

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	04/17/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 5/30/2014

2. COMAR Codification

Title Subtitle Chapter Regulation

10 25 15 01 - .08

3. Name of Promulgating Authority

Maryland Health Care Commission

4. Name of Regulations Coordinator

Amelia T Rutledge

Telephone Number

(410) 764-3322

Mailing Address

4160 Patterson Avenue

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Baltimore MD 21215

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5. Name of Person to Call About this Document

Suellen Wideman

Telephone No.

(410) 764-3326

Email Address

suellen.wideman@maryland.gov

6. Check applicable items:

X- New Regulations

Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: March 28, 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 Suellen Wideman, Assistant Attorney General, (telephone #(410) 764-3326) on April 17, 2014. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Craig P. Tanio

Title

Chairman

Telephone No.

(410) 764-3460

Date

April 17, 2014

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

10.25.15 Management Service Organization State Designation

Authority: Health-General Article, §§[4-301] 4-302, 19-103(c)(2)(i) and (ii), 19-109(a)(1), [and] 19-135(a), (b), and (d), and 19-143(h), Annotated Code of Maryland

Notice of Proposed Action

□

The Maryland Health Care Commission proposes to repeal Regulation .01 – .11 under COMAR 10.25.15 Management Service Organization State Designation and replace with Regulation .01–.08 under COMAR 10.25.15 Management Service Organization State Designation.

This action was considered by the Commission at an open meeting held on April 17, 2014, notice of which was given through publication in the Maryland Register, under State Government Article, §10-506, Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to expand the definition of a management service organization (MSO) and make other changes that will support health care reform initiatives and allow an MSO more flexibility in demonstrating compliance with federal and State privacy and security laws. The replacement regulations implement certain program changes recommended by an advisory panel assembled by the Commission. This action clarifies the State designation process and adds a procedure for the Commission review if an applicant or State-Designated MSO disagrees with a staff decision related to State designation status. The replacement regulations contain a specific requirement regarding the publication of notices updating the criteria for State designation.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

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

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to David Sharp, Director, Center for Health Information Technology, Maryland Health Care Commission, 4160 Patterson Ave, or call (410) 764-3578, or email to , or fax to (410) 358-1236. Comments will be accepted through 4:30 p.m. on June 30, 2014. A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Commission during a public meeting to be held on July 17, 2014 at 1:00 p.m., at 4160 Patterson Ave, Conference Room 100, Baltimore, Maryland 21215.

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?

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:

See Part A, Section I

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:

10.25.15.00 (March 28, 2014)

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

Chapter 15 Management Service Organization State Designation

“ALL NEW”

.01 Scope.

This chapter applies to the State designation of management service organizations. Only a management service organization that is awarded State Designation status by the Maryland Health Care Commission pursuant to this chapter may represent itself as a State Designated management service organization.

.02 Definitions.

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

B. Terms Defined.

(1) “Commission” or “MHCC” means the Maryland Health Care Commission.

(2) “Electronic health record” or “EHR” means a complete electronic record system that:

(a) Contains health-related information on one or more individuals; and

(b) Is certified by an authorized testing and certification body designated by the Office of the National Coordinator for Health Information Technology.

(3) “Entity” means an individual, trust or estate, general or limited partnership, joint stock company, unincorporated association or society, municipal or other corporation, incorporated association, limited liability partnership, limited liability company, the State, an agency or political subdivision of the State, a court, and any other governmental body.

(4) “Executive Director” means the Executive Director of the Commission.

(5) “Management service organization” or “MSO” means an entity that provides technology and consultative services to health care providers, and makes available one or more hosted electronic health records systems and other health information technology solutions.

(6) “MSO State Designation certificate” means a certificate provided to the MSO by the Commission that documents award of State Designation.

(7) “MSO State Designation criteria” means the standards published by the Commission on its website and by notice in the Maryland Register that an MSO must meet to qualify for State Designation.

(8) “State Designation” or “State Designated” means the status awarded by the Commission to an MSO that has met the MSO State Designation criteria required under this chapter.

.03 Procedure for Initial State Designation.

A. Application.

(1) An entity seeking MSO State Designation shall submit an application in a form and manner specified by the Commission.

(2) The application shall be signed by an individual authorized by the entity submitting the application.

B. Requirements for State Designation. An applicant for MSO State Designation shall:

(1) Demonstrate that it meets all MSO State Designation criteria in effect at the date of application;

(2) Affirm that the applicant, a related entity, or a person or entity that is a principal, owner, operator, or part of management of the entity has never:

(a) Pleaded guilty to, been convicted of, or received probation before judgment or similar diversionary disposition for a crime related to the operation of an MSO or for a crime involving fraud, dishonesty, or false dealing; or

(b) Been found in violation of State or federal laws or regulations governing the operation of an MSO.

