

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>
	07/29/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 9/5/2014

2. COMAR Codification

**Title Subtitle Chapter Regulation**

10 12 03 01-.12

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

**4. Name of Regulations Coordinator Telephone Number**  
Michele Phinney 410-767-5623

**Mailing Address**

201 W. Preston Street

**City State Zip Code**  
Baltimore MD 21201

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michele.phinney@maryland.gov

**5. Name of Person to Call About this Document Telephone No.**  
Christina Vogeley 410-402-8002

**Email Address**  
christina.vogeley@maryland.gov

6. Check applicable items:  
X- New Regulations

- Amendments to Existing Regulations
    - Date when existing text was downloaded from COMAR online: .
  - 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 Paul Ballard, Assistant Attorney General, (telephone #410-767-6918) on April 29, 2014. A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

Joshua M. Sharfstein, M.D.

**Title**

Secretary

**Date**

July 29, 2014

**Telephone No.**

410-767-6500

**Title 10**

# DEPARTMENT OF HEALTH AND MENTAL HYGIENE

## Subtitle 12 ADULT HEALTH

### 10.12.03 Cosmetic Surgical Facilities

Authority: Health-General Article, Title 19, Subtitle 3C, Annotated Code of Maryland

#### Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.12 under a new chapter COMAR 10.12.03 Cosmetic Surgical Facilities.

#### Statement of Purpose

The purpose of this action is to adopt regulations governing the licensing and operation of cosmetic surgical facilities that would not otherwise be subject to the licensure requirements for ambulatory surgical facilities because they only bill patients directly for their services.

#### Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

#### Estimate of Economic Impact

##### I. Summary of Economic Impact.

An accredited cosmetic surgical facility will pay a 3-year licensing fee of \$3,000, an annual cost of \$1,000. A facility that is not currently accredited will pay approximately \$9,430 for a 3-year cycle of accreditation, annual cost of \$3,143. The cost for continued accreditation is less than initial accreditation, so a facility that is currently accredited will pay less for on-going accreditation. Existing staff will conduct licensure and surveying activities for cosmetic surgery centers and will not create a revenue nor an expenditure. The total salary and benefit cost of \$191,600 will be provided through current funding sources. Accrediting industries and trade groups will refer to regulations concerning Ambulatory Care to develop accreditation curriculum for facilities.

II. Types of Economic Impact.	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(R-)	\$150,000
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+)	Magnitude

	Cost (-)
D. On regulated industries or trade groups:	(-) \$621,500
E. On other industries or trade groups:	(+) \$471,500
F. Direct and indirect effects on public:	NONE

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

A. The cost of the 3-year license is \$3,000, with an annual cost of \$1,000. The Department anticipates approximately 50 facilities to apply for a 3-year license (\$3,000 x 50 = \$150,000). The Office of Health Care Quality will utilize existing staff to complete licensure and surveying activities for cosmetic surgery centers at a cost of about \$191,600 annually in salaries and benefits.

D. All monies are based on a 3-year licensure period and 3-year accreditation. These regulations would establish mandatory accreditation for cosmetic surgery facilities; the assumption is that none of these facilities are currently accredited. The Department anticipates approximately 50 facilities to apply for a 3-year license and 50 facilities to apply for accreditation. The cost for 3-year licensure is \$3,000 and for 3 years in an accreditation cycle is approximately \$9,430. The total cost of accreditation and licensing is \$621,500 every three years for the industry (\$3,000 x 50 + \$9,430 x 50 = \$621,500). In addition, administrative penalties may be assessed for the very occasional serious deficiencies that may occur.

E. This is based on the assumption that there are no facilities currently accredited who will apply for this license. The cost of the 3-year accreditation is \$9,430. The Department anticipates approximately 50 facilities to apply for a 3-year accreditation (\$9,430 x 50 = \$471,500). Therefore, the revenue collected by accreditation organizations would be \$417,500 every 3 years.

**Economic Impact on Small Businesses**

The proposed action has a meaningful economic impact on small business. An analysis of this economic impact follows.

An accredited cosmetic surgical facility will pay a licensing fee of \$3,000 for 3 years. If a facility is not currently accredited, it will pay approximately \$9,430 for a three-year cycle of accreditation. If a facility is currently accredited, the facility will pay less for on-going accreditation. If not currently accredited, a cosmetic surgery center will pay an annual cost of \$4,143 to meet licensure requirements and to better ensure the health, safety, and welfare of individuals receiving services at these centers.

**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, or fax to 410-767-6483. Comments will be accepted through October 6, 2014. 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?

No

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:

The Office of Health Care Quality will absorb the cost of licensure and surveying activities with the existing staff.

