .07 of this chapter;

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

(c) Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the completion of the additional operating room capacity, consistent with Regulation .07 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 Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities (FGI Guidelines):

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

(b) An ASF shall meet the requirements in current 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 laboratory, radiology, and pathology services as needed, either directly or through contractual agreements.

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

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

(9) Impact.

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

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

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

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

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

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

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

(10) Preference in Comparative Reviews.

In 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. An applicant's commitment to provide charity care will be evaluated based on its past record of providing such care and its proposed outreach strategies for meeting its projected level of charity care.

.06 Exemption from Certificate of Need Review for the Establishment of an Ambulatory Surgical Facility.

A. Applicability.

The Commission may issue an exemption from Certificate of Need review to permit the establishment of an ambulatory surgical facility with two sterile operating rooms in the following circumstances, provided that the Commission determines that all applicable general and project review standards are met:

(1) The office of one or more health care practitioners or a group practice, as defined in §1-301 of the Health Occupations Article seeks to establish an ambulatory surgical facility with two operating rooms;

(2) A general hospital with two or more operating rooms seeks to establish an ambulatory surgical facility with two operating rooms in conjunction with conversion of the hospital to a freestanding medical facility on the same campus as the freestanding medical facility or immediately adjacent to the freestanding medical facility, if it seeks such an exemption:

(a) In conjunction with an exemption to convert to a freestanding medical facility; or

(b) After the issuance of an exemption to convert a general hospital to a freestanding medical facility and prior to the closure of the general hospital.

(3) A general hospital seeks to establish an ambulatory surgical facility with two operating rooms in conjunction with the closure of two dedicated outpatient or mixed-use operating rooms.

B. General and Project Review Standards.

(1) General Standards.

An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall meet the applicable standards in Regulation .05A(1)-(4) of this chapter.

(2) **Need.**

An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall:

(a) Demonstrate the need for two sterile operating rooms at the proposed ambulatory surgical facility utilizing the operating room capacity assumptions and other guidance included in Regulation .07 of this chapter; and

(b) Demonstrate that optimal capacity, as defined in Regulation .07 of this chapter will be reached for both operating rooms within three years of establishing the proposed ASF.

(3) **Design Requirements.**

An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under Regulation .06 of this chapter shall meet the following design requirements:

(a) The proposed expanded or new facility must be designed in conformance with the requirements for outpatient surgical facilities included in the current FGI Guidelines. An operating room shall be located in a restricted area. A non-sterile procedure room shall not be located in a restricted area. The clean and soiled work areas shall be physically separated; and

(b) Design or equipment features of a proposed expanded or new facility at variance with the current FGI Guidelines must be justified. Commission staff may consider the opinion of staff at the Facility Guidelines Institute, which publishes the Guidelines, in determining whether the proposed variance is acceptable.

(4) **Location.**

(a) An applicant seeking to establish an ASF with two operating rooms must identify a specific location for the proposed ASF and may not locate or operate the proposed ASF in a way that effectively results in the establishment of an ASF with three or more operating rooms.

(b) An applicant seeking to establish an ASF with two operating rooms through relocation of operating rooms from a hospital shall locate the proposed ASF within the service area of the hospital.

(c) A general hospital seeking an exemption to convert to a freestanding medical facility that is also seeking to establish an ambulatory surgical facility through an exemption process shall locate the proposed ambulatory surgical facility on the campus of the freestanding medical facility or an immediately adjacent location.

(5) Efficiency.

(a) An applicant proposing to establish an ambulatory surgical facility through an exemption from Certificate of Need under this regulation shall demonstrate how its project will result in the more efficient and effective delivery of surgical services by presenting an analysis that compares the level of efficiency and effectiveness of establishing a POSC instead of the proposed ASF.

(b) A hospital proposing to establish an ASF in conjunction with closure of two operating rooms shall demonstrate that the proposed ASF will result in an adjusted global budget that accounts for the lower surgical capacity of the hospital and is budget neutral or results in cost savings for Medicare and other payers, with respect to the global budget of the hospital, as determined by HSCRC.

(6) Construction Costs.

The estimated construction cost per square foot of the new construction required to establish an ambulatory surgical facility through an exemption from Certificate of Need under this regulation shall be reasonable and consistent with current industry cost experience.

(a) The projected cost per square foot of new construction shall be compared to the benchmark cost of good quality Class A construction for outpatient surgical centers given in the Marshall Valuation Service[®] guide. This standard does not apply to the costs of renovation or the fitting out of shell space.

(b) 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 necessity and reasonableness of the construction costs. An applicant may provide additional independent construction cost estimates or information on the actual cost of recently constructed surgical facilities similar to the proposed facility to support the applicant's analysis of the reasonableness of the construction costs.