(3) Provide all required documentation;

(4) Timely provide additional information requested by the Commission as needed to complete the application;

and

(5) Agree to comply with the requirements of this chapter.

C. Review of Applications.

(1) Commission staff shall review an application to determine compliance with the State Designation criteria.

(2) The Executive Director may approve or deny an application for State Designation.

(a) The Executive Director shall award State Designation to an MSO that meets the requirements set forth in this chapter.

(b) If the Executive Director determines that a application should be denied, the Executive Director shall, within 30 days of receipt of a complete application, notify the applicant in writing of the decision, and include the reasons for denial.

D. Duration of State Designation.

(1) State Designation is valid for two years from the date of issuance of an MSO State Designation certificate, unless suspended or revoked by the Commission.

(2) An MSO awarded State Designation shall accept the designation in writing and agree to the comply with the requirements of this chapter.

.04 Procedure for Renewal of State Designation.

- A. An application for renewal of State Designation shall:
- (1) Be made at least 30 days before the expiration of the State Designation in a form and manner specified by the Commission; and
 - (2) Demonstrate compliance with the MSO State Designation criteria in effect at the date of application for renewal.
- B. Commission staff shall review a renewal application to determine compliance with the State Designation criteria.
- C. The Executive Director may approve or deny an application for renewal.
- D. The Executive Director shall renew the State Designation of each MSO that meets the requirements set forth in this chapter.
- E. If the Executive Director determines that a renewal application should be denied, the Executive Director shall, within 30 days of receipt of a complete application for renewal, notify the applicant in writing of the decision, supported by reasons for denial.

.05 Denial of an Initial or Renewal Application.

- A. An MSO whose initial or renewal application was denied may seek Commission review of the denial.
- B. A written request for Commission review of the denial of an application shall:
- (1) Be filed within 20 days of the receipt of the denial;
 - (2) State with particularity the grounds and factual basis for the applicant's disagreement with the denial; and
 - (3) Be supported by relevant documentation and affidavits.
- C. The Commission may determine whether or not to affirm the denial of the application or approve the application:
- (1) After considering the written filing by the MSO and any response by Commission staff; or
 - (2) After hearing oral arguments on the written filings by the MSO and staff.

.06 Nontransferability of Designation.

State Designation issued pursuant to this chapter may not be sold, assigned, leased, or transferred in any way.

.07 Closure, Sale, or Transfer of All or Part of a State-Designated MSO.

- A. At least 60 days before the closure, sale, lease, assignment, or transfer of all or part of a State-Designated MSO to any person or entity that was not identified as an owner of the MSO at the time of the most recent certification by the Commission, the State Designated MSO shall notify the Commission of the impending closure, sale, lease, assignment, or transfer of the State Designated MSO and timely provide information required or requested by the Commission.
- B. If all or part of a State Designated MSO is closed, sold, leased, assigned, or transferred in any person or entity that was not identified as an owner of the MSO at the time of the most recent certification by the Commission, the Commission shall review current State Designation status pursuant to the renewal requirements set forth in Regulation .04 of this chapter.

.08 Commission Oversight of State-Designated MSOs.

- A. Commission staff may, on its own initiative or in response to information provided to the Commission, investigate any State-Designated MSO or applicant for State Designation.
- B. Following an investigation, the Executive Director may issue a notice of proposed action, which may include the following:
- (1) A time-limited opportunity to correct deficiencies identified by the investigation;
 - (2) Suspension of the State Designation of an MSO for a definite period of time after which, depending upon the circumstances of the case and completion of appropriate corrective actions, the MSO may seek reinstatement of its State Designation; or
 - (3) Revocation of State Designation.
- C. An MSO that receives a notice of proposed action from the Executive Director may request an opportunity to show cause why the proposed action should not be implemented.
- (1) A written request to show cause shall be filed with the Commission within 20 days of the issuance of the notice of proposed action and shall:
 - (a) State with particularity the grounds and factual basis for the applicant's disagreement with the denial;
 - (b) Include each fact upon which the person relies to show cause why the proposed action should not be taken.
 - (c) Be supported by relevant documentation and affidavits.
- D. The Commission may determine whether or not to impose the proposed action or a different action:
- (1) After considering the written show cause filing by the MSO and any response by Commission staff; or
 - (2) After hearing oral arguments on the written filings by the MSO and staff.

“END ALL NEW”