

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>
	10/27/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

**1. Desired date of publication in Maryland Register: 12/12/2014**

**2. COMAR Codification**

**Title Subtitle Chapter Regulation**

10 09 42 01-.06

**3. Name of Promulgating Authority**

Department of Health and Mental Hygiene

**4. Name of Regulations Coordinator**

Michele Phinney

**Telephone Number**

410-767-5623

**Mailing Address**

201 W. Preston Street

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**5. Name of Person to Call About this Document**

Michael Cimmino

**Telephone No.**

410-767-0579

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michael.cimmino@maryland.gov

**6. Check applicable items:**

New Regulations

Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: August 1, 2014.

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

**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 David Lapp, Assistant Attorney General, (telephone #410-767-5292) on September 10, 2014. A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

Joshua M. Sharfstein, M.D.

**Title**

Secretary

**Telephone No.**

410-767-6500

**Date**

October 27, 2014

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

**Subtitle 09 MEDICAL CARE PROGRAMS**

**10.09.42 Free-Standing Medicare-Certified Ambulatory Surgical Centers**

Authority: Health-General Article, §§2-104(b), 15-103, and 15-105, Annotated Code of Maryland

**Notice of Proposed Action**

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .01—.06 under COMAR 10.09.42 Free-Standing Medicare-Certified Ambulatory Surgical Centers.

**Statement of Purpose**

The purpose of this action is to change the rate and implement a payment methodology for the ASC facility fee for dental services.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

**I. Summary of Economic Impact.**

The Department of Health and Mental Hygiene (the Department) is proposing the coverage of dental services in an Ambulatory Surgery Center (ASC). With the dental services rendered at an ASC versus the Outpatient Department (OPD) of a hospital, the Department is projecting an overall cost savings.

<b>II. Types of Economic Impact.</b>	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(E+)	\$2,055,916
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude

D. On regulated industries or trade groups:		
Ambulatory Surgery Center	(+)	\$2,055,916
E. On other industries or trade groups:		
Hospital OPD	(-)	\$6,821,742
F. Direct and indirect effects on public:	NONE	

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

A. The proposed regulations have an overall cost savings to the Department. The Department is projecting an expenditure of \$2,055,916.00 to the ASC for the reimbursement of the facility costs associated with dental services that will be provided at the ASC; however, the Department is projecting a savings of approximately \$6,821,742.00 from the OPD of a hospital, which results in an overall cost savings.

D. See A.

E. See A.

**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 Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to [dhmh.regs@maryland.gov](mailto:dhmh.regs@maryland.gov), or fax to 410-767-6483. Comments will be accepted through January 12, 2015. A public hearing has not been scheduled.

**Economic Impact Statement Part C**

A. Fiscal Year in which regulations will become effective: FY 2015

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

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.

The Department believes the \$2,055,916 is a minimal impact on the ASCs.

G. Small Business Worksheet:

Attached Document:

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## Title 10

# DEPARTMENT OF HEALTH AND MENTAL HYGIENE

### Subtitle 09 MEDICAL CARE PROGRAMS

#### 10.09.42 Free-Standing Medicare-Certified Ambulatory Surgical Centers

Authority: Health-General Article, §§2-104(b), 15-103, and 15-105,

Annotated Code of Maryland

10.09.42 (8/1/14)

##### **.01 Definitions.**

A. (text unchanged)

B. Terms Defined.

[(1)] (1) "Ambulatory surgical center or ASC" means any distinct, Medicare-certified entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.]

[(2)] (1) (text unchanged)

(2) "*Dental Benefits Administrator (DBA)*" means an entity that administers the dental program for the Department of Health and Mental Hygiene.

(3) "*Dental services*" means emergency, preventive, or therapeutic services for oral diseases which are administered by or under the general supervision of a dentist in the practice of the profession.

[(3)] (4) (text unchanged)

[(4)] (5) "Free-standing [ambulatory surgical center or] Ambulatory Surgery Center (ASC)" means [a unit] an entity capable of providing ambulatory surgical services, which is not located in a hospital setting, and which is Medicare-certified to furnish ambulatory surgical services.

[(5)] (6)—[(7)] (8) (text unchanged)

[(8)] (9) "Medicare-certified facility" means a facility which:

(a)—(b) (text unchanged)

(c) Meets the conditions set forth by (CMS) in 42 CFR Part 416, *Subparts B, C, and Subpart F*, [§§416.164—416.167] §416.163.

[(9)] (10)—[(14)] (15) (text unchanged)

##### **.02 License Requirements.**

A. (text unchanged)

B. The provider shall ensure that all X-ray and other radiological equipment is maintained and inspected in compliance with the requirements of *the Maryland Radiation Act*, Environment Article, Title 8, Subtitle 3, Annotated

Code of Maryland, and meets the standards established by [COMAR 10.14.02] *COMAR 26.12.01 and COMAR 26.12.02* or other applicable standards established by the state in which the service is provided.

C. (text unchanged)

### **.03 Conditions for Participation.**

A. General requirements for participation in the Program are that a provider shall meet all conditions for participation as set forth in COMAR 10.09.36.03 and 42 CFR, Part 416, Subpart B.

