

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulation  
Department of Health and Mental Hygiene  
(DLS Control No. 16-163)**

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**Overview and Legal and Fiscal Impact**

The regulation establishes a new chapter in the State Health Plan for Facilities and Services that governs the establishment of freestanding medical facilities.

The regulation presents no legal issues of concern.

There is no fiscal impact on State or local agencies.

**Regulation of COMAR Affected**

**Department of Health and Mental Hygiene:**

Maryland Health Care Commission: State Health Plan for Facilities and Services:  
Freestanding Medical Facilities: COMAR 10.24.19.01

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**Legal Analysis**

**Background**

Chapters 549 and 550 of 2005 established the category of “freestanding medical facility” and required licensure of such facilities by the Department of Health and Mental Hygiene. A “freestanding medical facility” was defined as a facility in which medical and health services are provided that is physically separate from a hospital or hospital grounds and is an administrative part of a hospital or related institution. Freestanding medical facilities must be open 24 hours a day, seven days a week, and, according to regulations issued by the department’s Office of Health Care Quality, provide stabilizing treatment to a patient presenting with an emergency medical condition regardless of a patient’s medical condition, insurance status, or ability to pay.

Chapters 549 and 550 also established a freestanding medical facility pilot project in Montgomery County. Chapter 574 of 2007 added a second freestanding medical facility pilot project, located in Queen Anne’s County.

Chapters 505 and 506 of 2010 required the Health Services Cost Review Commission (HSCRC) to set rates for hospital services provided at freestanding medical facilities issued a certificate of need (CON) by the Maryland Health Care Commission (MHCC) after July 1, 2015; a freestanding medical facility licensed prior to July 1, 2007; and freestanding medical facility pilot projects. Chapters 505 and 506 required all payers subject to the rate-setting authority of

HSCRC, including insurers, nonprofit health service plans, health maintenance organizations, managed care organizations, and the Medical Assistance Program, to pay the HSCRC rates for hospital services at a freestanding medical facility issued a CON after July 1, 2015, and freestanding medical facility pilot projects. The law required that a freestanding facility receiving a CON after July 1, 2015, meet requirements for licensure as a freestanding medical facility and prohibited the licensure of any additional freestanding medical facilities before that date.

Chapter 420 of 2016 exempted, under specified criteria, the conversion of a licensed general hospital to a freestanding medical facility (and any related capital expenditures) from the requirement to obtain a CON and established the procedures for obtaining the exemption from MHCC. A CON is required to establish or operate a freestanding medical facility except if (1) the facility is established as the result of the conversion of a licensed general hospital; (2) through the conversion, the licensed general hospital will eliminate the capability to admit or retain patients for overnight hospitalization, except for observation stays; (3) the facility will remain on the site of or adjacent to the licensed general hospital, with certain exceptions; (4) at least 60 days before the conversion, written notice of intent to convert is filed with MHCC; (5) MHCC finds that the conversion is consistent with the State Health Plan, will result in the delivery of more efficient and effective health care services, will maintain adequate and appropriate delivery of emergency care as determined by the Emergency Medical Services Board, and is in the public interest; and (6) MHCC notifies the licensed general hospital of its findings within 60 days after receiving notice of intent to convert. A CON is also not required for the establishment or operation of a freestanding medical facility pilot project.

Notwithstanding these provisions, a licensed general hospital in Kent County may not convert to a freestanding medical facility before July 1, 2020. MHCC may approve a site for a freestanding medical facility that is not on the site of or adjacent to the licensed general hospital if (1) the hospital is either the only hospital in the county or one of two hospitals in the county that are part of the same merged asset system and are the only two hospitals in the county and (2) the site is within a five-mile radius and in the primary service area of the licensed general hospital. DHMH must issue a license to a freestanding medical facility that receives a CON or an exemption from obtaining a CON.

Chapter 420 altered the definition of “hospital services” for purposes of rate setting to include (1) emergency services provided at a licensed freestanding medical facility and (2) outpatient services, as specified by HSCRC in regulation, provided at a licensed freestanding medical facility that has received a CON or an exemption from obtaining a CON.

### **Summary of Regulation**

The regulation establishes a new chapter in the State Health Plan for Facilities and Services that governs the establishment of freestanding medical facilities. The regulation sets forth (1) issues and policies; (2) standards guiding MHCC’s regulation of freestanding medical facilities; and (3) requirements for an exemption from CON to convert a general hospital to a freestanding medical facility.

The issues and policies comprise (1) delivery of and regulatory policy with respect to emergency and urgent care; (2) cost effectiveness and efficiency of care; (3) quality of care; (4) rate regulation; (5) conversion of general hospital campuses to outpatient care centers; and (6) policy objectives.

The standards include general and project review standards for CON. The general standards for CON require the parent hospital (1) to be the applicant for a CON to establish, relocate, or expand a freestanding medical facility; (2) to meet the general standards in the State Health Plan for acute care hospital services; (3) to document consistency with licensure standards established by the department; and (4) to establish and maintain financial assistance and charity care policies at the proposed freestanding medical facility that match those of the parent hospital.

The project review standards for CON include standards for (1) demonstrating need; (2) improving access to emergency services; (3) demonstrating cost-effectiveness; (4) improving the delivery of emergency services in the service area; (5) demonstrating reasonable construction costs; (6) demonstrating financial feasibility and viability; (7) demonstrating the absence of an undue negative effect on an existing hospital or freestanding medical facility; and (8) providing high quality services. The project review standards also establish the basis for MHCC to give preference to one proposal over another in a comparative review.

