

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 16-018)**

Overview and Legal and Fiscal Impact

The regulations amend requirements for accessing, using, or disclosing protected health information (PHI) through a health information exchange (HIE) registered in the State and add requirements for accessing, using, or disclosing PHI through an HIE for secondary use and in an emergency.

The regulations present no legal issues 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: Health Information Exchanges:
Privacy and Security of Protected Health Information:
COMAR 10.25.18.01, .02, .03, .05, .06, .07, .08, .09, .10, and .11

Legal Analysis

Background

Chapter 615 of 2014 required the Maryland Health Care Commission (MHCC) to adopt regulations regarding PHI obtained or released through an HIE to govern the access, use, maintenance, disclosure, and redisclosure of PHI as required by State or federal law, including the federal Health Insurance Portability and Accountability Act (HIPAA) and the federal Health Information Technology for Economic and Clinical Health Act (HITECH Act).

A “health information exchange” is an infrastructure that provides organizational and technical capabilities for the electronic exchange of PHI among entities not under common ownership. “Protected health information” means all individually identifiable health information held or transmitted by a covered entity or its business associate protected under the U.S. Department of Health and Human Services Privacy Rule.

MHCC designated CRISP (Chesapeake Regional Information System for Our Patients) as the statewide HIE in 2009, and the infrastructure became operational in 2010. All 46 acute care

hospitals and 2 specialty hospitals in the State are connected and provide admission, discharge, and transfer information.

Summary of Regulations

The regulations amend requirements for accessing, using, or disclosing PHI through an HIE registered in the State and add requirements for accessing, using, or disclosing PHI through an HIE for secondary use and in an emergency.

Definitions: The regulations add definitions of “appropriate notice”, “authorization”, “care management organization”, “data use agreement”, “de-identified data”, “emergency”, “external and independent review committee”, “federalwide assurance”, “identifiable data”, “institutional review board”, “population care management purpose”, “privacy board”, “qualified research organization”, and “research”. In addition, the regulations make substantive amendments to the definitions of “electronic health record system” and “payor” and make technical and conforming amendments to several other definitions.

Rights of a Health Care Consumer Concerning Information Accessed, Used, or Disclosed through an HIE: The regulations require an HIE to develop and implement health care consumer educational materials that are not inaccurate or misleading. In addition, an HIE is required to make health care consumer educational materials readily available to participating organizations and their users. Whenever an HIE is notified of a potential or an actual breach or a non-HIPAA violation, the HIE shall begin an investigation of the matter upon receipt of the notification. An HIE shall maintain a log that records a patient’s participation in an HIE and the HIE shall retain the log for the duration required by State or federal law, whichever requires a longer retention. A participating organization shall inform each health care consumer of the types of information the participating organization will disclose to the HIE and for what purposes information accessed through the HIE may be used for treatment, payment, health care operations, and secondary use.

Requirements for Accessing, Using, or Disclosing Health Information through an HIE: The regulations repeal obsolete provisions regarding secondary use of HIE data. The regulations also require the system administrator of a participating organization to assign each authorized user an appropriate access level in coordination with the HIE.

Auditing Requirements: In order to ensure only authorized and authenticated access to HIE information, an HIE is required to develop and implement protocols, methodologies, and a monitoring approach designed to discover any unusual finding, including conducting ongoing electronic monitoring of user access logs and investigating any unusual findings.

Remedial Actions to be Taken by an HIE: The regulations require an HIE to conduct an investigation if there is reason to believe that a breach or non-HIPAA violation has occurred and the HIE must begin the investigation upon learning of the allegations giving rise to a potential breach or violation. The HIE shall immediately suspend access for an authorized user or participating organization when available information demonstrates a violation of State or federal law relevant to privacy or security. An HIE shall provide notice of each suspension and each

reinstatement of a person's authorization to access information through an HIE by sending electronic notice to MHCC on a monthly basis.

Registration of HIEs and Enforcement: To operate as an HIE in the State, the regulations require a person to complete an application for registration that includes the HIE's current audited financial statement that demonstrates the financial viability of the HIE. If a letter of guarantee or other financial instrument is required, the guarantor must submit a current balance sheet and income statement to MHCC. To renew the annual registration of an HIE, the HIE shall provide specified information to MHCC within 120 days after the close of its fiscal year.

Requirements for Accessing, Using, or Disclosing of Data through an HIE for Secondary Use: For purposes related to population care management, the regulations establish procedures that authorize an HIE to disclose de-identified data, a limited data set, or identifiable data to a care management organization. For research purposes, the regulations establish procedures that authorize an HIE to disclose de-identified data, a limited data set, or identifiable data to a qualified research organization. An HIE is not required to take action to enforce the requirements of the data use agreement. The regulations also establish specified reporting requirements for HIEs.

Requirements for Accessing, Using, or Disclosing of Data through an HIE in an Emergency: The regulations require an HIE to develop and implement emergency access policies and procedures that satisfy specified requirements.

Legal Issues

The regulations present no legal issues of concern.

Statutory Authority and Legislative Intent

MHCC cites §§ 4-301, 4-302.2, 19-101, and 19-143 of the Health – General Article as statutory authority for the regulations. Section 4-301 contains definitions for the subtitle on the confidentiality of medical records. Section 4-302.2 requires MHCC to adopt regulations to govern the access, use, maintenance, disclosure, and redisclosure of PHI as required by State or federal law, including HIPAA and the HITECH Act. Section 19-101 defines “Commission” to mean the Maryland Health Care Commission. Section 19-143 requires MHCC and the Health Services Cost Review Commission to designate a health information exchange for the State and requires MHCC to adopt regulations that require State-regulated payors to provide incentives to health care providers to promote the adoption and meaningful use of electronic health records.

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

Fiscal Analysis

There is no fiscal impact on State or local agencies.

Agency Estimate of Projected Fiscal Impact

The regulations alter and expand standards governing the privacy and security of protected health information accessed through Health Information Exchanges in Maryland. The Maryland Health Care Commission (MHCC) advises that the regulations have no impact on State or local governments. 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

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

Contact Information

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