



MARYLAND HEALTH CARE COMMISSION

4160 PATTERSON AVENUE – BALTIMORE, MARYLAND 21215
TELEPHONE: 410-764-3460 FAX: 410-358-1236

Guidance

Changes in CON Regulation of Ambulatory Surgical Facilities and Other Surgical Capacity due to Changes Adopted by the General Assembly in 2019

The General Assembly in its 2019 session passed and Governor Hogan signed Chapter 474, 2019 Maryland Laws (SB 940 - Health Care Facilities - Certificate of Need – Modifications) and Chapter 415 (HB 646 – MHCC - Certificate of Need for Hospital Capital Expenditures). The new law, which will become effective on October 1, 2019, reduces the scope of Certificate of Need (“CON”) regulation of ambulatory surgical facilities and makes other changes to Maryland law that were recommended by the Commission.¹

The 2019 changes will result in less CON regulation of the development of surgical facilities and capacity, even when the capacity is developed by hospitals, but retain CON regulation of the development of rate-regulated surgical facilities and capacity. Operators and others may wish to consider how the changes in law that will become effective October 1, 2019 will affect projects currently in a planning stage.

The changes in law will necessitate changes to COMAR 10.24.01, the Commission’s procedural regulations, and to COMAR 10.24.11, the Surgical Services Chapter of the State Health Plan for Facilities and Services. Because the changes to regulations may not be completed as of the October 1, 2019 effective of the new law, I am writing to inform you of both the changes to the law and Commission staff’s expectations of how those changes will impact the interaction of providers of surgical services with the Commission.

Changes in Maryland Law that Impact Providers of Surgical Services **Effective October 1, 2019**

Ambulatory surgical capacity in non-rate-regulated settings.

Effective October 1, 2019 the definition of ambulatory surgical facility (“ASF”) will change to include only a facility that contains three or more operating rooms (“ORs”).² This

¹ The Commission’s *Report on Modernization of the Maryland CON Program* may be accessed at <https://mhcc.maryland.gov/mhcc/pages/plr/plr/plr.aspx>

² See definition of “operating room” at COMAR 10.24.11.08B(19).

change in definition means that a CON will be required to establish an ASF (defined as having three or more ORs) or to add one or more ORs to an ASF that has three or more ORs.

Establishment of what is currently known in Commission regulations as a physician outpatient surgery center (“POSC”)³ will continue to be regulated through the issuance of a determination of coverage by Commission staff after review of required information.⁴ Effective October 1, a POSC can have up to two ORs.

As noted below, because of the new law, Commission staff can issue a determination of coverage for a surgery center that contains up to two ORs and/or any number of procedure rooms⁵ and that will become operational on or after October 1, 2019. Staff can issue such a determination of coverage for non-rate-regulated ambulatory surgical capacity sought by a hospital.⁶ Such hospital-sponsored, non-rate-regulated surgical capacity can be located on the campus of an FMF, that is, “at” or “adjacent to” – but not “in” – an FMF.⁷ This change in law renders unnecessary the requirement that a general hospital⁸ use the exemption from CON process to establish an ASF with two non-rate-regulated operating rooms in conjunction with the closure of two dedicated outpatient or mixed-use operating rooms or in conjunction with a hospital’s conversion to a freestanding medical facility (“FMF”).

The Commission anticipates that providers of surgical services may be interested in adding new OR capacity and recognizes the potential benefits to Maryland's performance on Total Cost of Care tests of delivering additional surgical services in the lower cost ASF setting. Therefore, Commission staff will accept requests for determination of coverage from persons seeking to establish a two-OR POSC that will go into operation on or after October 1, 2019. Requests will be reviewed in sequence based on date the completed paperwork is received.⁹ Commission staff will issue determinations of coverage with an effective date on/after October 1, 2019. A person or

³ COMAR 10.24.11.08B(25) currently defines a POSC as a location with no more than one sterile operating room that, among other attributes, seeks reimbursement from payors for the provision of ambulatory surgical services. The term is expected to change. Effective October 1, 2019, a center with two ORs (which is defined as an ASF under MHCC’s current statute) will no longer meet the definition for an ASF under the new law and will be classified in Commission records as a POSC.

