

LAND REGISTER

Proposed Action on Regulations

Comparison to Federal Standards Submission and Response

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In accordance with Executive Order 01.01.1996.03 and memo dated July 26, 1996, the attached document is submitted to the Department of Business and Economic Development for review.

The Proposed Action is not more restrictive or stringent than corresponding federal standards.

COMAR Codification: 10.05.01.05

COMAR Codification: 10.05.05.01

Corresponding Federal Standard:

42 CFR § 416.26

Discussion/Justification:

The proposed action is in alignment with the federal standard and is therefore not more restrictive or stringent.

TO BE COMPLETED BY DBED

- Agree

-Disagree

Comments:

Commerce believes DHMH has the appropriate subject matter expertise in this policy area and trusts their assertion the regulation is not more restrictive/stringent than corresponding federal.

Name: Sandy Popp

Date: 11/6/2015

_ -Submit to Governor's Office
Governor's Office Response

Comments:

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee 11/06/2015	TO BE COMPLETED BY DSD Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 12/11/2015

2. COMAR Codification

Title	Subtitle	Chapter	Regulation
10	05	01	05
10	05	05	01

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

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

201 W. Preston Street

City	State	Zip Code
Baltimore	MD	21201

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 05
FREESTANDING AMBULATORY CARE FACILITIES

10.05.01 General Requirements

Subtitle 05
FREESTANDING AMBULATORY CARE FACILITIES

10.05.05 Freestanding Ambulatory Surgical Facilities

Authority: See proposal.

Notice of Proposed Action

□

The Secretary of Health and Mental Hygiene proposes to amend:
 (1) Regulation .05 under COMAR 10.05.01 General Requirements; and
 (2) Regulation .01 under COMAR 10.05.05 Freestanding Ambulatory Surgical Facilities.

Email

michele.phinney@maryland.gov

5. Name of Person to Call About this Document

Amanda Thomas

Telephone No.

410-402-8054

Email Address

amanda.thomas@maryland.gov

6. Check applicable items: New Regulations Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: September 23, 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**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**Statement of Purpose**

The purpose of this action is to amend the definitions for “freestanding ambulatory surgical facility” and “surgical services” to be consistent with the statutory amendments to these definitions. Also, in accordance with statutory amendment, the proposal requires the Department to survey freestanding ambulatory care facilities in accordance with federal regulations.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

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

Impact on Individuals with Disabilities

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 October 9, 2015. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Van T. Mitchell

Title

Secretary

Telephone No.

410-767-6500

Date

November 2, 2015

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 January 11, 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:

General Funds.

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:

The proposed regulation amendments are procedural changes and have no economic impact.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

This proposal does not increase nor decrease any fees associated with licensure or operation of the facility.

G. Small Business Worksheet:

Attached Document:

Title 10
DEPARTMENT OF HEALTH AND MENTAL
HYGIENE
Subtitle .05 FREESTANDING AMBULATORY CARE FACILITIES
10.05.01 General Requirements

Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland

10.05.01.05 (9/23/15)

.05 Inspections by Secretary of Health and Mental Hygiene.

A. Open for Inspection. A licensed facility or an entity proposing to operate such 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 Department to:

(1) *Survey freestanding ambulatory care facilities as directed by the Centers for Medicare and Medicaid Services;*

[(1)] (2) Verify compliance with licensing regulations; [and] or

[(2)] (3) Investigate complaints.

B.—C. (text unchanged)

10.05.05 Freestanding Ambulatory Surgical Facilities

Authority: Health-General Article, §19-3B-01 et seq., Annotated Code of Maryland

10.05.05.01

.01 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) (text unchanged)

(2) Freestanding Ambulatory Surgical Facility.

(a) "Freestanding ambulatory surgical facility" means a facility, service, office facility, or other entity that:

(i) Operates [primarily] *exclusively* for the purpose of providing surgical services to patients requiring a period of postoperative observation but not requiring [overnight] hospitalization *and in which the expected duration of services would not exceed 24 hours following admission;* and

(ii) (text unchanged)

(b) (text unchanged)

(3)—(4) (text unchanged)

(5) *Surgery.*

(a) "*Surgery*" means a procedure conducted for the purpose of structurally altering the human body by the incision or destruction of tissues and is part of the practice of medicine.

(b) "*Surgery*" includes:

(i) *The diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include, lasers, ultrasound, ionizing radiation, scalpels, probes, and needles;*

(ii) *Cut, burned, vaporized, frozen, sutured, probed, or manipulated tissue by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means; or*

(iii) *Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system.*

[(5)] (6) "Surgical services" means [an invasive procedure whether therapeutic or diagnostic involving the use of:

(a) Any cutting instrument;

(b) Microscopic, endoscopic, arthroscopic, or laparoscopic equipment; or

(c) Laser for the removal or repair of an organ or other tissue.] *surgical procedures performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ambulatory surgical center in accordance with approved policies and procedures of the ambulatory surgical center.*

VAN T. MITCHELL

Secretary of Health and Mental Hygiene