

Requesting and 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 must come in the form of 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).

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 an “ambulatory surgery center” or “ASC.”

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, so long as all other MDH requirements for facility licensure are met. 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.

Seventeen items of information, as enumerated in the following list, must be included in a request for a determination of coverage to establish a new ASC. Some changes in the ownership of an existing ASC also require issuance of a new determination of coverage. So, in general, a determination of coverage letter for ambulatory surgery capacity is issued only for the person or persons specified. A new determination of coverage is required if the principal owner or a majority of other owners of the ASC changes. For a change in a principal owner or in majority ownership of an ASC, the notice and request for a new determination of coverage 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.

- (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 COMAR 10.24.11 9 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.

(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.

While a new determination of coverage is only required to establish an ASC or to make significant ownership changes, an existing or authorized ASC is required to notify MHCC prior to making any changes in its physical facilities, practitioners, or surgical specialties, or finalizing changes in ownership that do not constitute a change in the principal owner or in a majority of its ownership. In general, any changes in the information provided in an ASC's initial determination of coverage or an ASC's most recently issued determination of coverage must be reported to MHCC.

PLEASE NOTE: All facilities providing ambulatory surgical services, whether regulated under CON are not requiring CON approval, 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 ESTABLISHMENT OF NEW ASCs AND CHANGES OF OWNERSHIP, OR NOTIFICATIONS ABOUT

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