⁴ Details regarding required information in a request for determination of coverage may be found at: https://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_amsurg/hcfs_amsurg.aspx (see document entitled “Notification of Requirements for Determination of CON Coverage for Ambulatory Surgical Capacity in a Freestanding Setting”).

⁵ See definition of “procedure room” at COMAR 10.24.11.08B(24).

⁶ The 2019 changes in law will, as of October 1, 2019, remove the provision at Maryland Code Ann., Health-General §19-120(k)(9), which currently prohibits a hospital from expanding ambulatory surgical capacity in any setting without CON approval. As discussed later, establishment of rate-regulated ambulatory surgical capacity in a hospital or in a freestanding medical facility will require a CON or exemption from CON.

⁷ See discussion regarding surgical capacity in rate-regulated setting, *infra*, p. 3. Commission staff interprets the upcoming change to Health-General § 19-120(j)(1)(ii) to mean that non-rate-regulated ambulatory surgical capacity that is not located within a CON-approved or CON-exempt FMF can be established by Commission staff’s issuance of a determination of coverage.

⁸ See COMAR 10.24.11.06A(2) and (3).

⁹ See footnote 4.

entity issued a determination of coverage may proceed with the fitting out of the building space, as described in the approved request for a determination of coverage, as long as the ambulatory surgical capacity governed by the determination is not put into operation before October 1, 2019.

Other 2019 changes will remove the capital review threshold for non-hospital health care facilities¹⁰ and substantially increase the hospital capital review threshold.¹¹ Thus, it is unlikely that ambulatory surgical capacity that can be established through the determination of coverage process will exceed the relevant capital review threshold after October 1, 2019.

Surgical capacity in rate-regulated settings – in a hospital or in a freestanding medical facility.

Effective October 1, 2019, Maryland law, at Health-General § 19-120(j)(1)(ii), will provide that a CON “is required before the ... scope of any health care service is changed if [it] ... results in a change in operating room capacity in a hospital, freestanding medical facility, or an ambulatory surgical facility.” This clarifies Maryland law that a CON is required for a hospital to add an OR of any type (outpatient, inpatient, or mixed-use).¹² A CON will also be required to add one or more ORs in an FMF.¹³ Commission staff interprets this to mean that issuance of a CON is required to add one or more rate-regulated ORs in an existing FMF whether the FMF was established through CON or through an exemption from CON. A hospital seeking to convert to an FMF through the CON-exemption process or to establish an FMF through issuance of a CON may seek to establish rate-regulated surgical capacity in the FMF by obtaining approval for regulated rates from the Health Services Cost Review Commission¹⁴ during the CON or CON-exemption process before the MHCC.

If you have any questions concerning the information provided in this memorandum, please contact Paul Parker at 410-764-3261 or at paul.parker@maryland.gov or Suellen Wideman, Assistant Attorney General, at 410-764-3326, or at suellen.wideman@maryland.gov.

¹⁰ Changes to Health-General § 19-120(k)(2)(i).

¹¹ Changes to Health-General § 19-120(a)(4) increase the capital review threshold for hospitals to the lesser of \$50,000,000 or 25% of the hospital’s gross regulated charges for the immediately preceding year.

¹² The Maryland Health Care Commission has historically determined that CON review and approval was necessary for a general hospital to add mixed-use or dedicated outpatient general purpose operating rooms, but was not needed to add dedicated inpatient general purpose operating rooms.

¹³ See discussion, *supra*, page 2. Addition of up to two non-rate-regulated ORs outside (or “at”) an FMF may be added through issuance of a determination of coverage by MHCC staff

¹⁴ Such services, if approved for rates by HSCRC, would fall within the definition of “at the hospital” in Health-General § 19-201(d)(1)(iv); see also, COMAR 10.37.10.07-2D.