



COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information

COMAR 10.25.07, Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses

EMERGENCY REGULATIONS & PROPOSED REGULATIONS

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

OCTOBER 19, 2023

Background



- ▶ During the 2023 legislative session, the Maryland General Assembly passed Chapter 249 (House Bill 812), *Health – Reproductive Health Services – Protected Information and Insurance Requirements* (law)
 - Establishes protections for the disclosure of legally protected health care* by health information exchange (HIE) and electronic health network (EHN) entities operating in the State beginning December 1, 2023; fines for noncompliance begin June 1, 2024 (not to exceed \$10,000 per day)
- ▶ MHCC is required to adopt emergency regulations within nine months
 - Code of Maryland Regulations (COMAR) 10.25.07 and 10.25.18 are the framework to support implementation

* *Includes the disclosure mifepristone data, the diagnosis, procedure, medication, and related codes for abortion care, and other sensitive health services as determined by the Secretary of Health and Protected Health Care Commission*



Draft Emergency Regulations



- ▶ Draft proposed emergency regulations were presented during the September 21, 2023, Commission meeting
- ▶ Proposed emergency regulations were released for informal comment September 22, 2023; stakeholders were asked to submit comments by October 4, 2023*

* *See meeting materials for comments submitted and proposed amendments to COMAR 10.25.07 and 10.25.18*

Summary of Informal Comments



- ▶ 17 organizations submitted 133 total comments, 60 unique comments, 11 modifications were made to the proposed amendments
- ▶ Summary of comments which didn't require a modification to proposed amendments
 - 25 will be considered during the regulation modernization efforts currently underway
 - 15 require changes to statute
 - 11 will likely be addressed by the Maryland Department of Health (MDH) in their regulations/Technical Guidance Documentation
 - 4 were supportive of proposed amendments or represent questions



COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information* – Modifications*

* Section and Subsection – Bold Blue Font

Regulation .01 Scope and Purpose – *No Modifications*



- ▶ Aligns the definition of an HIE with Chapter 718 (House Bill 213), *Health Information Exchanges – Definition and Privacy Regulations (2022) – B(1)*
- ▶ Expands scope to include health information stored in or maintained by an HIE – *B(2)-(3)*
- ▶ Clarifies an HIE unable to meet a requirement may request an exemption – *D*



Regulation .02 Definitions



- ▶ Cites Maryland statute where HIE is defined – *B(31)*
- ▶ Clarifies references and explanations of certain terms – *B(11), B(18), B(28), B(30), B(36), B(56)*
- ▶ Adds definition for “Electronic health information,” “Health care,” “Health record,” “Interoperability,” and “Legally protected health information” – *B(20), B(27), B(32), B(39), B(40)*
- ▶ Revises definition of “Identifiable data” to “Individually identifiable health information” to align with the federal definition – *B(37)*
- ▶ Expands definition of “Sensitive health information” to include “Legally protected health information” – *B(64)*
 - Sensitive health information is a subset of PHI which consists of any information that has any specific legal protections in addition to those required under HIPAA or the Maryland Confidentiality of Medical Records Act, for example substance use disorder treatment information protected by federal regulation 42 CFR Part 2

Regulation .02 Definitions – *Modifications*



Modified Language	Rational
<p>(40) “Legally protected health information” means the health information subject to restrictions under Health-General Article, §4-302.5, Annotated Code of Maryland, including:</p> <ul style="list-style-type: none">(a) Mifepristone data, as defined by the Secretary; and(b) As provided <u>specified</u> in COMAR XX.XX.XX <u>the Technical Guidance Document issued by the Secretary</u>, the diagnosis, procedure, medication, and other codes related to:<ul style="list-style-type: none">(i) Abortion care; and(ii) Sensitive health services, as defined by Health-General, §4-301, Annotated Code of Maryland.	Technical modification

Regulation .03 Rights of a Health Care Consumer Concerning Information Accessed, Used, or Disclosed Through an HIE – *No Modifications*



- ▶ Defines the distribution channels an HIE may utilize to disseminate health care consumer education materials and requires HIEs to distribute materials timely and at no cost; specifies required content of educational materials regarding sensitive health services – *B(4)-(6)*



