



Chapter 249 (House Bill 812), *Health – Reproductive Health Services – Protected Information and Insurance Requirements (2023)*

Town Hall

MAY 17, 2024



Opening Remarks

Agenda



1. Welcome/Opening Remarks
2. Updates to the Implementation Guidance Documents
3. June 1st Validation
4. Exemption Request for HB812 Requirements
5. Regulations
6. Questions & Next Steps
7. Closing Comments



Implementation Guidance

HIE Question 4



How should HIEs approach situations in which their clients do not or delay upgrading the necessary technology for the regulated entity to be in compliance with the regulations?

RESPONSE:

The MHCC does not believe blocking the entire record of someone whose record contains legally protected health information complies with the intent of the law. COMAR 10.25.18.09G requires an HIE that has reasonably determined it is unable to independently meet any requirement included in the regulations to develop and implement policies to ensure the HIE's compliance through the execution of a written agreement with a participating organization or a business associate. These policies serve to emphasize the importance of legal compliance and help protect HIEs and providers using their systems.

HIE Question 4 (continued...)



RESPONSE:

HIEs that have made the software available to their clients, and one or more clients have declined to install the software by June 1, 2024, must submit an exemption request to MHCC for consideration. The exemption request must include a timeline indicating what percent of the HIE's Maryland clients plan to install the HIE's solution each month.

HIE Question 5



How will MHCC respond to entities that are not compliant with the regulations by June 1, 2024? How will MHCC assess penalties for entities when clients have not implemented the technology to be in compliance with the regulations?

RESPONSE:

The MHCC recommends HIEs that are unable to comply with the regulations by June 1, 2024 provide an update prior to the required April 1, 2024 status report and in advance of the June 1, 2024 validation deadline. The MHCC will consider penalties for non-compliance based on an HIE's tangible advancements in their implementation plan. The Commission will consider an HIE's progress detailed in the status report (due April 1, 2024) and validation that it possesses the technological capability to restrict from disclosure legally protected health information (due June 1, 2024) in determining whether to assess penalties for non-compliance (COMAR 10.25.18.04C(4)). Md. Code Ann., Health-Gen. § 4-302.5.

HIE Question 5 (continued...)



RESPONSE:

The MHCC requests HIEs that are not technically capable of blocking non-structured legally protect health information by June 1, 2024 elaborate on their stance and timeline and demonstrate measurable progress to ensure compliance. HIEs that fail to demonstrate measurable progress may be subject to a monetary penalty determined by the following criteria (COMAR 10.25.18.09C(3)) based on:

- The extent of actual or potential public harm caused by the violation;
- The cost of the investigation; and
- The person's prior record of compliance.

HIEs that have not made the software available to their clients as of June 1, 2024 must submit an exemption request to MHCC for consideration and include a detailed implementation plan that contains key milestones and dates.

HIE Question 14



Can legally protected health information be disclosed for credentialing purposes? Can identifiable legally protected health information be disclosed for research? Can patients request disclosure of legally protected health information through an HIE if the recipient is not a provider? When can legally protected health information be shared for benefits coverage determination or life insurance coverage?

RESPONSE:

No. The disclosure of legally protected health information to business entities by an HIE is limited to directed consent beyond the exchange for adjudication of claims. The regulations permit HIEs to disclose legally protected health information for the adjudication of claims or to a specific treating provider at the written request of and with the consent of a patient, for services for which the patient can provide consent, or a parent or guardian of a patient, for services for which the parent or guardian can provide consent under State law (COMAR 10.25.18.04C(1)).

HIE Question 14 (continued...)



RESPONSE:

While HIEs play a crucial role in enhancing interoperability within the health care system, connections to disability benefit administrators or life insurance companies are uncommon due to divergent data requirements not routinely exchanged by HIEs. The law does not restrict health care providers from disclosing legally protected health information unless an HIE is involved in the transmission of the data.

The restrictions on the disclosure of legally protected health information apply to printed or faxed materials and direct messaging if the disclosure is made by an HIE or EHN. The regulations do not prohibit a health care provider acting under a health care consumer's written request from using an HIE's fax capabilities or direct messaging to send information to a third-party.

EHN Question 10



Can identifiable legally protected health information be disclosed for research? When can legally protected health information be shared for benefits coverage determination or life insurance coverage?

RESPONSE:

No. The disclosure of legally protected health information to business entities by an EHN is limited to directed consent beyond the exchange for adjudication of claims. The regulations permit EHNs to disclose legally protected health information for the adjudication of claims or to a specific treating provider at the written request of and with the consent of a patient, for services for which the patient can provide consent, or a parent or guardian of a patient, for services for which the parent or guardian can provide consent under State law (COMAR 10.25.07.09A(4)).

EHN Question 10 (continued...)



RESPONSE:

The restrictions on the disclosure of legally protected health information apply to printed or faxed materials and direct messaging if the disclosure is made by an HIE or EHN. The regulations do not prohibit a health care provider acting under a health care consumers written request from using an EHN's fax capabilities or direct messaging to send information to a third-party.

HIE Question 16



How should legally protected health information stored in clinical notes be managed?

RESPONSE:

HIEs must block non-structured health information (COMAR 10.25.18.02B(31)) that relates to legally protected health information in clinical notes that pertain *to one or more codes included in COMAR 10.11.08, Abortion Care Disclosure*. This includes clinical notes encompassing a provider's narrative descriptions, observations, and interpretations of a patient's condition, treatment, and other relevant information. Unlike structured data, which is organized in a standardized format with defined fields and categories, clinical notes rely on free-text and may vary in format and content from one provider to another.

