

Obtaining a Determination of Coverage to Establish a Freestanding Ambulatory Surgical Facility in Maryland

Establishing a “freestanding ambulatory surgical facility,” as defined in regulation at COMAR 10.05.05.01A(2), requires prior written approval from the Maryland Health Care Commission (“MHCC” or “the Commission”). This approval will be through either a Certificate of Need (“CON”), if more than two operating rooms are planned, or a letter, called a determination of coverage, stating that the proposed facility does not require CON review and approval. Individuals or organizations must either apply for a CON or seek a determination from MHCC that a proposed center with no more than two operating rooms does not fall within the Commission’s definition of “ambulatory surgical facility,” as defined in Health-General §19-114(b). **Please note that this statutory definition of “ambulatory surgical facility,” was changed effective October 1, 2019. Changes to procedural regulations, COMAR 10.24.01.01 and State Health Plan regulations, COMAR 10.24.11, have not, at the time of this writing, been revised to reflect this change. At this time, those regulations continue to contain a definition of “ambulatory surgical facility” stating that it is “an entity or part of an entity with two or more operating rooms.” Effective October 1, 2019, the statutory definition, which supersedes these regulations, has been modified to define an “ambulatory surgical facility” as any center, service, office, facility, or office of one or more health care practitioners or a group practice that . . . has three or more operating rooms.”**

In order to distinguish between an “ambulatory surgical facility,” defined in Maryland’s CON statute as a facility with three or more operating rooms and, as such, a facility subject to CON regulation and a freestanding ambulatory surgical facility that is not subject to CON regulation, because it has no more than two operating rooms, the State Health Plan refers to this latter category of facility as a “physician outpatient surgery center” or “POSC.”

The Office of Health Care Quality (“OHCQ”) of the Maryland Department of Health (“MDH”) will process an application for a freestanding ambulatory surgical facility license when a person seeking to license a freestanding ambulatory surgical facility has this documentation from MHCC, i.e., either an approved CON or a determination of coverage stating that a CON is not required, and meets all of the other MDH requirements for facility licensure. Centers that do not include any sterile operating rooms but only include non-sterile procedure rooms must obtain a determination of coverage from MHCC that its proposed facility does not require a CON before OHCQ will issue a facility license.

The following information is required for the Commission to make such a determination of coverage, in the case of: (1) establishment of a new POSC; (2) the addition of an operating room by an existing POSC; or a change in the principal owner or a majority of other owners of an existing POSC. Commission regulations require notification in writing, at least 45 days before a person establishes a new freestanding ambulatory surgical facility or makes any changes in the information provided for initial determination of coverage by CON. While all of the information listed below is not required in the case of notifications concerning the addition of non-sterile procedure rooms or other types of non-operating room space, renovations of existing space, or changes in the surgical specialties provided by an existing center, notification concerning changes of this type must still be provided to MHCC.

- (1) The name and address of the proposed POSC at which surgical services will be provided or the existing POSC.
- (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 each sterile operating room and the types of anesthesia that will be used in each sterile operating room; and the specific procedures that will

be performed in each 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.

(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 principal owner of the proposed center or facility:

In the proposed POSC, no more than two rooms will be used as sterile operating rooms, in which surgical procedures are performed and a facility fee can be charged. 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.

PLEASE NOTE:

All facilities providing ambulatory surgical services, whether or not regulated under CON, are required to participate in the Commission's annual data survey of ambulatory surgery providers.

FOR FURTHER INFORMATION:

Any questions regarding this required information or the procedural rules related to a request for determination of Certificate of Need coverage may be directed to Paul Parker, Director, Health Care Facilities Planning and Development, Maryland Health Care Commission at (410) 764-3261 or via e-mail to paul.parker@maryland.gov

PLEASE NOTE THAT DETERMINATIONS OF COVERAGE FOR NEW AMBULATORY SURGICAL CAPACITY, CHANGES OF OWNERSHIP, OR OTHER CHANGES TO THE PHYSICAL FACILITIES OF OR THE SERVICES PROVIDED BY EXISTING CENTERS REQUIRE 45 DAYS PRIOR WRITTEN NOTICE TO THE COMMISSION. Requests should be typed in letter form, and all accompanying information should be clearly labeled.