Regulation .04 Access, Use, or Disclosing of Sensitive Health Information



- ▶ Cites Maryland statute pertaining to access, use, and disclosure of sensitive health information – **A(1)**
- ▶ Requires an HIE to comply with a procedure for disclosing or re-disclosing legally protected health information – **C(1)**
- ▶ By December 18, 2023, an HIE is required to affirm it possesses the technological capability to filter and restrict from disclosure of legally protected health information OR submit an implementation plan describing steps the HIE is taking and the timeline to implement the requirements by June 1, 2024 – **C(2)**



Regulation . 04 Access, Use, or Disclosing of Sensitive Health Information – *Modifications*



Modified Language	Rational
<p><i>C. Procedures for disclosing or re-disclosing legally protected health information.</i></p> <p><i>(1) An HIE shall be in compliance with Health-General Article, §4-302.5, Annotated Code of Maryland and COMAR XX.XX.XXX.</i></p>	Technical modification

Regulation . 04 Access, Use, or Disclosing of Sensitive Health Information – *Modifications*



Modified Language	Rational
<p><i>(2) By December 18, 2023, an HIE shall submit to the Commission:</i></p> <p><i>(a) An affirmation that <u>it</u>:</i></p> <p><i><u>(i) Pit possesses the technological capability to filter and restrict from disclosure legally protected health information to the extent required by law;</u></i></p> <p><i><u>(ii) Is parsing restricted codes and conveying all other information in the health record that is not prohibited by law to exchange; and</u></i></p> <p><i><u>(iii) Possesses the technological capacity to allow a consumer to request and consent to the exchange of legally protected health information to a specific treating provider; or</u></i></p>	<p>Clarifies affirmation</p>

Regulation . 04 Access, Use, or Disclosing of Sensitive Health Information – *Modifications*



Modified Language	Rational
<p><i>(b) An implementation plan that includes:</i></p> <p><i>(i) An affirmation that despite its best efforts, the HIE lacks the technological capability to fully comply with §C(1) of this regulation as of December 1, 2023, including a detailed explanation of the HIE’s limitations;</i></p> <p><i>(ii) A detailed description of the steps the HIE is taking to ensure compliance with §C(1) of this regulation by June 1, 2024;</i></p> <p><i>(iii) A timeline to implement the requirements Health-General Article § 4-302.5, Annotated Code of Maryland and COMAR XX.XX.XXX by June 1, 2024; and...</i></p>	Technical modification

Regulation .04 Access, Use, or Disclosing of Sensitive Health Information *(Continued)*



- ▶ Requires an HIE submitting an implementation plan to:
 - Provide written notice to participating organizations by December 18, 2023, that it is unable to comply with *C(1)* and the extent legally protected health information and other health information will be restricted during implementation of its plan;
 - Provide a status report to the Commission by April 1, 2024, detailing progress made under its implementation plan – *C(3)(b)*; and
 - Submit validation to the Commission by June 1, 2024, that the HIE possesses the technological capability to filter and restrict from disclosure of legally protected health information – *C(3)(c)*
- ▶ The Commission will consider the HIE’s implementation plan and progress report when assessing penalties for violation – *C(4)*

Regulation .06 Auditing Requirements – *No Modifications*



- ▶ Specifies the timeline for reporting an unusual finding to participating organizations (within 5 business days, if fewer than 10 patients) – *A(7)*
- ▶ Clarifies scope, frequency, and supporting policies and procedures for annual audits conducted by an independent party to determine privacy, security, and legal compliance – *C*
- ▶ Requires HIEs to use audit findings for education and training, and evaluation and implementation of new controls – *F(1)*



Regulation .07 Remedial Action to be Taken by an HIE – *No Modifications*



- ▶ Requires an HIE to submit a corrective action plan after concluding an investigation of a non-HIPAA violation and clarifies the timeline and to whom an HIE must provide information related to the investigation – C(2), C(3)
 - A non-HIPAA violation includes inappropriate use, access, maintenance, or disclosure of health information that is not a HIPAA violation, but is inconsistent with State or federal law, or this chapter, including violation of 42 CFR Part 2

Regulation .09 Registration and Enforcement



- ▶ Clarifies Commission staff can take action to request a corrective action plan and recommend suspension or withdrawal of HIE registration, financial penalties, or referral to another State or federal agency – **C(2)**
- ▶ Adds civil and criminal penalties of up to \$10,000 per day for noncompliance and specifies that criminal penalties take effective June 1, 2024 – **C(3)**