B. Specific requirements for participation in the Program [as a free-standing Medicare-certified ambulatory surgical center include all of the following:] *are that the provider shall meet all specific conditions for participation as set forth in 42 CFR, Part 416, Subpart C, to include the following:*

(1)—(7) (text unchanged)

### **.04 Covered Services.**

The Program covers the following:

A.—B. (text unchanged)

C. Surgical procedures which meet the standards described in 42 CFR Part 416, Subpart [F, §416.75] D, §416.65, and as published by the Centers for Medicare and Medicaid Services[.]; and

D. *Dental services that have been pre-authorized by the Dental Benefits Administrator (DBA).*

### **.05 Limitations.**

The Program does not cover the following:

A.—E. (text unchanged)

F. Surgical procedures which:

(1)—(7) (text unchanged)

(8) Are otherwise excluded under 42 CFR §411.15 (a)—(h) and (j)—(s);

G.—N. (text unchanged)

### **.06 Payment Procedures.**

A. [Reimbursement by the Program is for facility services provided by a free-standing ambulatory surgical center in connection with covered surgical procedures, including but not limited to] *The Program reimburses a facility fee when the free-standing Medicare certified ambulatory surgery center provides a covered surgical procedure, in accordance with 42 CFR §416.166 to an eligible Medicaid recipient. Reimbursement for the facility fee includes, but is not limited to the following:*

(1)—(6) (text unchanged)

(7) Supervision of the services of a nurse anesthetist by the operating surgeon; [and]

(8) Ancillary items and services that are integral to a covered surgical procedure as defined in 42 CFR

§416.166[.]; and

(9) *Any laboratory testing performed under a Clinical Laboratory Improvement Amendment of 1988 (CLIA) certificate of waiver.*

B. Reimbursement Methodology:

(1) Reimbursement fees equal [98] 80 percent of the [2007] *current* Medicare-approved ASC facility fee for services furnished to Medicaid recipients in connection with covered surgical procedures.

[(2) For those procedure codes with reimbursement rates capped by the Deficit Reduction Act of 2005 (DRA), reimbursement is at 100 percent of the Medicare approved ASC facility fee.]

[C.] (2) If one covered surgical procedure is furnished to a recipient, payment is at the Maryland Medicaid Program payment amount which is [98] 80 percent of the [2007] *current* Medicare approved facility fee for that procedure.

[D.] (3) If more than one covered surgical procedure is provided to a recipient in a single operative session, payment is made at 100 percent of the Maryland Medicaid Program payment amount for the procedure with the highest reimbursement rate. Other covered surgical procedures furnished [in] *during* the same session are reimbursed at 50 percent of the Maryland Medicaid Program payment amount for each [of those procedures] *procedure*.

[D-1.] (4) When a covered surgical procedure is terminated before the completion due to extenuating circumstances or circumstances that threaten the well-being of the patient, the Medicaid Program payment amount is based on one of the following:

[(1)] (a) If the *covered* procedure for which the anesthesia is planned is discontinued after the induction of anesthesia or after the procedure is started, the reimbursement amount is [98] 80 percent of the [2007] *current* Medicare approved facility fee; or

[(2)] (b) [One-half of the 2007 Medicare approved facility fee will be reimbursed if the procedure for which anesthesia is planned is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed, but before the anesthesia is induced or if a covered surgical procedure for which anesthesia was not planned is discontinued after the patient is prepared for surgery and taken to the room where the procedure is to be performed.] *If the patient is prepared for surgery and the surgery is then cancelled before the induction of anesthesia, reimbursement shall be 50 percent of Maryland Medicaid payment amount.*

C. *Dental services rendered in an ASC on or after October 1, 2014, shall be reimbursed as follows:*

(1) For covered dental services that have a reimbursement amount of \$1,000 through \$2,999.99, the ASC facility fee will be \$600;

(2) For covered dental services that have a reimbursement amount of \$3,000 through \$4,999.99, the ASC facility fee will be \$1,250;

(3) For covered dental services that have a reimbursement amount of \$5,000 through \$7,999.99, the ASC facility fee will be \$2,500; and

(4) For covered dental services that have a reimbursement amount of \$8,000 and over, the ASC facility fee will be \$3,000.

[E.] D.—[F.] E. (text unchanged)

[G. The provider shall bill the Program the composite Medicare rate for free-standing ambulatory surgical center services.]

[H.] F. The Program shall authorize payment on Medicare cross-over claims only if:

(1) (text unchanged)

(2) Medicare makes direct payment to the provider; [and]

(3) Medicare has determined that the services are medically [necessary] *justified, excludes dental services.*

[I.] G. The Department shall make supplemental payment on Medicare cross-over claims subject to the following provisions:

(1) Deductible [and co-insurance,] *is paid* in full;

(2) *Coinsurance shall be paid lesser of:*

(a) *100 percent of the coinsurance amount; or*

(b) *The balance remaining after the Medicare payment is subtracted from the Medicaid rate; and*

[(2)] (3) Services not covered by Medicare, but considered medically necessary by the Program, according to the limitations of Regulation .04C of this chapter.

[J.] H. The provider may not bill the Program for:

(1)—(2) (text unchanged)

(3) Professional services rendered by mail or telephone; [and]

(4) Services which are provided at no charge to the general public[.]; *and*

(5) *Providing a copy of a recipient's medical record when requested by another licensed provider on behalf of the recipient.*

[K.] I.—[M.] K. (text unchanged)

**JOSHUA M. SHARFSTEIN, M.D.**

**Secretary of Health and Mental Hygiene**