



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

UPDATES TO THE EMERGENCY & PROPOSED REGULATIONS

NOVEMBER 16, 2023

Why the Law Matters



Since the *Dobbs v Jackson Women's Health Organization* (June 2022) decision¹, select states have enacted laws to ban access to abortion and other reproductive health services

▶ PROVIDERS

- Health care providers face challenges in response to new restrictions to providing comprehensive reproductive health services
- Concerns with facing criminal, civil, or administrative penalties imposed by some states on lawful care delivered in Maryland

▶ CONSUMERS

- Women and families face new barriers and must travel across State lines to seek care
- Disproportionately impacts communities already affected by inequitable access to quality health care
- Patients have experienced severe, life-threatening pregnancy complications with limited access to emergency care

▶ ELECTRONIC HEALTH INFORMATION

- With recent advancement in electronic health record systems, protected health information, including reproductive health records, are easily accessed across providers in multiple states to support care coordination and clinical decision making
- Electronic disclosure of reproductive health care has the potential to put health care providers and consumers at risk for possible litigation, prosecution, or intimidation

¹ A landmark decision of the U.S. Supreme Court in which the court held that the Constitution of the United States does not confer a right to abortion.

What the Regulations Accomplish

Implements State law



Intentions

- ▶ Safeguard privacy, safety, and confidentiality of patients who obtain reproductive health care services, medications, and supplies in Maryland
- ▶ Enhance privacy protections for providers lawfully providing reproductive health services
- ▶ Preserve access to and quality of reproductive health care services to meet the needs of underserved and vulnerable populations
- ▶ Empower patients to have more control over who has access to their medical information through directed consent
- ▶ Ensure stakeholder perspectives are considered regarding sensitive health services that should be determined by the Secretary to be legally protected health care

Unintended Outcomes

- ▶ Potential patient safety risks posed by limiting patient information (e.g., medical/medications) previously available through an HIE
- ▶ Due to increasing health risks from parsed medical and surgical treatment records in HIEs, a more thorough level of provider education is needed
- ▶ Requires directed consent as opposed to informed consent; granular consent management tools are not yet available
- ▶ Varying approaches to data segmentation by HIEs could result in disclosure of legally protected health information



- ▶ Chapter 249 (House Bill 812), *Health – Reproductive Health Services – Protected Information and Insurance Requirements* (law) passed during the 2023 legislative session and requires MHCC to develop emergency regulations within nine months (March 2024)
- ▶ The 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
 - The Maryland Department of Health (MDH) and MHCC are required to adopt supporting regulations

Draft Regulations



- ▶ Proposed emergency regulations were released for informal comment September 22th, 2023; stakeholders were asked to submit comments by October 4th, 2023
- ▶ 17 organizations submitted 133 total comments, 60 unique comments, 11 modifications were made to the proposed amendments
- ▶ Draft emergency regulations and proposed permanent regulations were adopted by the Commission at its October 19th, 2023 meeting

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



► Modifications at a glance

- Add definitions for ‘adjudication of claims,’ ‘health information technology developer of certified health information technology,’ and ‘21st Century Cures Act’
- Amend definition of ‘legally protected health information’ and ‘population health management purpose’
- Move due dates for an HIE to submit an affirmation or implementation plan to January
- Add steps an HIE must take to request an exemption
- Include miscellaneous edits (e.g., grammar or updated and new definitions that are included throughout)



Regulation .02 Definitions



Modified Language	Rational
<p><i>(2) “Adjudication of claims’ means 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:</i></p> <ul style="list-style-type: none"><i>(a) Determinations of eligibility or coverage, including coordination of benefits or the determination of cost sharing amounts;</i><i>(b) Reasonable prospective, concurrent, or retrospective utilization review or predetermination of benefit coverage;</i><i>(c) 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;</i><i>(d) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance, and related health care data processing; and</i><i>(e) Risk adjustments based on enrollee health status and demographic characteristics.</i>	<p>Incorporate recommendations from stakeholders</p>

Regulation .02 Definitions



Modified Language	Rational
<p><i>(33) “Health information technology developer of certified health information technology” or “developer” means an entity that develops, sells, licenses, provides or offers health information technology, as defined in 42 U.S.C. 300jj(5), to persons in the State and has one or more health information technology modules certified under a program that is kept or recognized by the National Coordinator in accordance with 42 U.S.C. 300jj011(c)(5)</i></p>	<p>Clarifies definition of health information technology developer</p>