Regulation .09 Registration and Enforcement – *Modifications*



Modified Language	Rational
<p><i>(3) Civil and criminal penalties.</i></p> <p><i>(a) Civil penalties. A person who knowingly fails to comply with this chapter shall be subject to a civil penalty <u>imposed by the Commission</u> not exceeding \$10,000 per day for each person impacted by the non-compliance based on:</i></p> <ul style="list-style-type: none"><i>(i) The extent of actual or potential public harm caused by the violation;</i><i>(ii) The cost of the investigation; and</i><i>(iii) The person's prior record of compliance.</i>	<p>Clarifies who may impose civil penalties</p>



Regulation .10 Requirements for Accessing, Using, or Disclosing of Data Through an HIE for Secondary Use – *No Modifications*



- ▶ Prohibits an HIE from using or disclosing a patient's sensitive health information for secondary use unless permitted by applicable federal and State laws and regulations – *A(1)*
 - Secondary use means any use or disclosure of data accessed, used or disclosed through an HIE that is not a primary use; this could include use of HIE data for conducting research or improving patient safety



COMAR 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses* – Modifications*

* Section, Subsection, and Paragraph – Bold Blue Font



Regulation .02 Definitions

- ▶ Adds definition for “Disclose/disclosure,” “Health information,” and “Legally protected health information” – *B(2)*, *B(7)*, ***B(8)***
- ▶ Revises the definition of “Qualified accreditation or certification organization” to be inclusive of a national recognized entity that has established privacy and security standards for EHNs – *B(13)*
 - EHN certification is valid for two years



Regulation .02 Definitions – *Modifications*



Modified Language	Rational
<p>(8) “Legally protected health information” means the health information subject to restrictions under Health-General Article, §4-302.5, Annotated Code of Maryland, including</p> <ul style="list-style-type: none">(a) Mifepristone data, as defined by the Secretary, and(b) <u>As specified in the Technical Guidance Document issued by the Secretary</u> As provided in COMAR XX.XX.XXX, the diagnosis, procedure, medication, and other codes related to:<ul style="list-style-type: none">(i) Abortion care; and(ii) Sensitive health services, as defined by Health-General, §4-301, Annotated Code of Maryland.	Technical modification



Regulation .05 Standard for Certification

- ▶ Requires an EHN to provide MHCC with an attestation that the EHN has the ability to restrict disclosure of legally protected health information – **A(2)(c)**



Regulation .05 Standard for Certification – *Modifications*



Modified Language	Rational
<i>(c) Provide an attestation signed by an officer of the applicant that the applicant restricts disclosure of legally protected health information as required by Health-General Article, §4-302.5, Annotated and COMAR XX.XX.XX;</i>	Technical modification

Regulation .09 Withdrawal of Certification and Other Penalties



- ▶ Allows the Commission to withdrawal certification from an EHN in the event the EHN discloses legally protected health information – *A(4)*
 - By December 18, 2023, an EHN is required to affirm to MHCC that it possess the technological capability to filter and restrict from disclosure legally protected health information OR submit an implementation plan describing the timeline and steps the EHN is taking to implement the requirements by June 1, 2024 – ***B(1)***
- ▶ EHNs that submit an implementation plan are required to provide a status report to the Commission by April 1, 2024, detailing progress made and to submit validation to the Commission by June 1, 2024, that the EHN possesses the technological capability to filter and restrict from disclosure legally protected health information – *B(2)*
- ▶ Adds civil and criminal penalties of up to \$10,000 per day for noncompliance and specifies that criminal penalties take effect June 1, 2024 – *C*

Regulation .09 Withdrawal of Certification and Other Penalties – *Modifications*



Modified Language	Rational
<p><i>B. An MHCC-Certified EHN must report on compliance progress to the Commission.</i></p> <p><i>(1) By December 18, 2023, an MHCC-certified EHN shall submit to the Commission:</i></p> <p><i>(a) An affirmation that <u>to the extent required by Health-General Article, §4-302.5, Annotated Code of Maryland it:</u></i></p>	<p>Aligns with the law</p>