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 12 ADULT HEALTH**

### **10.12.03 Cosmetic Surgical Facilities**

Authority: Health-General Article, Title 19, Subtitle 3C, Annotated Code of Maryland

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

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) *Cosmetic Surgical Facility.*

(a) "Cosmetic surgical facility" means an office or a facility in which a cosmetic surgical procedure is performed.

(b) "Cosmetic surgical facility" does not include:

(i) An ambulatory surgical facility;

(ii) A hospital; or

(iii) An office owned or operated by one or more dentists providing services within the scope of practice of dentistry.

(2) **Cosmetic Surgical Procedure.**

(a) "Cosmetic surgical procedure" means the use of surgical services to reshape the structure of a human body to change the appearance of an individual.

(b) "Cosmetic surgical procedure" does not include:

(i) A procedure done under local anesthesia or mild sedation; or

(ii) Liposuction that removes less than 1,000 cubic centimeters of aspirate.

(3) "Department" means the Department of Health and Mental Hygiene.

(4) "Facility" means a cosmetic surgical facility as defined in §B(1) of this regulation.

(5) "Health care practitioner" means an individual who is licensed, certified, or otherwise authorized under the Health Occupations Article, Annotated Code of Maryland, to provide health care services in the ordinary course of business or practice of a profession.

(6) "License" means a document issued by the Secretary to a person to operate a cosmetic surgical facility.

(7) "Licensee" means the person, association, partnership, or corporation to whom a license is issued.

(8) "Secretary" means the Secretary of Health and Mental Hygiene or the Secretary's designee.

**.02 License Required.**

A. A person may not establish or operate a cosmetic surgical facility without obtaining a license from the Secretary.

B. License Period and Fee.

(1) A license is valid for 3 years from the date of issuance, unless suspended or revoked by the Secretary.

(2) The applicant shall submit a nonrefundable fee of \$3,000 for a 3 year period, with an application for initial licensure, or submit a nonrefundable fee of \$3,000 with an application for license renewal for a 3 year period.

C. A license issued under this chapter is not transferable.

**.03 Licensing Procedures.**

A. A person desiring to operate a facility shall:

(1) Be in compliance with all applicable federal, State, and local laws and regulations and be accredited as a cosmetic surgical facility by:

(a) The American Association for Accreditation of Ambulatory Surgical Facilities;

(b) The Accreditation Association for Ambulatory Health Care;

(c) The Joint Commission; or

(d) An accreditation organization approved by the Secretary; or

(2) Be certified to participate in the Medicare Program, as enacted in Title XVIII of the Social Security Act.

B. In addition to the requirement of §A of this regulation, a person desiring to operate a facility shall:

(1) File a complete application on a form provided by the Department;

(2) Pay the licensure fee set forth in Regulation .02 of this chapter; and

(3) Submit to an initial survey upon request by the Department.

C. An officer of a corporation or association shall apply for a license on behalf of the entity. The owner shall apply on behalf of a sole proprietorship. An applicant shall submit the names of the entity's board members, owners, and investors having at least 2 percent ownership.

D. An authorized individual of a government unit or agency shall apply for a license on behalf of the government unit or agency.

E. Based on information provided to the Department by the applicant and the Department's own investigation, the Secretary shall:

(1) Approve the application unconditionally if the applicant complies with all requirements of this chapter;

(2) Approve the application conditionally; or

(3) Deny the application if the applicant:

(a) Has been convicted of:

(i) A felony that relates to Medicaid or Medicare,

(ii) A crime involving moral turpitude; or

(b) Does not comply with the requirements of this chapter.

F. Denial of License for Prior Revocation or Consent to Surrender License. The Secretary may deny a license to:

(1) A corporate applicant if the corporate entity has an owner, director, officer, or other person with a substantial interest:

(a) Whose conduct caused the revocation of a prior license, or

(b) Who held the same or similar position in another corporate entity which had its license revoked;

(2) An individual applicant:

(a) Whose conduct caused the revocation of a prior license, or

(b) Who held a position as owner, director, or officer in a corporate entity which had its license revoked; or

(3) An individual or corporate applicant that has consented to surrender a license as a result of a license revocation action.

G. The Secretary shall also consider the factors identified in Regulation .10C of this chapter when deciding whether to deny a license.

H. A person aggrieved by a decision of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .12 of this chapter.

**I. Renewal of License.**

(1) At least 60 days before a license expires, the licensee shall submit a renewal application to the Secretary.

(2) The Secretary shall renew the license for an additional 3-year period for a licensee that meets the requirements of this chapter.

