MARYLAND Health Care Commission

Randolph S. Sergent, Esq., Chairman
Ben Steffen, Executive Director

Chapter 249/House Bill 812 (2023)

Health – Reproductive Health Services – Protected Information and Insurance Requirements

IMPLEMENTATION GUIDANCE: HEALTH INFORMATION EXCHANGES

March 25, 2024 – Version 2

Overview

During the 2023 legislative session, the Maryland General Assembly passed Chapter 249, *Health – Reproductive Health Services – Protected Information and Insurance Requirements* ("law").[1] The law establishes protections for the disclosure of legally protected health information by health information exchange ("HIE") and electronic health network entities operating in the State. The Maryland Department of Health ("MDH") and Maryland Health Care Commission ("MHCC" or "Commission") adopted emergency regulations as required by the law; COMAR 10.11.08, *Abortion Care Disclosure* (MDH) and COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information* (MHCC)[2] are the regulatory frameworks to ensure HIEs filter and restrict legally protected health information with a date of service after May 31, 2022.

This document serves as a resource for HIEs in the management, disclosure, and protection of legally protected health information. **Included herein are responses to questions MHCC receives from HIEs, which aim to provide guidance to support compliance with statutory and regulatory requirements.** ***Note: items italicized reflect updated information from a prior version of this guidance document dated January 26, 2024.*** The information does not constitute legal advice and should not be considered a substitute for a thorough review of the regulations. Questions about this document can be directed to Ms. Anna Gribble at anna.gribble1@maryland.gov.

Questions

1. **Does patient consent need to be shared with a State registry?**

   The use of a State registry is not required by the regulations. A patient consent State registry does not exist at this time. The MHCC anticipates the establishment of such registry maintained by the State Designated HIE (CRISP) in Q4 2024.

2. **What information should be included in the implementation plan and in what format?**

   COMAR 10.25.18.04C(2)(b) requires the implementation plan (or "plan") to minimally include the following:

[1] Md. Code Ann., Health-Gen. § 4-302.5.
[2] On February 9th, the regulations were adopted as emergency and published in the Maryland Register.

- An affirmation that despite the HIE's best efforts, the HIE lacks the technological capability to fully comply with COMAR 10.25.18.04C(1), including a detailed explanation of the HIE's limitations;

- A detailed description of the steps the HIE is taking to ensure compliance with COMAR 10.25.18.04C(1) by June 1, 2024;

- A timeline to implement the requirements of Health-General Article § 4-302.5, Annotated Code of Maryland by June 1, 2024;

- A description of the extent legally protected health information, and other health information, will be restricted through the HIE during the implementation of its plan; and

- HIEs that submit a plan must acknowledge their compliance with the requirement to provide a status report to the Commission by April 1, 2024 detailing the progress the HIE has made under its plan.

The MHCC requests that the plan highlight short or long-term goals to ensure compliance with the regulations and the HIE's approach to achieving the stated goals. The plan needs to include a description of an HIE's technical approach to restrict codes identified in COMAR 10.11.08, *Abortion Care Disclosure*, and to block structured text and language related to legally protected health information in clinical notes. The plan must be signed by an executive level employee of the HIE and include their contact information.

Plans should be submitted via email as a PDF attachment to Ms. Anna Gribble at anna.gribble1@maryland.gov. The MHCC will respond with a formal acknowledgment on the sufficiency of the plan within 45 business days of receipt noting any areas where the plan is inadequate and does not meet the necessary requirements set forth in the regulation. The MHCC will provide suggestions for addressing plan areas in need of attention before the required status report due to MHCC by April 1, 2024. In a commitment to transparency, status reports will be accessible to the public.

3. Can the notification of current capabilities included in the emergency regulations be moved to after the deadline for creating a plan?

The MHCC will grant HIEs that submit a plan additional time to notify participating organizations as required by COMAR 10.25.18.04C(3)(a). The MHCC advised participants during the December 18th Town Hall meeting that the regulations are under review by the Administrative, Executive, and Legislative Review ("AELR") Committee[3] and are expected to be posted on February 9, 2024 in the Maryland Register. The MHCC requests that HIEs notify all participating organizations by February 9, 2024.

