

Requesting and Obtaining a Determination of Coverage To Establish or Expand an Ambulatory Surgery Center in Maryland

Introduction

Establishing a “freestanding ambulatory surgical facility,” as defined in regulation at COMAR 10.05.05.01B(2), requires prior written approval from the Maryland Health Care Commission (MHCC or the Commission). The type of approval required differs depending on the number of operating rooms at the proposed facility. The Office of Health Care Quality (OHCQ) of the Maryland Department of Health will not process an application for a freestanding ambulatory surgical facility license unless the applicant has first received the appropriate MHCC approval.

An “ambulatory surgical facility” or “ASF,” as defined at Health-General §19- 114(b), is a facility with three or more operating rooms. If an applicant wants to establish an ASF, they must apply for a Certificate of Need (CON) pursuant to COMAR 10.24.01. An “ambulatory surgery center,” or “ASC,” as defined at COMAR 10.24.11, is a facility with two operating rooms or less, including centers with only procedure rooms. If an applicant wants to establish an ASC, they must submit a request for a “determination of coverage” in which the applicant confirms that the proposed center will not have more than two operating rooms and therefore does not fall within the Commission’s definition of “ambulatory surgical facility.”¹

ASC: Determination of Coverage Requirements

In accordance with COMAR 10.24.11 and 10.24.01, 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 or make changes to an existing ASC:

- (1) The name and address of the proposed ASC 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,

¹ Please note that use of the procedure rooms shall conform with the definition at COMAR 10.24.11.07B(30).

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 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.

An existing ASC must file a new request for a determination of coverage if it seeks to add a new procedure room or operating room² or to make any changes in the information that resulted in MHCC's issuance of an initial determination. 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 there are no additional changes from the original determination of coverage in the physical facilities, physicians or other health care practitioners, staff, or surgical specialties and that changes are limited to ownership.

IMPORTANT NOTES:

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. Please submit the response electronically, in both Word and PDF format, mhcc.confilings@maryland.gov and to Deanna Dunn, deanna.dunn4@maryland.gov.

All facilities providing ambulatory surgical services 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 Wynee Hawk, Director, Health Care Facilities Planning and Development, Maryland Health Care Commission at (410) 764-3261 or via e-mail to wynnee.hawk1@maryland.gov and mhcc.confilings@maryland.gov.

² The facility must obtain a CON if the change will result in a facility with more than two operating rooms.