**J. Temporary License.**

(1) The Department shall issue a temporary license not to exceed 1 year to a facility that has filed an application to be:

(a) Certified to participate in the Medicare Program, as enacted in Title XVIII of the Social Security Act; or

(b) Accredited by:

(i) The American Association for Accreditation of Ambulatory Surgical Facilities;

(ii) The Accreditation Association for Ambulatory Health Care;

(iii) The Joint Commission; or

(iv) An accreditation organization approved by the Secretary.

(2) The Department may extend the period for a temporary license beyond 1 year for good cause.

(3) The Department shall issue a license to a facility once the facility has:

(a) Received certification or accreditation; and

(b) Met all the other requirements for licensure as a cosmetic surgical facility.

(4) The Department shall void a temporary license upon receiving notice that the facility's application for certification or accreditation has been denied.

K. **Transfer or Assignment of License Prohibited.** If the sale, transfer, assignment, or lease of a cosmetic surgical facility causes a change in the person or persons who control or operate the facility, the Department shall consider the facility to be a new facility and the licensee shall conform to all regulations applicable at the time of transfer of operations.

L. **Return of License.** The current license shall become void immediately and the licensee shall return the license to the Secretary if the facility:

(1) Is sold or leased;

(2) Ceases to operate;

(3) Moves to a new permanent location;

(4) Has had its Medicare Program certification or accreditation issued by an accreditation organization denied or revoked; or

(5) Has its license denied, suspended or revoked.

**.04 Service Standards.**

A. The licensee is responsible for compliance with all laws and regulations applicable to the operation of a cosmetic surgical center including Health Occupations Article, §14-404 (a)(14), Annotated Code of Maryland.

**B. Accreditation Standards.**

(1) The licensee shall meet the standards for the operation of a cosmetic surgical center issued by the licensee's accreditation organization.

(2) If a licensee loses its accreditation, the licensee shall immediately:

(a) Cease operations;

(b) Notify the Department; and

(c) Return the license certificate to the Department.

**.05 Investigation by the Secretary.**

A. The Secretary may investigate complaints concerning the conformance of a cosmetic surgical facility to the requirements of this chapter and for compliance with the standards for the operation of a cosmetic surgical center issued by its accreditation organization.

B. A facility shall be open during normal business hours, or any other times that the facility is serving patients, for inspection by the Department and by any other agency designated by the Secretary to investigate complaints.

C. The Department shall refer complaints concerning a health care practitioner's performance or a health care practitioner's conformance to the standards of medical practice to the appropriate health occupations board that licenses, certifies, or otherwise regulates the health care practitioner under the Health Occupations Article, Annotated Code of Maryland.

**D. Noncompliance.**

(1) If the Secretary determines that a licensee fails to meet any provision of this chapter or fails to comply with the standards for the operation of a cosmetic surgical center issued by its accreditation organization, the Secretary shall:

(a) Advise the licensee of the exact nature of the violation; and

(b) *Require that the facility specify what corrective action it is taking and monitor the facility to ensure that it takes corrective action.*

(2) *This section does not preclude the Secretary from imposing any of the sanctions set forth in this chapter.*

(3) *The Secretary may not specify that a licensee correct a violation of a standard that is a higher standard than that required of an ambulatory surgical facility under Health-General Article, Title 19, Subtitle 3B, Annotated Code of Maryland, and its implementing regulations.*

*E. Records and Reports. The facility shall make its records and reports available to the Department or its designee for inspection during the investigation of a complaint. On the written request of the Department, the facility shall immediately provide photocopies or electronic images of records and reports, including clinical records of patients.*

**.06 Medical Records.**

*A. The facility shall maintain a complete, comprehensive, and accurate medical record for a patient.*

*B. A patient's medical record shall include at least the following:*

- (1) Patient identifier;*
- (2) Significant medical history and results of a physical examination;*
- (3) Documentation of care or services provided;*
- (4) Evidence of consent; and*
- (5) Discharge diagnosis.*

*C. The facility shall:*

*(1) Send a copy of the medical record with the patient on referral to another health care provider or on transfer to a hospital;*

*(2) Use the medical record, if appropriate, in instructing the patient and the family; and*

*(3) Comply with all disclosure requirements as set forth in Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland.*

**.07 Patient's Rights.**

*A. The administrator shall ensure that the facility develops and implements written policies and procedures concerning patients' rights and responsibilities.*

*B. The facility shall make the policies and procedures available to patients, guardians, or other health care decision makers, as defined by Health-General Article, Title 5, Subtitle 6, Annotated Code of Maryland, and the public.*

*C. The policies and procedures shall ensure that:*

*(1) The facility informs patients of services that are available and the charges for services not covered by third-party payors;*

*(2) A physician, dentist, podiatrist, or other qualified health care practitioner informs patients of their medical conditions unless medically contraindicated as documented in their medical records;*