HIE Question 16 *(continued)*



RESPONSE:

The MHCC encourages HIEs that are not capable of blocking non-structured legally protected health information by June 1, 2024 to demonstrate measurable progress in implementing technology to block text-based data in their April 1, 2024 status report and June 1, 2024 validation that it possesses the technological capability to restrict from disclosure legally protected health information. HIEs that fail to demonstrate measurable progress may receive a monetary penalty (COMAR 10.25.18.09C(3)).

EHN Question 11



How should legally protected health information stored in clinical notes be managed?

RESPONSE:

EHNs that facilitate the exchange of non-structured health information (COMAR 10.25.07.02B(8)) must block non-structured health information that relates to legally protected health information in clinical notes that pertain *to one or more codes included in COMAR 10.11.08, Abortion Care Disclosure*. This includes clinical notes encompassing a provider's narrative descriptions, observations, and interpretations of a patient's condition, treatment, and other relevant information. Unlike structured data, which is organized in a standardized format with defined fields and categories, clinical notes rely on free-text and may vary in format and content from one provider to another.

EHN Question 11 *(continued)*



RESPONSE:

The MHCC encourages EHNs that are not capable of blocking non-structured legally protected health information by June 1, 2024 to demonstrate measurable progress in implementing technology to block text-based data in their April 1, 2024 status report and June 1, 2024 validation that it possesses the technological capability to restrict from disclosure legally protected health information. EHNs that fail to demonstrate measurable progress may receive a monetary penalty (COMAR 10.25.07.09C).

HIE Question 22



Can de-identified legally protected health information be disclosed for certain purposes?

RESPONSE:

De-identified legally protected health information may be exchanged for population health management and research in a manner that aligns with regulatory requirements described in COMAR 10.25.18.10 Requirements for Accessing, Using, or Disclosing Data Through an HIE for Secondary Use.

Note: COMAR 10.25.18.02B(18) “De-identified data” means health information that neither identifies nor provides a reasonable basis to identify an individual and that meets the standards and specifications provided in 45 CFR §164.514(a)—(b).

EHN Question 9



Can de-identified legally protected health information be disclosed for certain purposes?

RESPONSE:

De-identified legally protected health information may be exchanged in accordance with COMAR 10.25.07 and other laws governing the privacy and security of protected health information, including HIPAA.



Validation

HIEs and EHNs that submitted an implementation plan must submit a validation by June 1st that they possess the technological capability to filter and restrict from disclosure legally protected health information to the extent required by law

Validation Reporting Structure



The validation must describe approaches to comply with Health-General §4-302.5

- **Scope of Validation:** Specify the extent to which the HIE possesses the technological capability, as of June 1, 2024, to:
 1. Filter and restrict from disclosure codes and text-based legally protected health information
 2. Facilitate the exchange of legally protected health information to a specific treating provider when a patient, or parent or guardian of the patient, provides consent for the disclosure

Describe activities underway and planned to achieve full compliance

Validation Reporting Structure *(continued...)*



Include information on the following:

- **Development:** Overview the established technical solution(s) and policy(ies) for filtering and restricting and facilitating the exchange of legally protected health information; specify planned capabilities that will be developed in the future
- **Implementation:** Detail the status of the implementation of software updates/upgrades by the HIE's clients, as well as any policy(ies) and written agreements to support compliance with the regulations
- **Client Training to Support:** Specify ongoing awareness building activities to educate Maryland based clients to ensure compliance with the regulations

Please note, MHCC intends to post validations on its website. Please omit trade secrets or confidential business and financial information as defined in the Maryland Public Information Act



Request for Exemptions

An HIE that is unable to fully validate compliance with the 2023 law may submit a time-limited exemption request with their validation

Process



- ▶ A request for exemptions must be submitted with the validation for HIEs working to fully comply with the 2023 law
 - Requests should be submitted on company letterhead and signed by a corporate officer with authority to conduct business transactions on behalf of the HIE
- ▶ The MHCC will consider the merits of each request before granting an exemption; additional information may be requested by MHCC to make a determination
- ▶ Failure to provide MHCC with the information requested within 4 business days of the written request may result in a denial of the request for exemption
- ▶ Within 45 days of receiving a complete request for exemption, MHCC shall :
 1. Grant the exemption by providing written notification; or
 2. Deny the exemption request by providing written notification that enumerates the reasons for the denial to the HIE

What to Include



The MHCC will consider requests for exemptions specific to the requirements for legally protected health information, please include the following:

- **Regulatory Citation:** List each regulatory requirement from which the HIE is seeking exemption, noting the applicable regulation codification number(s)
- **Rationale:** Provide justification as to why additional time is needed to comply with the regulatory requirement; include:
 - Key challenges that prevented blocking codes and text-based legally protected health information by June 1st;
 - How each requested exemption is addressed in the HIE's implementation plan/status report, noting any deviation from the implementation plan/status report previously submitted

What to Include *(continued...)*



- **Timeframe for Compliance:** Detail timing and plans to achieve compliance for each requested exemption; include:
 - The additional time needed and circumstances that influenced the chosen time period for each exemption requested
 - A detailed compliance plan noting key milestones and timelines to block codes and associated text-based legally protected health information
- **Supporting Documentation:**
 - Provide necessary context or background information to justify the need for an exemption and any potential risks or negative consequences if an exemption is not granted
 - Describe your communication strategy to clients regarding implementing the direct consent requirement in the regulations



Regulations Update



MHCC Regulations Status



Supporting regulations were posted as final in the Maryland Register on May 3rd with an effective date of May 13th

- ▶ COMAR 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses*
- ▶ COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*

Questions?





Closing Remarks



Thank you!

For questions related to the MHCC regulations,
please contact anna.gribble1@maryland.gov.