

Notification Requirements for Determination of CON 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. This approval will be through either a Certificate of Need, if more than one operating room is planned, or a letter stating that the proposal does not require Certificate of Need review and approval. Individuals or organizations must either apply for a Certificate of Need, or seek a determination from the Commission that a single operating room and/or non-sterile procedure room(s) in an office-based, non-hospital setting do not fall within the Commission's definition of ambulatory surgical facility.¹

The Office of Health Care Quality will issue a State license with this documentation from the Commission. In addition, a person or entity seeking to establish a "freestanding endoscopy facility," as defined in statute at Health-General §19-3B-01, must receive a determination from the Commission that its proposed facility does not require a Certificate of Need before the Office of Health Care Quality will issue a State license to the endoscopy center.

The following information is required for the Commission to make such a determination of coverage. Items 1 through 10 are based on the requirements as set forth in COMAR 10.24.01.05A(5). 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 or facility at which surgical services will be provided.

¹ Under Health-General Article §19-114, Annotated Code of Maryland, an "ambulatory surgical facility" is a health care facility requiring Certificate of Need approval by the Maryland Health Care Commission prior to establishment. The statute defines this facility as "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." [§19-114(b)(1)]

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 facility or alteration/expansion of an existing center or facility.

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

5. A statement attesting that the center or facility intends to meet the quality² 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 or facilities must provide documentation of State licensure and Medicare certification.

6. The names of all persons, corporate entities, or other organizations with an ownership interest in the proposed center or facility and percentage of ownership, and the officers, directors, partners, and owners of those entities or organizations.

7. 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 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 as the proposed new or expanded ambulatory surgical capacity.

9. A list of any contractual relationships to provide ambulatory surgical services between the center or facility 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 facility, or who currently provide services (in the case of an existing center or facility seeking to expand surgical capacity), as well as the general types of surgical procedures performed by these practitioners.

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Although the Commission's regulations require either State licensure or Medicare certification, facilities intending to obtain licensure from OHCQ as an ambulatory surgery facility should be aware that for purposes of that licensure, OHCQ requires Medicare certification.

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 or facility, 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, 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. Label the sterile corridor, if any.

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 or surgical facility, 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 (non)-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 Christine Parent at (410) 764-3834.

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.