

Key Administrative Requirements for Registered Health Information Exchanges

All health information exchanges (HIEs) registered in Maryland are subject to the requirements of COMAR 10.25.18.09, *Health Information Exchanges: Privacy and Security of Protected Health Information*. This document provides key administrative requirements under COMAR 10.25.18 by subsection that involve notification or reporting by a registered HIE to Maryland Health Care Commission (MHCC), or that involve performing audit-related activities at the request of MHCC. For all requirements, please refer to the regulation at:

http://www.dsd.state.md.us/comar/SubtitleSearch.aspx?search=10.25.18.*

.06 Auditing Requirements

This section sets forth auditing requirements for HIEs and those using HIEs in order to ensure the presence of appropriate control measures and the proper access, use and disclosure of health information through an HIE or maintained by an HIE. Under these provisions, among other things, an HIE must:

- Provide the findings from the HIE's annual privacy and security audit to MHCC annually as part of the HIE's registration renewal; and provide the results of any audit that is required by the regulations, including supporting documentation
- Upon the request of MHCC:
 - Utilize a qualified third party to conduct an audit regarding access, use, and disclosure of information through and the maintenance of information by the HIE
 - Conduct additional unscheduled audit(s) and provide the results of the audit(s) with any supporting documentation to MHCC within the time frame specified by the MHCC

.07 Remedial Actions taken by an HIE

This section details the processes that HIEs must perform if an HIE or a user of an HIE has reason to believe that a breach or violation has occurred. Key concepts include: investigations; remedial actions; suspension and termination of access; and notifications. Under these provisions, among other things, an HIE must:

- Provide findings in writing that describe the results of an investigation conducted by the HIE regarding a potential breach or non-Health Insurance Portability and Accountability Act (HIPAA) violation, including:
 - Remedial actions to be taken to mitigate the harm that may be caused by the breach or non-HIPAA violation and future actions for remediation; and
 - The time frame and person that is responsible for carrying out each action
- Provide notice to MHCC within 24 hours of a suspension of a person's access to information through the HIE due to a breach or non-HIPAA violation by the person, and a reinstatement of a person's authorization after certain remedial actions have been taken by the person, including:

- The name of the person and name of any affected participating organization; and
- The basis for the suspension or reinstatement and the effective date of the suspension or reinstatement
- At the request of MHCC, notify an affected health care consumer whose information was breached; or accessed, used, maintained, or disclosed in a manner that constitutes a non-HIPAA violation

.08 Notice of Breach and non-HIPAA Violation

This section provides details regarding how and when a health care consumer is notified of a breach of the consumer's protected health information. This section also establishes requirements concerning notification to certain authorities in the event of a breach or violation, in addition to applicable HIPAA notification requirements. Under these provisions, among other things, an HIE must:

- Promptly send MHCC a report concerning any violations of federal or State privacy or security law sent to the federal or State authorities

.09 Registration and Enforcement

This section sets forth processes for an HIE to register and receive recognition from MHCC. This section also establishes enforcement action that may be taken by MHCC against a person who is alleged to have violated a provision of COMAR 10.25.18.09. Under these provisions, among other things, an HIE must:

- Annually renew HIE registration with MHCC within 120 days of the end of the HIE's fiscal year, including a submission of:
 - Updates that reflect any changes regarding information provided at the HIE's registration;
 - Results of the annual privacy and security audit;
 - Audited financial statements; and
 - Other information requested by MHCC
- Notify MHCC if the HIE ceases to operate in Maryland