Regulation .09 Withdrawal of Certification and Other Penalties – *Modifications*



Modified Language	Rational
<p><i>(i) Possesses the technological capability to filter and restrict from disclosure legally protected health information to the extent required by Health-General Article, §4-302.5, Annotated Code of Maryland and COMAR XX.XX.XX;</i></p> <p><i>(ii) <u>Is parsing restricted codes and conveying all other information in the health record that is not prohibited by law to exchange; and</u></i></p> <p><i>(iii) <u>Possesses the technological capacity to allow a consumer to request and consent to the exchange of legally protected health information to a specific treating provider; or</u></i></p>	Clarifies affirmation

Regulation .09 Withdrawal of Certification and Other Penalties – *Modifications*



Modified Language	Rational
<p><i>(b) An implementation plan that includes:</i></p> <p><i>(i) An affirmation that despite its best efforts, the MHCC-certified EHN lacks the technological capability to fully comply with Health-General Article, §4-302.5, Annotated Code of Maryland as of December 1, 2023, including a detailed explanation of the EHN’s limitations;</i></p> <p><i>(ii) A detailed description of the steps the MHCC-certified EHN is taking to ensure compliance with Health-General Article, §4-302.5, Annotated Code of Maryland by June 1, 2024;</i></p> <p><i>(iii) A timeline to implement Health-General Article, §4-302.5, Annotated Code of Maryland and COMAR XX.XX.XX A by June 1, 2024; and</i></p>	Technical modification



Next Steps

Regulations – The Process



Step 1

EMERGENCY REGULATIONS

- ▶ Amendments to COMAR 10.25.07 and 10.25.18 will be published in the Maryland Register as Emergency Regulations
 - Emergency Regulations are adopted for 180 days
- ▶ Emergency Regulations are proposed today as Chapter 249 requires MHCC to adopt emergency regulations

Step 2

PROPOSED REGULATIONS

- ▶ Amendments to COMAR 10.25.07 and 10.25.18 will be published in the Maryland Register to solicit formal comment
- ▶ Requires step in process to submit Proposed Permanent Regulations

Commission Action



- ▶ Proposed Amendments take into account stakeholder feedback through an informal comment process and fulfills regulatory requirements in Chapter 249 (House Bill 812), *Health – Reproductive Health Services – Protected Information and Insurance Requirements*
 - Staff requests the Commission adopt COMAR 10.25.07 and 10.25.18 as emergency regulations
 - Staff requests the Commission approve COMAR 10.25.07 and 10.25.18 for posting as proposed in the Maryland Register

Questions

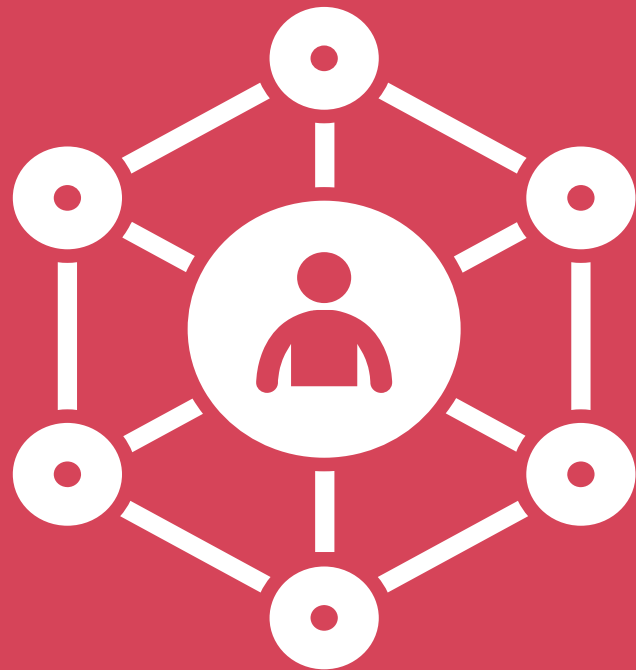




Appendix



About HIEs



- ▶ HIEs determine, control, or have the discretion to administer any requirement, policy, or agreement that allows, enables, or requires the use of any technology or services for access, exchange, or use of electronic protected health information
 - Inclusive of regional entities and developers of health information technology and (e.g., electronic health record vendors)
 - Entities operating in Maryland that meet the statutory definition of an HIE are required to register with MHCC (*see appendix for a listing of the 16 registered HIEs*)