*(3) All patients are afforded an opportunity to participate in planning their medical treatments and to refuse to participate in experimental research; and*

*(4) All patients are ensured confidential treatment of their medical records, and may approve or refuse release of records to any individual outside the facility, except as provided by federal or State law.*

**.08 Physical Environment.**

*A. The facility shall meet all federal, State, and local laws, ordinances, and regulations for construction.*

*B. The facility shall meet all safety requirements of the National Fire Protection Association, NFPA 101 "Life Safety Code", which is incorporated by reference at COMAR 29.06.01.06.*

*C. The facility shall meet the requirements for handling, treatment, and disposal of special medical wastes as provided in COMAR 10.06.06.*

**.09 Emergency Suspension.**

*A. The Secretary may immediately suspend a license on a finding that the public health, safety, or welfare requires emergency action.*

*B. The Department shall deliver a written notice to the licensee informing the licensee of the emergency suspension:*

*(1) Giving the reasons for the action and the regulation or regulations with which the licensee has failed to comply that forms the basis for the emergency suspension; and*

*(2) Notifying the licensee of the licensee's right to request a hearing and to be represented by counsel.*

*C. The filing of a hearing request does not stay the emergency action.*

*D. When a license is immediately suspended, the licensee shall:*

*(1) Immediately return the license to the Department; and*

*(2) Stop providing services immediately.*

*E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .11 of this chapter.*

*F. Hearing.*

*(1) The Office on Administrative Hearings shall:*

*(a) Conduct a hearing as set forth in Regulation .09 of this chapter; and*

(b) Issue a proposed decision within 10 business days of the close of the hearing record.

(2) Exceptions may be filed by an aggrieved person pursuant to COMAR 10.01.03.

**G. Final Decision**

(1) The Secretary shall make a final decision pursuant to COMAR 10.01.03.

(2) If the Secretary's final decision does not uphold the emergency suspension, the licensee may resume operation.

**.10 Revocation of License**

A. The Secretary, for cause shown, shall notify the licensee of the Secretary's decision to revoke the facility's license. The revocation shall be stayed if a hearing is requested.

B The Secretary may revoke a license if the licensee:

(1) Has been convicted of a :

(a) Felony that relates to Medicaid or Medicare; or

(b) Crime involving moral turpitude;

(2) Does not comply with the requirements of this chapter;

(3) Fails to comply with the standards for the operation of a cosmetic surgical center issued by its accreditation organization; or

(4) Engages in conduct that requires revocation to protect the public health, safety, or welfare.

C. The Secretary shall also consider the following factors when deciding whether to revoke a license:

(1) The number, nature, and seriousness of the violations;

(2) The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;

(3) The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility;

(4) The efforts made by, and the ability of, the licensee to correct the violation or violations in a timely manner; and

(5) Such other factors as justice may require.

D. The Secretary shall notify the licensee in writing of the following:

(1) The effective date of the revocation;

(2) The reason for the revocation;

(3) The regulations with which the licensee has failed to comply that form the basis for the revocation;

(4) That the licensee is entitled to a hearing if requested, and to be represented by counsel;

(5) That the facility shall stop providing services on the effective date of the revocation if the licensee does not request a hearing;

(6) That the revocation shall be stayed if a hearing is requested; and

(7) That the licensee is required to surrender the license to the Department if the revocation is upheld.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .12 of this chapter.

**.11 Penalties.**

A. Administrative Penalty. The Secretary may impose an administrative penalty of up to \$1,000 for a violation of any provision of this chapter.

B. When considering whether to impose an administrative penalty and the amount of the penalty, the Secretary shall consider the following factors:

(1) The number, nature, and seriousness of the violations;

(2) The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;

(3) The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility;

(4) The efforts made by, and the ability of, the licensee to correct the violation or violations in a timely manner; and

(5) Such other factors as justice may require.

C. A person aggrieved by the action of the Secretary under §A of this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .12 of this chapter.

**.12 Hearings.**

A. A request for a hearing shall be filed with the Office of Administrative Hearings, with a copy to the Office of Health Care Quality of the Department, not later than 30 days after receipt of notice of the Secretary's action. The request shall include a copy of the Secretary's action.

B. A hearing requested under this chapter shall be conducted in accordance with:

(1) State Government Article, §10-201 et seq., Annotated Code of Maryland;

(2) COMAR 28.02.01; and

(3) COMAR 10.01.03.

- C. The burden of proof is as set forth in COMAR 10.01.03.28.*
- D. Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in COMAR 28.02.01.*
- E. The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35.*
- F. The Secretary shall issue a final decision in accordance with COMAR 10.01.03.35.*

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

**Secretary of Health and Mental Hygiene**