

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 14-077)**

Overview and Legal and Fiscal Impact

The Maryland Health Care Commission is repealing and replacing the regulations under COMAR 10.25.15, the chapter which governs State designation of management service organizations (MSOs). Among other things, the regulations clarify the State designation process and add a procedure for commission review if an applicant or State-designated MSO disagrees with a staff decision related to State designation status.

These regulations present no legal issue of concern.

There is no fiscal impact on State or local agencies.

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Maryland Health Care Commission: Management Service Organization State
Designation: COMAR 10.25.15.01-.08

Legal Analysis

Summary of Regulations

The Maryland Health Care Commission is repealing and replacing the regulations under COMAR 10.25.15, the chapter which governs State designations of MSOs.

Regulation .01 specifies that the chapter applies to the State designation of MSOs. It also specifies that only an MSO that is awarded State designation status by the commission may represent itself as a State-designated MSO.

Regulation .02 contains definitions for the chapter. The defined terms include “electronic health record,” “management service organization,” and “MSO State Designation criteria.” “Management service organization” or “MSO” is defined as 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.

Regulation .03 governs the procedure for initial State designation. An entity seeking MSO State designation must submit an application in a form and manner specified by the commission. The application must be signed by an authorized individual. The applicant must, among other things, demonstrate that it meets all the MSO State designation criteria, provide all

required documentation, and agree to comply with the requirements of the chapter. The commission staff is required to review an application to determine compliance with the State designation criteria. The Executive Director of the commission may approve or deny an application, but is required to award State designation to a MSO that meets the requirements of the chapter. If the Executive Director denies an application, the Executive Director must, within 30 days of receipt of a complete application, notify the applicant in writing of the decision and include the reasons for the denial. State designation is valid for two years from the date of issue, unless it is suspended or revoked by the commission.

Regulation .04 governs the procedure for renewal of a MSO's State designation. The application for renewal must be made at least 30 days before the expiration of the State designation and must demonstrate compliance with the MSO State designation criteria in effect on the date of application. The remainder of the process is the same as for that of an initial State designation.

Regulation .05 relates to the denial of an initial or renewal application. If an initial application or a renewal application is denied, the MSO may seek commission review of the denial. A written request for review must be filed within 20 days of the receipt of the denial, state with particularity the grounds and factual basis for the disagreement with the denial, and be supported by relevant documentation and affidavits. The commission may determine whether or not to affirm the denial or approve the application after considering the written filing of the MSO and any response of commission staff or after hearing oral arguments on the written filings.

Regulation .06 provides that a State Designation cannot be sold, assigned, leased, or transferred in any way.

Regulation .07 relates to the closure, sale, or transfer of all or part of a State-designated MSO. The MSO must notify the commission of an impending closure, sale, lease, assignment, or transfer at least 60 days before it occurs if the other party in the transaction was not identified as an owner of the MSO at the time of the most recent certification by the commission. The MSO must also timely provide information required or requested by the commission. The commission must review the current State designation status in the same manner as a renewal application would be reviewed.

Finally, Regulation .08 governs commission oversight of State-designated MSOs. Commission staff can investigate any State-designated MSO or applicant for State designation on its own initiative or in response to information provided to the commission. Following an investigation the Executive Director may issue a notice of proposed action. The notice may include a time-limited opportunity to correct deficiencies identified by the investigation, suspension of the State designation for a definite period of time, or revocation of the State designation. An MSO that receives a notice of proposed action may request an opportunity to show cause why the proposed action should not be implemented. A written request to show cause must be filed within 20 days of the issuance of the notice of proposed action. The request must state with particularity the grounds and factual basis for the disagreement, include each fact on which the MSO is relying to show cause why the proposed action should not be taken, and be supported by relevant documentation and affidavits. Then, the commission may determine whether or not to impose the proposed action or a different action after considering the filing and any response by commission staff or after hearing oral arguments on the filings.

Statutory Authority and Legislative Intent

The commission cites §§ 4-302, 19-103(c)(2)(i) and (ii), 19-109(a)(1), 19-135(a), (b), and (d), and 19-143(h) of the Health – General Article as authority for the regulations. More specifically, § 4-302 governs the confidentiality and disclosure of medical records by health care providers. Section 19-103(c)(2)(i) and (ii) provides that one of the purposes of the commission is to promote the development of a health regulatory system that provides financial and geographic access to quality of health care services at a reasonable cost by (1) advocating policies and systems to promote the efficient delivery of and improved access to health care services and (2) enhancing the strengths of the current health care service delivery and regulatory system. Section 19-109(a)(1) authorizes the commission to adopt rules and regulations to carry out the provisions of the subtitle. Section 19-135(a) authorizes the commission to implement a system to encourage health care practitioners to voluntarily control the costs of health care services. Additionally, § 19-135(b) authorizes the commission to require health care practitioners of selected health care specialties to cooperate with licensed operators of clinical resource management systems that allow the practitioners to critically analyze their charges and utilization of services in comparison to their peers. Section 19-135(d) authorizes the commission to adopt regulations to govern the licensing of clinical resource management systems to ensure the accuracy and confidentiality of information provided by the system. Finally, § 19-143(h) requires the commission to designate one or more management service organizations to offer services throughout the State.

The authority is complete. The regulations comply with the legislative intent of the law.

Technical Corrections and Special Notes

The commission is making a technical change to COMAR 10.25.15.04(a)(2). Currently, the subsection refers to “criteria in effect at the date of application”; however, it should read “on the date” rather than “at the date.” The change will be made before the regulations are published in the *Maryland Register*.

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations replace the chapter governing State designation of MSOs, including clarifying the designation process and establishing a procedure for Maryland Health Care Commission review if an applicant or State-designated MSO disagrees with a staff decision related to State designation status. The department advises that the regulations have no economic impact. The Department of Legislative Services concurs.

Impact on Budget

There is no impact on the State operating or capital budget.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations have minimal or no economic impact on small businesses in the State. The Department of Legislative Services concurs.

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