Registered Health Information Exchanges

Health Information Exchanges

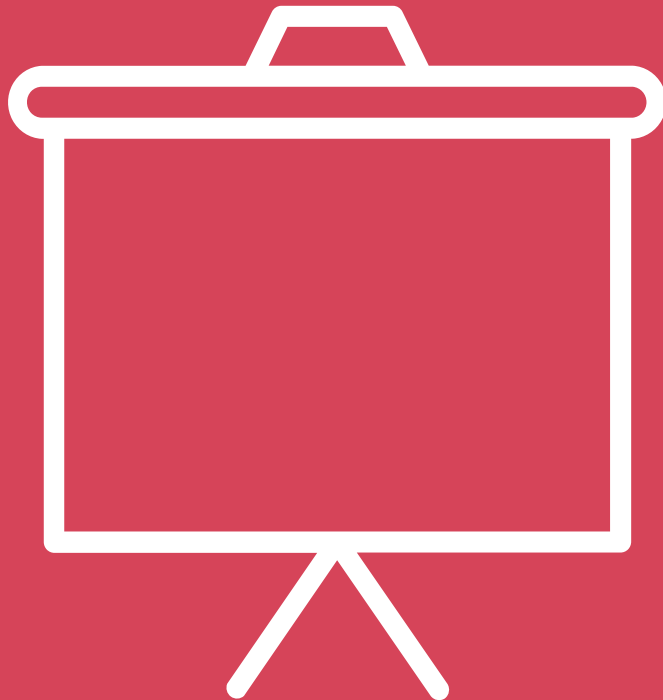


HIEs Registered with MHCC

1	Altera Digital Health, Inc.	9	Greenway Health
2	Athenahealth	10	Medical Information Technology, Inc. (MEDITECH)
3	Audacious Inquiry, LLC	11	NextGen Healthcare, Inc.
4	Cerner Corporation	12	PointClickcare Technologies, Inc.
5	Chesapeake Regional Information System for Our Patients (CRISP)	13	Quest Diagnostics Clinical Laboratories, Inc.
6	Delaware Health Information Network	14	Surescripts, LLC
7	eClinicalworks	15	Syntellis Performance Solutions, LLC
8	Epic	16	Veradigm Inc.



Background COMAR 10.25.18



- ▶ Chapter 535 of the Laws of Maryland (2011) | House Bill 784 *Medical Records – Health Information Exchanges* required MHCC to adopt regulations for the privacy and security of protected health information obtained or released through an HIE; regulations adopted March 2014
- ▶ Chapter 18 builds upon minimal privacy and security protections for protected health information (PHI) established by HIPAA (1996), as amended by HITECH (2009) (*see appendix for a more information on efforts to modernize Chapter 18 beginning in 2020*)



About EHNs



- ▶ EHNs exchange electronic health care administrative transactions (claims, referrals, authorizations, remittance) between payers and providers to increase efficiencies in health care operations and reduce administrative costs
 - Includes verifying the accuracy of data submitted, reporting on errors identified, and formatting transactions to align with HIPAA standards
 - Payers that accept electronic health care transactions originating in Maryland are required to accept transactions only from MHCC certified EHNs (*see appendix for a listing of the 29 certified EHNs*)



Certified Electronic Health Networks

Electronic Health Networks



EHNs Certified by MHCC

1	athenaEDI™	11	Inmediata Health Group, LLC	21	QS/1 Data Systems
2	Availity, LLC	12	Inovalon Provider, Inc.	22	RelayHealth Pharmacy Solutions
3	Carestream Dental LLC	13	InstaMed Communications, LLC	23	Smart Data Solutions, LLC
4	Change Healthcare	14	NantHealth, Inc.	24	The SSI Group, LLC
5	Cyfluent, Inc.	15	Office Ally, LLC	25	Surescripts
6	EDI Health Group, Inc. (dba dentalXchange)	16	Optum	26	Veradigm Inc.
7	Experian Health	17	Optum 360	27	Vyne Dental
8	Eyefinity, Inc.	18	Oracle Cerner	28	TriZetto Provider Solutions, LLC
9	FinThrive Healthcare, Inc	19	PNC Bank, NA	29	Waystar
10	FinThrive Revenue Systems, LLC	20	PNT Data Corp.		