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?

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

[3] The AELR Committee is tasked with determining if regulations conform to legislative intent; the regulations are effective the date they are published in the Maryland Register.

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. HIE's should execute written agreements by June 1, 2024 to avoid blocking all records that contain legally protected health information as a result of a client's decision to delay implementing an HIE's technical solution. It is common for HIEs to include clauses in their contracts stipulating that users must comply with State and federal laws, especially those related to data privacy. These clauses serve to emphasize the importance of legal compliance and help protect HIEs and providers using their systems.

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?**

   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[4] status report and in advance of the June 1, 2024 validation deadline. The MHCC will consider penalties for non-compliance based on an HIEs 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)). 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.

6. **If an HIE changes their technological approach to complying with the regulations, will they be expected to share that with MHCC?**

   An HIE that makes a strategic decision to change its technical approach to better align with the regulations is not required to notify MHCC. HIEs are encouraged to update MHCC on any changes to its implementation plan that improve the efficiency and effectiveness of its technical compliance efforts in the April 1, 2024 status report or June 1, 2024 validation that it possesses the technological capability to restrict from disclosure legally protected health information (COMAR 10.25.18.04C(3)).

7. **Clarify if legally protected health information can be shared within an electronic health record ("EHR") instance or between providers within a health system?**

   The MHCC emphasizes the critical importance of safeguarding legally protected health information and the vital role of HIEs in upholding individuals' reproductive health privacy. The regulations do not permit the

[4] See n.1, *Supra.*

exchange of legally protected health information with providers who share the same EHR instance or are part of the same health system unless the exchange of information meets the requirements under COMAR 10.25.18.01C(1). Permitted exchanges include:

- Between a hospital and a health care professional credentialed by that hospital to deliver care;
- Among credentialed professionals of a hospital's medical staff;
- Between a hospital and its affiliated ancillary clinical service provider who is affiliated with the hospital and who, if required by HIPAA, has entered into a business associate agreement with the hospital; and
- Among entities under common ownership as defined at Health-General Article §4-301, Annotated Code of Maryland for health care treatment, payment, or health care operations purposes, as those terms are defined in 45 CFR §164.501.

8. **Can a patient consent to having their legally protected health information disclosed to multiple providers or future providers by an HIE? Do providers who receive legally protected health information from a prior treating provider need to obtain consent from the patient before sharing with another treating provider?**

   A patient cannot provide general consent to an HIE for the release of legally protected health information. The use of general consent could result in the unintentional over-sharing of legally protected health information. The regulations require legally protected health information only be released by an HIE to a specific treating provider at the written request of a patient, for services for which the patient can provide consent under State law, or a parent or guardian of a patient, for services which the parent or guardian can provide consent under State law. Consent is not required for the release of information to a payer or its business associates for the adjudication of claims (COMAR 10.25.18.04C(1)).

9. **What does implementation look like for non-Maryland based providers who are providing legally protected health care to Maryland-based residents via telehealth as well as Maryland-based providers providing legally protected health care services to patients outside of Maryland? What is the impact on health care organizations with sites in Maryland and in other states?**

   The regulations apply to the disclosure of legally protected health information related to services provided when either the patient or the provider is physically located in Maryland, or both. COMAR 10.25.18.02B(30) defines health care provider as follows:

   - A person who is licensed, certified, or otherwise authorized under Health Occupations Article, Annotated Code of Maryland, or Education Article, §13–516, Annotated Code of Maryland, to provide health care in the ordinary course of business or practice of a profession or in an approved education or training program; or
   - A facility where health care is provided to patients or recipients, including:
     - A facility as defined in Health-General Article, §10–101(e), Annotated Code of Maryland;

- A hospital as defined in Health-General Article, §19-301(f), Annotated Code of Maryland;
- A related institution as defined in Health-General Article, §19-301(o), Annotated Code of Maryland;
- A State-certified substance use disorder program, as defined in Health-General Article, §8-403, Annotated Code of Maryland;
- A health maintenance organization as defined in Health-General Article, §19–701(g), Annotated Code of Maryland;
- An outpatient clinic; or
- A medical laboratory.

