MARYLAND Health Care Commission

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Chapter 249/House Bill 812 (2023)

Health – Reproductive Health Services – Protected Information and Insurance Requirements

IMPLEMENTATION GUIDANCE: ELECTRONIC HEALTH NETWORKS

April 1, 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 electronic health networks ("EHN") and health information exchange 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 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses* (MHCC)[2] are the regulatory frameworks to ensure EHNs filter and restrict legally protected health information with a date of service after May 31, 2022.

This document serves as a resource for EHNs in the management, disclosure, and protection of legally protected health information. **Included herein are responses to questions MHCC receives from EHNs, which aim to provide guidance to support compliance with statutory and regulatory requirements.** ***Note: new items are listed under the header March 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. **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 EHN may disclose legally protected health information to a payer or its business associate in response to an Administrative Simplification Standard Transaction (transactions) request by a provider. Transactions include:

   - Health care claim X12 837
   - Health care claim payment advice X12 835
   - Health care claim status request/notification X12 276/277

[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.

- Eligibility, coverage, or benefit inquiry/information X12 270/271
- Benefit enrollment and maintenance X12 834
- Health care service review information X12 278
- Payment order/remittance advice X12 820

The standards commonly used for adjudication of claims are EDI-X12 and HL7. Other transaction standards used for adjudication of claims are subject to the regulations.

2. What information should be included in the Implementation Plan and in what format?

COMAR 10.25.07.09B(1)(b) requires the implementation plan (or "plan") to minimally include the following:

- An affirmation that despite the EHN's best efforts, the EHN lacks the technological capability to fully comply with Health-General Article, §4-302.5, Annotated Code of Maryland, including a detailed explanation of the EHN's limitations.

- A detailed description of the steps the EHN is taking to ensure compliance Health-General Article, §4-302.5, Annotated Code of Maryland 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 EHN during the implementation of its Plan.

- EHNs that submit a Plan must acknowledge their compliance with the requirement to provide a Status Report to the Commission by April 1, 2024[3] detailing the progress the EHN has made under its Plan.

The MHCC recommends that the plan highlight short or long-term goals to ensure compliance with the regulations and the EHN's approach to achieving the stated goals. The plan must be signed by an executive level employee of the EHN 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 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.[4] In a commitment to transparency, plans will be accessible to the public.

3. Please clarify the scope of data that must be redacted, is it based on a Maryland place of service, provider location, patient location, or patient home address.

[3] The MHCC may extend the required status report due date of April 1, 2024 in future guidance.
[4] *Ibid.*

EHNs, when providing non-adjudication of claims services, must block legally protected health information. The regulations apply to the disclosure of legally protected health information by a provider licensed in Maryland or when the transaction originates in Maryland.

4. **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 will consider penalties for non-compliance based on an EHN's tangible advancements in their implementation plan. The MHCC will consider an EHN's progress detailed in the status report (due April 1, 2024[5]) 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. The MHCC requests EHNs 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. EHNs that fail to demonstrate measurable progress may be subject to a monetary penalty determined by the following criteria (COMAR 10.25.07.09C):

   - 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.

5. **If an EHN changes their technological approach to comply with the regulations, will they be expected to share that with MHCC?**

   An EHN that makes a strategic decision to change its technical approach to better align with the regulations is not required to notify MHCC. At its discretion, an EHN may 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 10.25.07.09B(2)).

6. **Can information relating to the prescribing of mifepristone be shared if the prescription was 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 not included in HCPCS?**

   EHNs that provide services beyond adjudication of claims 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 EHNs 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).

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

7. **What sort of advance notice should health care organizations anticipate when the definition of legally protected health information changes?**

   The MHCC will notify EHNs 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.

8. **Is consent needed for an entity to disclose legally protected health information to pharmacies via e-prescribing, laboratories, or other ancillary care providers?**

   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. EHNs only supporting adjudication of claims are not required to obtain directed consent. The Commission may withdraw certification from an MHCC-certified EHN if the Commission finds the EHN disclosed legally protected health information (COMAR 10.25.07.09A(4)) in violation of 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.

9. **Please clarify if deidentified data falls under the definition of Health Information or Legally Protected Health Information.**

   Yes, de-identified data falls under the definition of “health information” and “legally protected health information.” De-identified information pertaining to reproductive health services as identified in COMAR 10.11.08 may not be disclosed unless authorized by the patient or if the disclosure is required by State law. The definition of “health information” is broader than the definition of “protected health information” and includes any information relating to the physical or mental health or condition of an individual, provision of health care to an individual or payment for the provision of health care to an individual, whether or not that data contains direct or indirect identifiers.

Updates – March 2024

10. **Can identifiable or de-identified legally protected health information be disclosed for research? 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 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)).

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.

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

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. 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 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).

12. When developing methods to suppress text-based information, should EHNs 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 for those EHNs that facilitate the exchange of non-structured health information. Educating providers on the appropriate use of the Sensitive Notes tool should be incorporated into written agreements with participating organizations or a business associate.