

**Maryland General Assembly  
Department of Legislative Services**

**Proposed Regulation  
Department of Health and Mental Hygiene  
(DLS Control No. 15-184)**

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**Overview and Legal and Fiscal Impact**

The regulation specifies that certain outpatient services associated with the federal 340B Drug Pricing Program under the federal Public Health Service Act are subject to the rate-setting jurisdiction of the Health Services Cost Review Commission.

The regulation presents no legal issues of concern.

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy note for Chapter 263 of 2015.

**Regulation of COMAR Affected**

**Department of Health and Mental Hygiene:**

Health Services Cost Review Commission: Rate Application and Approval Procedures:  
COMAR 10.37.10.07-1

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**Legal Analysis**

**Background**

The federal 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible covered entities at significantly reduced prices. Chapter 263 of 2015 allows Maryland hospitals to have similar flexibility as hospitals nationally in moving their 340B programs to a related merged asset hospital, in compliance with federal 340B law and regulation. Hospitals in other states are allowed to move their hospital outpatient services to other sites and still maintain their drug discount, but because of Maryland's unique hospital payment system, legislation was needed to allow this to occur in Maryland.

**Summary of Regulation**

COMAR 10.37.10.07-1C specifies that outpatient services associated with the federal 340B program under the federal Public Health Service Act provided in a department of a regulated hospital which is located at another regulated hospital under a merged asset hospital system, are subject to the rate-setting jurisdiction of the Health Services Cost Review Commission. The change applies to regulated hospitals that were under a merged asset hospital system on or before June 1, 2015.

## **Legal Issues**

The regulation presents no legal issues of concern.

## **Statutory Authority and Legislative Intent**

The commission cites §§ 19-201 and 19-207 of the Health – General Article as statutory authority for the regulation. Section 19-201 was amended by Chapter 263 of 2015 to clarify that merged asset hospital systems may operate a federal 340B Drug Pricing Program at another system hospital. Section 19-207 authorizes the commission to adopt regulations to carry out its duties.

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

## **Fiscal Analysis**

There is no fiscal impact on State or local agencies beyond that already assumed in the fiscal and policy note for Chapter 263 of 2015.

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

The regulation requires that outpatient services associated with the federal 340B Drug Pricing Program that are provided in a department of a regulated hospital that, on or before June 1, 2015, is under a merged asset hospital system and which are physically located at another regulated hospital under the same merged asset hospital system be subject to the rate-setting jurisdiction of the Health Services Cost Review Commission. The regulation implements Chapter 263 of 2015 (House Bill 613). The commission advises that the regulation has no impact on State or local governments. The Department of Legislative Services concurs as any impact has already been assumed in the fiscal and policy note for House Bill 613.

### **Impact on Budget**

There is no impact on the State operating or capital budget beyond that already assumed in the fiscal and policy note for House Bill 613.

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

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

## **Additional Comments**

Chapter 263 of 2015 altered the definition of “hospital services” for purposes of rate setting to clarify that merged asset hospital systems may operate a federal 340B Drug Pricing Program at another system hospital. Specifically, “hospital services” includes a hospital outpatient service (1) of a hospital, that on or before June 1, 2015, is under a merged asset

hospital system; (2) that is designated as a part of another hospital under the same merged asset hospital system to make it possible for the hospital outpatient service to participate in the federal 340B program; and (3) that complies with all federal requirements for the 340B program and related regulations. The fiscal and policy note for House Bill 613 projected that increased participation by hospitals in the 340B program results in net savings for the Medicaid program (50% general funds, 50% federal funds). Given the significant variation in rebates received, the exact savings cannot be reliably estimated.

## **Contact Information**

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