An HIE may share legally protected health information across sites in Maryland and in other states providing the disclosure meets the requirements under COMAR 10.25.18.01C(1) (refer to question seven above for more information).

10. Can information relating to the prescribing of mifepristone be shared if the prescription was provided to treat a diagnosis not related to abortion care? Should entities suppress prescription information for generic medications for drugs with NDCs on the list of legally protected health information? Should entities suppress medication information within a health record that is not included in HCPCS?

HIEs are required to block legally protected health information identified in COMAR 10.11.08 (MDH regulations). Mifepristone has applications beyond its use in medical abortion and is used in the treatment of certain medical conditions. The MDH regulations include a list of diagnoses, procedure, and medication codes for mifepristone specific to abortion care. Brand name and generic drugs prescribed for abortion care listed in the regulations must be blocked. It is anticipated that HIEs will need to crosswalk the related medication codes in the regulations with codes included in RxNorm (www.nlm.nih.gov/research/umls/rxnorm/index.html).

11. What sort of advance notice should health care organizations anticipate if the definition of legally protected health information changes?

The MHCC will notify HIEs of any changes to the regulations within 30-60 days prior to their publication in the Maryland Register. The effective date shall be determined after consideration of various factors, i.e., policy or technology, and will be noted in the Maryland Register posting. The Protected Health Care Commission, established by the law, is required to submit semiannual reports to the Secretary of Health on recommendations regarding services that should be treated as legally protected health information; the Secretary of Health will consider the recommendations within 60 days of receiving the report. Questions regarding the codes released by MDH should be directed to: reproductive.health@maryland.gov.

12. For HIEs who sent participating organization the required communication by December 18, 2023, is the expectation that they will need to re-send that same communication by the next deadline date?

HIEs are not required to issue a second communication regarding its compliance with the regulations to participating organizations. HIEs who have already notified participating organizations have met the requirement in regulation (COMAR 10.25.18.04C(3)). HIEs are encouraged to communicate with participating organizations and other stakeholders as they deem necessary to support implementation of the regulations.

13. Is consent needed for an entity to disclose legally protected health information to pharmacies via e-prescribing, laboratories, or other ancillary care providers? Can legally protected health information be disclosed through provider direct messaging?

The direct consent requirement in law is satisfied when a patient or guardian directs a provider to a specific pharmacy to send an electronic prescription. The direct consent requirement is also met when a patient or a patient's guardian consents to a specific provider for the ordering of ancillary services, such as laboratory and diagnostic services. COMAR 10.25.18.04C(1) requires HIEs to comply with Health General § 4-302.5, Annotated Code of Maryland and COMAR 10.11.08, where among other things, legally protected health information may only be disclosed 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 under State law, a parent or guardian of a patient, for services for which the parent or guardian can provide consent under State law, or for the adjudication of claims. The use of direct messaging between providers is permitted unless an HIE is involved in the transmission of the message (COMAR 10.25.18.01C(2)).

14. Can legally protected health information be disclosed for credentialing purposes? Can identifiable or de-identified 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*?

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)). 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.

Version 2 – Modification

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 HIE's fax capabilities or direct messaging to send information to a third-party.

15. What disclosures associated with the adjudication of claims are allowable under the exception for disclosure of legally protected health information? Are the regulatory requirements applicable to all transaction methods (i.e., C-CDA, FHIR, HL7 or EDI transactions)?

