

MARYLAND REGISTER

**Proposed Action on Regulations**

<b>Transmittal Sheet</b>  <b>PROPOSED OR REPROPOSED</b>  <b>Actions on Regulations</b>	<b>Date Filed with AELR Committee</b>	<b>TO BE COMPLETED BY DSD</b>
	12/10/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

**1. Desired date of publication in Maryland Register: 1/8/2016**

**2. COMAR Codification**

**Title Subtitle Chapter Regulation**

10 37 10 07-1

**3. Name of Promulgating Authority**

Health Services Cost Review Commission

**4. Name of Regulations Coordinator Telephone Number**  
Diana M Kemp 410-764-2576

**Mailing Address**

4160 Patterson Avenue

**City State Zip Code**  
Baltimore MD 21215

**Email**  
dkemp@hsrc.state.md.us

**5. Name of Person to Call About this Document Telephone No.**  
Diana Kemp 410-764-2576

**Email Address**  
diana.kemp@maryland.gov

**6. Check applicable items:**

- New Regulations
- Amendments to Existing Regulations  
Date when existing text was downloaded from COMAR online: 12/01/2015.
- Repeal of Existing Regulations
- Recodification
- Incorporation by Reference of Documents Requiring DSD Approval
- Reproposal of Substantively Different Text:  
:  
Md. R  
(vol.) (issue) (page nos) (date)  
Under Maryland Register docket no.: --P.

**7. Is there emergency text which is identical to this proposal:**

Yes  No

If yes, corresponding proposed text published in:

- same issue
- future issue
- previous issue; it appeared in  
:  
Md. R  
(vol.) (issue) (page no's) (date)  
Under Maryland Register docket no.: --E.

**8. Incorporation by Reference**

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

**9. Public Body - Open Meeting**

- OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to State Government Article, §10-506(c), Annotated Code of Maryland.
- OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

**10. Children's Environmental Health and Protection**

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

**11. Certificate of Authorized Officer**

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Leslie C. Schulman, Assistant Attorney General, (telephone #410-764-2576) on December 10, 2015. A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

John M. Colmers

**Title**

Chairman

**Date**

December 10, 2015

**Telephone No.**

410-764-2605

**Title 10**

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

**Subtitle 37 HEALTH SERVICES COST REVIEW COMMISSION**

**10.37.10 Rate Application and Approval Procedures**

Authority: Health-General Article, Sections 19-201; 19-207; and 19-219(c), Annotated Code of Maryland

**Notice of Proposed Action**

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The Health Services Cost Review Commission proposes to amend Regulation .07-1 under COMAR 10.37.10 Rate Setting and Approval Procedures. This action was considered and approved for promulgation by the Commission at a previously announced open meeting held on December 10, 2015, notice of which was given pursuant to General Provisions Article, Section 3-301(c), Annotated Code of Maryland. If adopted, the proposed amendments will become effective on or about April 11, 2016.

**Statement of Purpose**

The purpose of this action is to allow the Commission to set rates for outpatient services associated with the federal 340B Program in anticipation of the hospital's obtaining federal provider-based status.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

**I. Summary of Economic Impact.**

Economic Impact is based on hospitals paying less for certain outpatient drugs under the federal 340B Program.

**II. Types of Economic Impact.**

Revenue (R+/R-)

Expenditure (E+/E-)

Magnitude

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A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude

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D. On regulated industries or trade groups:	NONE	
(1) Regulated Industries or Trade Groups	(+)	Moderate
E. On other industries or trade groups:	NONE	
(2) Other Industries or Trade Groups	(+)	Moderate
F. Direct and indirect effects on public:	NONE	
(3) Direct and Indirect Effects on Public	(+)	Moderate

**III. Assumptions.** (Identified by Impact Letter and Number from Section II.)

D(1). The assumption of moderate benefit to regulated hospitals, third party payers and the public, as identified in Section II D, E and F, is based on hospitals paying less for certain outpatient drugs under the federal 340B Program, which translates to payers and patients paying less as well.

E(2). The assumption of moderate benefit to regulated hospitals, third party payers and the public, as identified in Section II D, E and F, is based on hospitals paying less for certain outpatient drugs under the federal 340B Program, which translates to payers and patients paying less as well

F(3). The assumption of moderate benefit to regulated hospitals, third party payers and the public, as identified in Section II D, E and F, is based on hospitals paying less for certain outpatient drugs under the federal 340B Program, which translates to payers and patients paying less as well.

**Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

**Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

**Opportunity for Public Comment**

Comments may be sent to Diana Kemp, Regulations Coordinator, Health Services Cost Review Commission, 4160 Patterson Avenue, Baltimore, MD 21215, or call 410-764-2576, or email to [diana.kemp@maryland.gov](mailto:diana.kemp@maryland.gov), or fax to 410-358-6217. Comments will be accepted through February 8, 2016. A public hearing has not been scheduled.

### **Economic Impact Statement Part C**

- A. Fiscal Year in which regulations will become effective: FY 2016
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?  
Yes
- C. If 'yes', state whether general, special (exact name), or federal funds will be used:  
100% Special Funds - Hospital Assessments
- D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:
  
- E. If these regulations have no economic impact under Part A, indicate reason briefly:
  
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.
  
- G. Small Business Worksheet:

Attached Document:

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## **Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

### **Subtitle 37 HEALTH SERVICES COST REVIEW COMMISSION**

#### **10.37.10 Rate Application and Approval Procedures**

Authority: Health-General Article, §§ 19-201; 19-207; and 19-219(c), Annotated Code of Maryland

##### **.07-1 Outpatient Services – At the Hospital Determination.**

- A. (text unchanged)
- B. (text unchanged)
- C. In accordance with Health-General Article, § 19-201, Annotated Code of Maryland, the Commission's rate-setting jurisdiction extends to outpatient services provided at the hospital. Outpatient services associated with the federal 340B Program under the federal Public Health Service Act 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, shall be subject to the rate-setting jurisdiction of the Commission. *The Commission may begin setting rates for these services in anticipation of the hospital's obtaining provider-based status for purposes of the 340B Program.*
- D.-J. (text unchanged)

JOHN M. COLMERS  
Chairman  
Health Services Cost Review Commission