C. Transferability and Procedural Requirements.

(a) An exemption from Certificate of Need is not transferable.

(b) An exemption from Certificate of Need may be issued with conditions if the Commission determines that approval with conditions is appropriate.

(c) A capital project approved through an exemption from Certificate of Need is subject to the performance requirements in COMAR 10.24.01.12 and the requirements relating to changes in an approved Certificate of Need in COMAR 10.24.01.17.

(d) Prior to first use of an ASF approved through an exemption from CON, an applicant shall request first use approval from Commission staff in writing not less than 60 days but not more than 120 days before first use of any portion of the facility and shall detail:

- (i) The anticipated date for first use;
- (ii) Status of inspection and licensing by the Office of Health Care Quality; and
- (iii) The final cost of the project.

.07 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.

(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, which includes the time during which surgical procedures are being performed and room turnaround time between surgical cases.

(b) Dedicated Outpatient General Purpose Operating Room:

(i) Is 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, unless an applicant demonstrates that a different optimal capacity standard is applicable based on:

1. The ability of the ASF 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 the proposed ASF and the benefits and costs for each surgeon when the ASF 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:

(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 rules in §07D 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 surgical facility or to add one or more 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 in Regulation .05B(2) or .05B(3) of

this chapter. 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) An applicant proposing to add a sterile operating room at an existing physician office surgery center through a request for exemption from CON review shall demonstrate that its existing sterile operating room was utilized at or above optimal capacity in the most recent 12-month period for which data has been reported to the Commission.

(3) Applicants proposing to consolidate two physician outpatient surgery centers to establish a single ambulatory surgical facility with two sterile operating rooms through a request for exemption from CON review are not required to demonstrate that their existing OR capacity is currently utilized at or above optimal capacity. Current operating room utilization levels may be a factor in evaluating the applicants' future utilization projections.

(4) An applicant proposing to establish a two-operating room ambulatory surgical facility through a request for exemption from CON review in conjunction with the establishment of a freestanding medical facility through conversion of a general hospital with at least two operating rooms is not required to demonstrate that its existing OR capacity is currently utilized at or above optimal capacity. Current operating room utilization levels may be a factor in evaluating the applicant's future utilization projections.

(5) The operating room capacity assumptions in §07A of this regulation and the operating room inventory rules in §07C 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 §07A(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 the assumptions used shall be presented.

(6) 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.

(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.

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.

(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.

.08 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 operating rooms;
- (b) Operates exclusively for the purpose of providing surgical services to patients requiring postoperative observation but who do not require hospitalization and in which the expected duration of services would not exceed 24 hours following admission;
- (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.

COMAR 10.24.11

- (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, 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 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, 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) "Commission" means the Maryland Health Care Commission or, as appropriate, the staff of the Maryland Health Care Commission.
- (5) "Dedicated inpatient operating room" means a sterile operating room that is used exclusively for inpatient surgery and is located at a hospital.
- (6) "Dedicated outpatient operating room" means a sterile operating room that is used exclusively for ambulatory surgery, located at a hospital or ambulatory surgical facility.
- (7) "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.
- (8) "Full capacity" means the operating room capacity assumed for each specific type of operating room, as described in Regulation .07A of this chapter.
- (9) "Green design principles" means the design principles outlined in the LEED® for Healthcare Rating System of the ROC Report.
- (10) "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.
- (11) "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.
- (12) "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*.

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

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

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

(16) “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.

(17) “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.

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

(19) “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.

(20) “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.

(21) "Optimal capacity," unless otherwise specified in this Chapter, means 80 percent of full capacity.

(22) “Outpatient Operating Room” means a sterile operating room that is used for outpatient surgical procedures located in an ambulatory surgical facility, POSC, hospital, or other health care facility.

(23) "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.

(24) “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.

(25) “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 sterile 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.

(26) “Procedure room” means a non-sterile room in which minor surgical procedures are performed under only topical, local, regional anesthesia, or minimal intravenous sedation. A deeper level of intravenous sedation in a procedure room is only appropriate for a minor procedure, such as an endoscopy, that is minimally invasive. 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 procedure room shall be accessed only from a semi-restricted corridor or an unrestricted corridor.

(27) “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.

(28) “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.

(29) “Smart and sustainable growth policies” means the policies articulated in §5-7A-01 of the State Finance and Procurement Article.

(30) "Special-purpose operating room" means a sterile 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.

(31) “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 one or more parts of the body affected, the complexity of the operation, and the expected recovery time.

(32) "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.

(33) "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 *International Classification of Diseases, 10th edition*.

COMAR 10.24.11

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