

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	07/22/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 9/2/2016

2. COMAR Codification

Title Subtitle Chapter Regulation

10 24 19 01

3. Name of Promulgating Authority

Maryland Health Care Commission

4. Name of Regulations Coordinator

Julie Deppe

Telephone Number

(410) 764-3563

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4160 Patterson Avenue

City State Zip Code

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5. Name of Person to Call About this Document

Suellen Wideman

Telephone No.

410-764-3326

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suellen.wideman@maryland.gov

6. Check applicable items:

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 General Provisions Article, §3-302(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 Suellen Wideman, Assistant Attorney General, (telephone #410-764-3326) on July 21, 2016. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Craig P. Tanio, MD

Title

Chair

Telephone No.

410-764-3460

Date

July 21, 2016

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 24 MARYLAND HEALTH CARE COMMISSION

10.24.19 State Health Plan for Facilities and Services: Freestanding Medical Facilities

Authority: Health-General Article, §§19-109(a)(1), 19-114(d)(1)(viii), 19-118 (a)(2)(i), 19-120(j)(2)(iv), and 19-120(o)(1) & (3), Annotated Code of Maryland

Notice of Proposed Action

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The Maryland Health Care Commission proposes to adopt new Regulation .01 under COMAR 10.24.19 State Health Plan for Facilities and Services: Freestanding Medical Facilities.

This action was considered by the Commission at an open meeting held on July 21, 2016, notice of which was given through publication in the Maryland Register, under General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to establish COMAR 10.24.19, a new chapter in the State Health Plan for Facilities and Services that governs the establishment of Freestanding Medical Facilities. Two recent pieces of legislation directed the Commission to adopt: Certificate of Need regulations regarding freestanding medical facilities; and regulations governing conversion of an underutilized general hospital to a freestanding medical facility through an exemption from Certificate of Need. Previously, two freestanding medical facilities were established as pilot projects, and there was not an established regulatory process for considering approval of additional facilities of this type. The Freestanding Medical Facilities Chapter contains policies and standards that will guide the Certificate of Need review process for a general hospital that seeks to establish a satellite freestanding medical facility to address access issues or overcrowding. It also contains policies and standards that will guide the exemption from Certificate of Need process for a hospital seeking to convert to a freestanding medical facility.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

This Chapter of the State Health Plan for Facilities and Services: Freestanding Medical Facilities is expected to have a minimal economic impact on the issuing agency, the Maryland Health Care Commission (MHCC), as well as a few other State agencies. The affected agencies are the Department of Health and Mental Hygiene (DHMH), specifically the Office of Health Care Quality (OHCQ), the Health Services Cost Review

Commission (HSCRC), and the Maryland Institute for Emergency Medical Services Systems. The affected regulated industries include hospitals and ambulatory surgical facilities (ASFs), and the impacts on these may vary depending on the circumstances of individual hospitals and ASFs. There will not be an impact on local government or other industries or trade groups. Overall, the benefit to the public is expected to be positive.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency: MHCC	(E+)	Within Budget
B. On other State agencies:		
(1) DHMH/OHCQ	(E+)	Minimal
(2) HSCRC	(E+)	Within Budget
(3) MIEMSS	(E+)	Within Budget
C. On local governments:	NONE	No Impact

	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:		
(1) Hospitals	(+)	Moderate
(1) Hospitals	(-)	Moderate
(2) Ambulatory Surgical Centers	(+)	Minimal
(2) Ambulatory Surgical Centers	(-)	Minimal
E. On other industries or trade groups:		
(1) Urgent Care Centers	(-)	Minimal
(2) Emergency Transport Services	(+)	Minimal
(2) Emergency Transport Services	(-)	Minimal
F. Direct and indirect effects on public:		
Public	(+)	Moderate

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

A. Maryland Health Care Commission. Staff will review CON applications and CON exemption requests for a new type of facility. Staff anticipates receiving only a small number of CON applications and requests for an exemption from CON to establish an FMF. Consequently, the review of these applications and requests can be accommodated by current staff within the Commission's budget.

B(1). The Office of Health Care Quality. OHCQ will issue licenses for new FMFs and ambulatory surgical facilities. Due to the small number of CON applications and

requests for an exemption from CON to establish an FMF, Staff anticipates the impact will be minimal for OHCQ.