Regulation .02 Definitions



Modified Language	Rational
<p>(420) “Legally protected health information” means the health information with a date of service after May 31, 2022 that is subject to restrictions under Health-General Article, §4-302.5, Annotated Code of Maryland and COMAR 10.11.08, including:</p> <ul style="list-style-type: none">(a) Mifepristone data, as defined by the Secretary; and(b) As specified in the Technical Guidance Document issued by the Secretary, 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.	<p>Incorporate recommendations from stakeholders</p>

Regulation .02 Definitions



Modified Language	Rational
<p>(4957) “Population [care] <i>health</i> management purpose” means the use of data, for secondary use, available from or through an HIE for population-based activities relating to the improvement of patient and population health or the reduction of health care costs, including but not limited:...</p>	<p>Align with existing text throughout the Chapter</p>
<p><i>(71) “21st Century Cures Act” means the 21st Century Cures Act, P.L. 114-255, as amended, and the pertinent regulations at 45 CFR Parts 156, 170, and 171 and 42 CFR Parts 422, 431, 438, 457, 482, and 485.</i></p>	

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



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 10.11.08.</i></p> <p><i>(2) By December 18 January 8, 2024, an HIE shall submit to the Commission:...</i></p> <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 January 8, 2024, including a detailed explanation of the HIE's limitations;</i></p>	<p>Allow additional time for HIEs</p>

Regulation .09 Registration and Enforcement



Modified Language	Rational
<p><i>G. 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. Every year as a part of the registration renewal process, the HIE shall submit a written attestation by an independent third party auditor to the Commission, attesting that the HIE has been in full compliance with the requirements of this chapter for the 12-month period prior to the audit.</i></p>	<p>Ensures compliance with regulations</p>

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



► Modifications at a glance

- Add definition for ‘adjudication of claims’
- Amend definition of ‘legally protected health information’
- Update certification process
- Move due dates for an EHN to submit an affirmation of implementation plan to January
- Include miscellaneous edits



Regulation .02 Definitions



Modified Language	Rational
<p><i>(2) “Adjudication of claims’ means 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:</i></p> <ul style="list-style-type: none"><i>(a) Determinations of eligibility or coverage, including coordination of benefits or the determination of cost sharing amounts;</i><i>(b) Reasonable prospective, concurrent, or retrospective utilization review or predetermination of benefit coverage;</i><i>(c) 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;</i><i>(d) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance, and related health care data processing; and</i><i>(e) Risk adjustments based on enrollee health status and demographic characteristics.</i>	<p>Incorporate recommendations from stakeholders</p>

Regulation .02 Definitions



Modified Language	Rational
<p>(420) “Legally protected health information” means the health information with a date of service after May 31, 2022 that is subject to restrictions under Health-General Article, §4-302.5, Annotated Code of Maryland and COMAR 10.11.08, including:</p> <ul style="list-style-type: none">(a) Mifepristone data, as defined by the Secretary; and(b) As specified in the Technical Guidance Document issued by the Secretary, 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.	<p>Incorporate recommendations from stakeholders</p>

Regulation .04 Procedure to Obtain Certification



Modified Language	Rational
<p>B. Fees.</p> <p>(1) An application fee shall be paid to the Commission [at the time the MHCC Electronic Health Network Certification application is filed] <i>within 30 days of receipt of an invoice from the Commission.</i></p> <p>(2) For an electronic health network with one operational site, an application fee of \$400 shall be paid [at the time the application is filed] <i>within 30 days of receipt of an invoice from the Commission.</i></p> <p>(3) For an electronic health network with more than one operational site, an application fee of \$400, plus a \$200 fee for each additional operational site, shall be paid [at the time the application is filed] <i>within 30 days of receipt of an invoice from the Commission.</i></p>	<p>Reflect current procedures and State processes</p>

Regulation .09 Withdrawal of Certification and *Other* Penalties



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 January 8, 2024, an MHCC-certified EHN shall submit to the Commission...</i></p> <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 January 8, 2024, including a detailed explanation of the EHN's limitations;</i></p>	<p>Allow additional time for EHNs</p>



