

Notification Requirements for a Determination of Coverage for Ambulatory Surgical Capacity in a Freestanding Setting

Establishing an ambulatory surgery center or facility, as defined in statute at Health-General Article §19-114, 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 one operating room is planned, or a letter, called a determination of coverage, stating that the proposal 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 one operating room does not fall within the Commission’s definition of “ambulatory surgical facility.”¹

The Office of Health Care Quality (“OHCQ”) of the Maryland Department of Health (“MDH”) will issue a facility license when a person applying to license an 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 developed by persons seeking to license such centers as ambulatory surgical facilities 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. Items 1 through 10 are based on the requirements set forth in regulation. Additional information and documentation (items 11 through 16) are also needed to establish the nature and proposed use of the proposed operating room/procedure room(s).

Commission regulations require notification in writing, at least 45 days before a person or entity establishes new ambulatory surgical capacity, and also before an existing facility makes any change in information previously provided to the Commission as part of a previous determination of coverage request.

Please submit the following information to the Maryland Health Care Commission at least 45 days prior to establishing a new center or facility, or making changes to an existing center or facility:

1. The name and address of the proposed surgical center at which surgical services will be provided.

¹ “Any center, service, office, facility, or office of one or more health care practitioners or a group practice, . . . that (i) has two or more operating rooms; (ii) operates primarily for the purpose of providing surgical services to patients who do not require overnight hospitalization; and (iii) seeks reimbursement from payers as an ambulatory surgical facility.”

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

3. The date anticipated for initiation of surgical and/or other services by the proposed center or the date anticipated for completion of alteration/expansion of an existing center.

4. The number of sterile operating rooms and the number of non-sterile procedure rooms proposed for the center.

5. A statement attesting that the center 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, and medical record-keeping. Existing centers must provide documentation of State licensure and Medicare certification. (Please note that obtaining licensure from OHCQ as an ambulatory surgical facility requires Medicare certification.)

6. The names of all persons, corporate entities, or other types of entity with an ownership interest in the proposed center, and the officers, directors, partners, and owners of those entities. Private proprietary corporations or other entities should identify all natural persons with an ownership interest in the corporation or entity and provide the percentage of ownership interest for each person.

7. The names and locations of any other ambulatory surgical facilities or centers with ambulatory surgical capacity, in which individuals, corporations, or other entities listed in response to Item 6 have an interest or other economic relationship, as an officer, director, partner, member, or owner.

8. A list of any other ambulatory surgical centers or facilities at the same address or on the same premises as the proposed new or expanded ambulatory surgical capacity.

9. A list of any contractual relationships to provide ambulatory surgical services between the center 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.

10. The names and specialties of physicians, podiatrists, or other qualified health care practitioners who will perform surgical and/or other services at the proposed center, or who currently provide services (in the case of an existing center seeking to expand surgical capacity), as well as the general types of surgical procedures performed by these practitioners.

11. 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 the non-sterile procedure room(s).

12. An architectural drawing of the entire center, with the functions, dimensions, fixed equipment, and nature of the connecting corridors (restricted/sterile, non-restricted, non-sterile) of each room and area **clearly labeled**.

13. A detailed description of the physical characteristics of the operating room and any procedure rooms, the equipment that will be included in the rooms, and the furnishing of the rooms, including the features which 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.

14. 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.

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

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

“In the proposed ambulatory surgery center or facility, 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.”

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 of the Commission staff at (410) 764-3261.

PLEASE NOTE THAT DETERMINATIONS OF COVERAGE FOR NEW AMBULATORY SURGICAL CAPACITY OR FOR CHANGES TO EXISTING CENTERS REQUIRE 45 DAYS PRIOR WRITTEN NOTICE TO THE COMMISSION.

Requests should be typed in letter form, and accompanying information should be clearly labeled.