B(2). Health Services Cost Review Commission. HSCRC will need to perform additional analyses when MHCC receives CON applications for an FMF or CON exemption requests to establish an FMF. However, as noted above, Staff anticipates the number of such requests will be small.

B(3). Maryland Institute for Emergency Medical Services Systems. MIEMSS will be required to participate in the process for reviewing requests for an exemption from CON to establish an FMF. In addition, Staff may potentially request analyses for CON applications for FMFs. Staff anticipates the impact on MIEMSS will be minimal and can be handled within its existing budget, based on the small number of such requests anticipated.

C. Local Government. Local governments are not involved with the provision of hospital services or surgical services in ambulatory surgical facilities. As a result, there will not be an impact on local government providers.

D(1). Regulated Industries or Trade Groups. The proposed regulations are expected to have a positive impact on Maryland hospitals when a Maryland hospital is converting to an FMF due to the reduced costs to the health care system. If the FMF resulting from the conversion of a hospital includes surgical capacity, it is unlikely to negatively affect other ASFs in the area, if the FMF provides a volume and scope of ambulatory surgical services similar to that of the hospital being replaced.

D(1). An FMF established to address access issues or crowding at the parent hospital is more likely to have a negative impact on the market share of other hospitals with an overlapping service area. The establishment of an FMF to address access issue or crowding at the parent hospital may result in a loss of revenue for the parent hospital, but some of these costs may be offset through achieving better patient care.

D(2). If the FMF resulting from the conversion of a hospital includes surgical capacity, it is unlikely to negatively affect other ASFs in the area, if the FMF provides a volume and scope of ambulatory surgical services similar to that of the hospital being replaced.

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E(1). Urgent care centers, to some extent may be regarded as an alternative source of care for patients who may otherwise seek care at a hospital ED or FMF. Development of an FMF may draw patients away from urgent care centers, with negative financial consequences for some urgent care centers. However, the Chapter includes standards that require an applicant to address the strategies that will be used to discourage inappropriate use of the FMF.

E(2). Emergency transport services may increase or decrease with the addition of a new FMF, depending on whether people in the service area of the FMF and parent hospital are more or less likely to use these services.

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F. Public. Overall, the public should benefit from FMFs by having improved access to unscheduled emergent or urgent care or, in the case of a hospital conversion, more access to such care than would be the case if the hospital merely closed. An applicant seeking to establish an FMF must address how the proposed facility will affect the efficient delivery of health care services. FMFs that are expected to result in less efficient delivery of health care shall not be approved. As noted, by providing an alternative to closing a hospital altogether, converting to an FMF, there is a greater likelihood that those in the service area of the hospital will continue to obtain appropriate health care services locally through a more efficient health care delivery system.

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 Eileen Fleck, Chief, Acute Care Policy & Planning, Maryland Health Care Commission, 4160 Patterson Avenue, or call 410-764-3287, or email to eileen.fleck@maryland.gov, or fax to 410-358-1311. Comments will be accepted through 4:30 pm on October 3, 2016 . A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Maryland Health Care Commission during a public meeting to be held on October 20, 2016 at 1:00 pm, at 4160 Patterson Avenue, Room 100, Baltimore, MD 21215.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017

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:
Maryland Health Care Commission

Special 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:

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 small businesses affected by the regulations are primarily ASFs owned and operated by individual physicians or physician partners. These ASFs already operate in an environment with competition from hospitals and other ASFs. In addition, due to the small number of FMFs that are likely to include surgical capacity, the impact of the proposed regulations will likely be minimal.

G. Small Business Worksheet:

Attached Document:

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 24 MARYLAND HEALTH CARE COMMISSION

Chapter 19 State Health Plan for Facilities and Services: Freestanding Medical Facilities

Authority: Health-General Articles, §§19-109(a)(1), 19-114(d)(1)(viii), 19-118 (a)(2)(i), 19-120(j)(2)(iv), and 19-120(o)(1) & (3),
Annotated Code of Maryland

.01 Incorporation by Reference.

The State Health Plan for Facilities and Services: Freestanding Medical Facilities is incorporated by reference.