Next Steps

Amendments Timeline – Next Steps



▶ Emergency Regulations

- Amendments to COMAR 10.25.07 and 10.25.18 are anticipated to be published in the Maryland register in December and adopted for a maximum of 180 days

▶ Proposed Regulations

- Amendments to COMAR 10.25.07 and 10.25.18 will be published in the Maryland Register for a formal comment period
- Proposed permanent regulations are anticipated to be presented to the Commission during its February meeting



Commission Action



- ▶ Staff requests the Commission adopt COMAR 10.25.07 and 10.25.18 as emergency regulations
- ▶ Staff requests the Commission approve the updates to COMAR 10.25.07 and 10.25.18 for posting as proposed in the Maryland Register

Questions

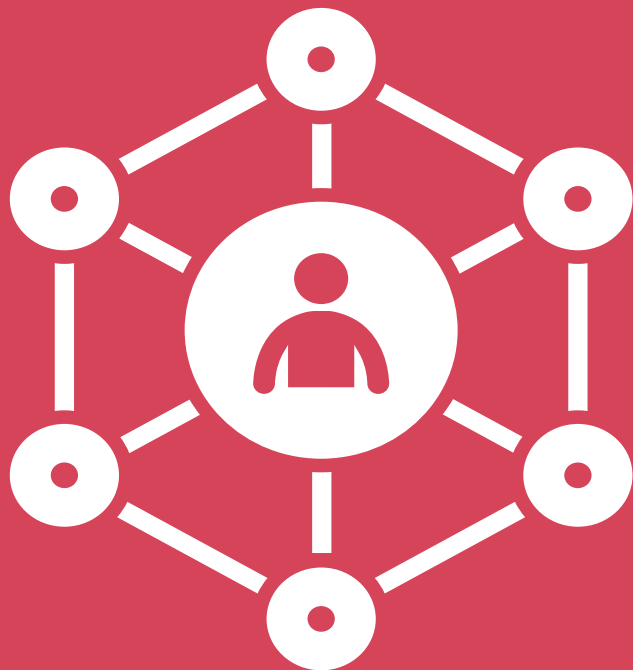




Appendix



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

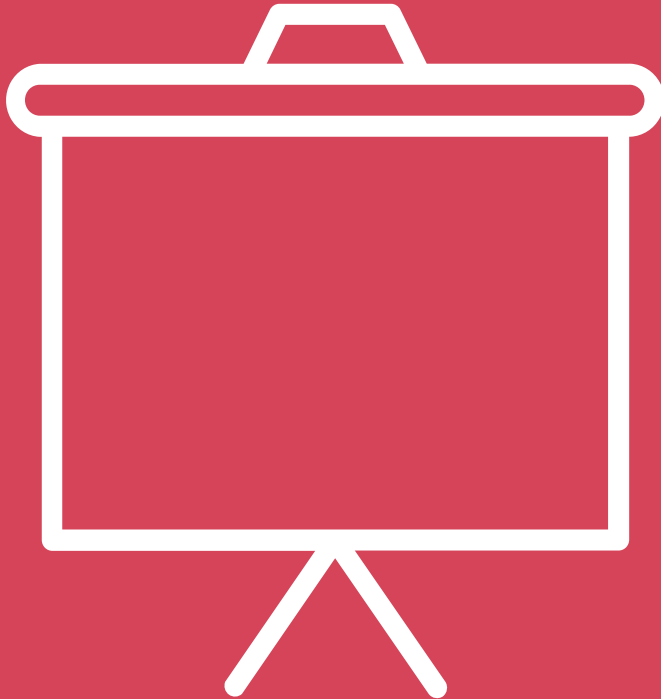


HIEs Registered with MHCC

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.		



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

Regulation .01 Scope and Purpose - *No Modifications to Proposed Amendments*



- ▶ 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 .03 Rights of a Health Care Consumer Concerning Information Accessed, Used, or Disclosed Through an HIE - *No Modifications to Proposed Amendments*



- ▶ 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 *(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 to Proposed Amendments*



- ▶ 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 to Proposed Amendments*



- ▶ 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 .10 Requirements for Accessing, Using, or Disclosing of Data Through an HIE for Secondary Use - *No Modifications to Proposed Amendments*



- ▶ 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* – Summary of Amendments



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 .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 .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*