The requirements for an exemption from CON to convert a general hospital to a freestanding medical facility include a requirement that the converting hospital and its parent hospital jointly file with MHCC a notice of intent to seek an exemption. MHCC may only accept the notice after (1) the converting hospital publishes on its website, at least 14 days before holding a public informational hearing, the hospital's proposed transition plan; (2) the converting hospital, in consultation with MHCC and after providing at least 14 days' notice on its website and in a daily newspaper in its jurisdiction, holds a public informational hearing; (3) within 10 working days after the public informational hearing, the converting hospital provides to specified persons a written summary of the hearing and all written feedback; (4) the State Emergency Medical Services Board has determined that the proposed conversion will maintain adequate and appropriate delivery of emergency care; and (5) the applicants provide any additional information determined necessary by MHCC staff.

The exemption requirements also include requirements for the applicants to provide specified data; assess the availability and accessibility of specified services; and demonstrate consistency with specified assessments, guidance, and cost experience. Notably, the regulation allows a converting hospital to seek authorization for outpatient surgical capacity that (1) is co-located with or adjacent to the freestanding medical facility and (2) meets requirements necessary to obtain the license determined by the Office of Health Care Quality to be appropriate for the ambulatory surgical services to be provided. MHCC must grant a requested exemption from CON within 60 days of receipt of a complete notice of intent to convert to a freestanding medical facility, if MHCC finds that the proposed action meets specified requirements.

## **Legal Issues**

The regulation presents no legal issues of concern.

## **Statutory Authority and Legislative Intent**

MHCC cites §§ 19-109(a)(1), 19-114(d)(1)(viii), 19-118(a)(2)(i), and 19-120(j)(2)(iv) and (o)(1) and (3) of the Health – General Article as statutory authority for the regulation. Section 19-109(a)(1) authorizes MHCC to adopt rules and regulations to carry out the provisions of law for which it is responsible. Section 19-114(d)(1)(viii) defines a “health care facility” to include a freestanding medical facility. Section 19-118(a)(2)(i) requires the State Health Plan adopted by MHCC to include the methodologies, standards, and criteria for CON review. Section 19-120(j)(2)(iv)2.A.IV provides an exemption from CON for a change in the type or scope of a health care service if MHCC finds that the proposed change is pursuant to the conversion of a licensed general hospital to a freestanding medical facility in accordance with the provisions of law that govern CON for a freestanding medical facility. Section 19-120(o)(1) requires, with a certain exception, a person to have a CON before a person establishes or operates a freestanding medical facility.

Section 19-102(o)(3) authorizes an exception from CON to establish or operate a freestanding medical facility if (1) the freestanding medical facility is established as the result of a conversion of a licensed general hospital; (2) through the conversion the licensed general hospital will eliminate the capability of the hospital to admit or retain patients for overnight hospitalization, except for observation stays; (3) with certain exceptions, the freestanding medical facility will remain on the site of, or on a site adjacent to, the licensed general hospital; (4) at least 60 days before the conversion, written notice of intent to convert the licensed general hospital to a freestanding medical facility is filed with MHCC; (5) MHCC in its sole discretion finds that the conversion is consistent with the State Health Plan, will result in the delivery of more efficient and effective health care services, will maintain adequate and appropriate delivery of emergency care within the statewide emergency medical services system as determined by the State Emergency Medical Services Board, and is in the public interest; and (6) within 60 days after receiving notice, MHCC notifies the licensed general hospital of its findings. MHCC may approve a site for a freestanding medical facility that is not on the site of or adjacent to the licensed general hospital, if the site is within a five-mile radius and in the primary service area of the hospital; and the hospital is (1) the only hospital in the county or (2) one of two hospitals in the county that are part of the same merged asset system and are the only two hospitals in the county. The section prohibits a licensed general hospital in Kent County from converting to a freestanding medical facility before July 1, 2020.

This authority is correct and complete. The regulation complies with the legislative intent of the law.

## **Special Note**

In response to a legal issue raised by the Department of Legislative Services (DLS), MHCC agreed to change a provision of the regulation relating to retention of outpatient surgical capacity

by a hospital seeking to convert to a freestanding medical facility. As originally proposed, the regulation would have allowed a converting hospital to seek authorization for outpatient surgical capacity to be co-located with or adjacent to the freestanding medical facility and licensed as a freestanding ambulatory surgical facility. DLS contended that MHCC did not have statutory authority to allow the establishment of a freestanding ambulatory surgical facility that did not obtain a CON as a freestanding ambulatory care facility. The revised regulation does not explicitly allow the establishment of a freestanding ambulatory surgical facility but instead requires any outpatient surgical capacity approved by MHCC for retention to meet requirements necessary to obtain the license determined by the Office of Health Care Quality (OHCQ) to be appropriate for the ambulatory surgical services to be provided. Should OHCQ determine that the appropriate license is the freestanding ambulatory care facility license, DLS believes the statute requires the converting hospital to obtain a CON before establishing the freestanding ambulatory care facility.

## **Fiscal Analysis**

There is no fiscal impact on State or local agencies.

### **Agency Estimate of Projected Fiscal Impact**

The regulation adopts policies and standards to guide the certificate of need process (including exemptions) for freestanding medical facilities as required by Chapter 420 of 2016 (Senate Bill 707). The department advises that, due to the low number of anticipated applications, any fiscal impact on State agencies (including the Maryland Health Care Commission, Health Services Cost Review Commission, Office of Health Care Quality, and Maryland Institute for Emergency Medical Services Systems) will be minimal and can be handled within existing budgeted resources. The Department of Legislative Services concurs and notes that this impact was reflected in the fiscal and policy note for Senate Bill 707.

### **Impact on Budget**

There is no impact on the State operating or capital budget.

### **Agency Estimate of Projected Small Business Impact**

The department advises that the regulation has minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

## **Contact Information**

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