An HIE may disclose legally protected health information to a payer or its business associate; patients furnish details about their insurance coverage. Disclosures for the adjudication of claims typically include diagnoses, procedure, and medication codes. COMAR 10.25.18.02B(2) defines adjudication of claims as the activities necessary for the adjudication or subrogation of a health benefit claim that has been filed or may be filed by a patient, or with the authorization of a patient on the patient's behalf, including:

- Determinations of eligibility or coverage, including coordination of benefits or the determination of cost sharing amounts;
- Reasonable prospective, concurrent, or retrospective utilization review or predetermination of benefit coverage;
- Review, audit, and investigation of a specific claim for payment of benefits with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;
- Billing, claims management, collection activities, obtaining payment under a contract for reinsurance, and related health care data processing; and
- Risk adjustments based on enrollee health status and demographic characteristics.

The referenced standards (C-CDA, FHIR, HL7 or EDI transactions) contribute to the efficiency of sharing data and do not dictate the content of specific transactions associated with the standards. HIEs must block the content of transactions utilizing these standards for the codes listed in COMAR 10.11.08, unless the disclosure meets one of the limited exceptions under the law.

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

HIEs must block non-structured health information (COMAR 10.25.18.02B(31)) that relates to legally protected health information in clinical notes. 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. 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)).

17. Are printed or faxed materials in scope?

The restrictions on the disclosure of legally protected health information apply to printed or faxed materials if the disclosure is made by an HIE or EHN.

18. Is it acceptable to completely restrict the sharing of any of the patient's clinical information in order to comply with the reproductive health statute?

No. To be in full compliance with the law, the regulations require HIEs to affirm that they are "parsing restricted codes and conveying all other information in the health record that is not prohibited by law to exchange." Completely restricting the sharing of a patient's clinical information may also be prohibited by other State or federal law, such as the 21st Century Cures Act.

Updates – March 2024

Note: Question 14 has been modified; change appears in italics

19. Is there a particular timeframe by which the client needs to commit to upgrade or implement the necessary technology? Will MHCC assess penalties if all parties committed to upgrade or implement the necessary technology?

COMAR 10.25.18.09G states that "*If an HIE has reasonably determined that it is unable to independently meet any requirements of this chapter, then the HIE shall 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 that will bring the HIE into compliance with this chapter*." The regulations and HIE Implementation Guidance document are not prescriptive on the role of an HIE client.

HIEs are required in the regulations to comply with the law by June 1, 2024. The January 26, 2024 HIE Implementation Guidance document, question 5, states that "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 HIEs tangible advancements in their implementation plan. The Commission will assess 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))." HIEs that fail to demonstrate measurable progress may be subject to a monetary civil and criminal penalties determined by the following criteria (COMAR 10.25.18.09C(3)(a) and (b)) 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.

An HIE that plans to request an exemption should include the request along with its June 1, 2024 validation, COMAR 10.25.18.04C(3)(c). The requirements for an exemption request are detailed in COMAR 10.25.18.09.H.

20. Who is included in the definition of "health care provider" when considering who, or what entities, could receive legally protected health care information as a "treating provider"?

Any individual or entity within the definition of a "health care provider" can be considered a "treating provider" when considering who or what entity can receive legally protected health information. The definition of health care provider includes individual clinicians and organizational providers. Under Health-Gen. § 4-301, health care provider also includes the "agents, employees, officers, and directors of a facility and the agents and employees of a health care provider." See question 9 for the definition of a "health care provider" under COMAR 10.25.18.02B(30).

21. **When developing methods to suppress text-based information, should HIEs create tools that allow providers to flag notes as "sensitive," then suppress text-based information flagged as "sensitive," or develop a system rule to suppress notes based on coded data documented elsewhere in the chart. The flagged approach may require additional provider training and the coded data would suppress the text-based information only in the circumstances in which the coded data is available in the chart.**

    MHCC recommends a dual strategy to blocking the disclosure of text-based legally protected health information that relies on a provider education and a rules-based approach. Educating providers on the appropriate use of the Sensitive Notes tool should be incorporated into written agreements with participating organizations or a business associate. COMAR 10.25.18.09G states that "If an HIE has reasonably determined that it is unable to independently meet any requirements of this chapter, then the HIE shall 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 that will bring the HIE into compliance with this chapter."