

Guide to State Regulations Affecting Freestanding Ambulatory Surgery Providers in Maryland*

Annual Maryland Freestanding Ambulatory Surgical Facility Survey

1. All Maryland non-hospital ambulatory surgery providers are required to complete the Maryland Health Care Commission's (MHCC's) annual Maryland Freestanding Ambulatory Surgical Facility Survey. The survey is conducted in the second quarter of the year and surveys the preceding calendar year. The survey is Internet-based and is completed and submitted online.
2. Ambulatory surgery providers should begin collecting necessary data as soon as surgical cases are performed at the center in anticipation of completing the survey. Providers are responsible for submitting data for any part of the year the center is operational. If the center closes mid-year, please make arrangements with MHCC to complete the survey. A list of the survey data fields is available from MHCC upon request.

Developing New Ambulatory Surgery Capacity

1. Developing any new ambulatory surgery capacity in Maryland requires obtaining, from MHCC, a Certificate of Need (CON), an exemption from CON review, or a written determination stating that your proposed center does not require a CON or an exemption from CON review. Developing a facility with two or more operating rooms requires a CON or an exemption from CON review. Please contact Kevin McDonald, Chief, Certificate of Need at 410-764-5982 for additional information on filing a CON application or a request for an exemption from CON review. A physician's office seeking to establish one operating room may not need a CON, but requires a determination of coverage under the CON rules. To begin the process, please refer to the Commission's website <http://mhcc.maryland.gov/>. For information on filing a request for determination of coverage go to http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_con_coverage_determination. (See COMAR 10.24.01.05).
2. Determination of coverage letters informing persons that the project proposed by the person does not require a CON or an exemption from CON review are effective for two (2) years from the date the letter is issued. If the project is not implemented within two years, a new determination letter must be obtained from MHCC.

Making Changes to Your Plans Prior to Completion of the Project

You must notify MHCC in writing 45 days in advance of making any of the following changes to your plans to develop ambulatory surgery capacity (See COMAR 10.24.01.05). Examples of the types of changes requiring notification include;

- a. Change in ownership

- b. Change in legal structure
- c. Change in floor plan
- d. Change in location
- e. Change in operating and/or procedure room capacity

Opening Your New Surgery Center

1. All ambulatory surgery centers seeking third party reimbursement for a facility fee must obtain a license from the Office of Health Care Quality (OHCQ) of the Maryland Department of Health. A determination of coverage letter or a CON or exemption from CON review from MHCC is required by OHCQ in order to obtain a license (see COMAR 10.05.05).
2. The licensing and certification process requires:
 - a. Medicare certification;
 - b. Fire Marshall Survey; and
 - c. Licensing survey

Making Changes to Your Existing Ambulatory Surgery Center

You must notify MHCC and OHCQ in writing of the following planned changes to your existing ambulatory surgery center at least 45 days prior to implementation of any of these changes (see COMAR 10.24.01.05)

- a. Center name;
- b. Specialties provided;
- c. Ownership (also see below);
- d. Addition of new physicians;
- e. Legal structure;
- f. Closure of surgery center;
- g. Change in floor plan; and/or
- h. Change in surgical capacity

Moving or Expanding Your Ambulatory Surgery Center

1. If you are planning to move your center to another location and/or are considering a change in operating room capacity, you must apply to MHCC for a CON or, in the case of a single operating room facility a new determination of coverage, at least 45 days in advance (See COMAR 10.24.01.05). Increasing operating room capacity will require a CON or an exemption from CON review if the facility has a single operating room.

2. You must also contact OHCQ as soon as possible before your move. Please notify OHCQ with an effective date of the move to schedule an on-site inspection and to arrange for a replacement license.

Changes in Ownership

Notification requirements for ambulatory surgical facilities with two or more operating rooms are outlined at COMAR 10.24.01.03A.

If a majority of the ownership interest in an ambulatory surgery center with no more than one operating room changes or if the principal owner changes, a new determination of coverage is required. Please note that the principal owner includes both the person issued the original letter of determination and, when there are multiple owners, the person or entity that holds the largest percentage of ownership in the ambulatory surgery center.

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***This guide is intended to illustrate the basic policies governing regulatory oversight of ambulatory surgical facilities development. It is not intended to provide authoritative guidance or legal advice. Consult applicable State law and regulation for complete information.**