

*Health Information Exchange
Privacy and Security*

Proposed Regulations

COMAR 10.25.18

October 17, 2013



The MARYLAND
HEALTH CARE COMMISSION

Overview

- **Legislative Authority**
 - A 2011 law requires MHCC to adopt regulations for the privacy and security of protected health information (PHI) exchanged through a health information exchange (HIE)
- **The HIE Policy Board (a staff advisory group)**
 - A stakeholder group that advises staff on HIE privacy and security policies
 - Developed privacy and security policies that became the framework for the initial draft HIE regulations

Development Process

- Initial informal draft regulations were released for public comment in February 2012; approximately 33 organizations provided comments
- Revisions were made to the 2012 draft regulations, which aimed to balance privacy and security with access
- Second informal draft regulations were released in March 2013; approximately 17 organizations provided comments

Comments – General Observations

- **More granular clarification requested in several areas:**
 - **Entities or activities where the regulations do not apply**
 - **Permissible exchange of sensitive health information**
 - **Exclusions to the opt-out process**
- **Consumers expressed preference for more transparency around audit results and breach notification**

Section Summaries – Key Areas

- **Health care consumer rights concerning information accessed, used, or disclosed through an HIE**
 - **Control over the exchange of their protected health information (PHI); access to the PHI being exchanged; information concerning who has accessed their PHI; and accurate and current information about these rights**
- **Access, use, or disclosure of sensitive health information**
 - **How HIEs and those using HIEs may exchange PHI that requires additional patient consent or authorization under applicable law**

Section Summaries – Key Areas (Continued)

- **Requirements for accessing, using, or disclosing PHI through an HIE**
 - **Procedural and technical controls that must be in place for the exchange of PHI through an HIE; key concepts include authorization and authentication**
- **Auditing requirements**
 - **Auditing requirements for HIEs and those using HIEs to ensure appropriate control measures and proper access, use, and disclosure of PHI through an HIE**

Section Summaries – Key Areas (Continued)

- **Remedial actions to be taken by an HIE**
 - **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**
- **Notice of breach or violation**
 - **How and when a consumer is notified of a violation of the consumer's PHI; establishes requirements concerning notification to certain authorities in the event of a breach or violation**
- **Registration and enforcement**
 - **Processes for an HIE to register and receive recognition from MHCC; enforcement action that may be taken by MHCC**

Key Changes to the Second Informal Draft

- Point-to-point transactions are excluded from regulation, unless an HIE is involved in the transmission of the message
- Emergency access allowed in certain cases when exchanging information regulated by the Confidentiality of Alcohol and Drug Abuse Patient Records regulations
- Patient medication fill/refill may be disclosed to the ordering provider, even if a patient opts-out
- Align regulations with re-disclosure laws, particularly around sensitive health information
- Audit results shall be posted on the HIE website when a breach or violation occurs

Recommendation and Final Action

- **Staff recommends that the regulations be adopted as proposed permanent**
- **If adopted, staff expects to propose for final action in late winter of 2014**

*Thank
You!*

