



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

FINAL REGULATIONS

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

APRIL 18, 2024

Background – State Law



- ▶ During the 2023 legislative session, the General Assembly passed Chapter 249 (House Bill 812), *Health – Reproductive Health Services – Protected Information and Insurance Requirements* (Md. Code Ann., Health-Gen §4-302.5 or law)
- ▶ 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
 - Legally protected health care is health information with a date of service after May 31, 2022 that is subject to the restrictions under the law and regulations developed by the Maryland Department of Health; Code of Maryland Regulations (COMAR) 10.11.08 *Abortion Care Disclosure*
 - Includes mifepristone data, the diagnosis, procedure, medication, and other codes related to abortion care and other sensitive health services

See appendix for more information about the law and legally protected health information

Regulations



- ▶ COMAR 10.25.07 and 10.25.18 are the frameworks to support implementation of the law
- ▶ Informal comments to draft regulations informed proposed permanent regulations approved at the November 2023 Commission meeting
- ▶ The regulations were published in the Maryland Register on January 12, 2024; an opportunity for public comment was open through February 12, 2024



Comments – At a Glance



- ▶ Comments were received from HIEs and EHNs, professional health associations, consumer organizations, and providers
- ▶ All combined, 13 organizations and 23 individual providers submitted 56 comments
 - 30 comments were supportive of the proposed regulations
 - 9 comments suggested technical amendments
 - 17 comments were miscellaneous
 - 6 included implementation considerations for MHCC
 - 6 required changes to the State or federal law
 - 4 provided perspective on the estimate of the economic impact
 - 1 included a consideration for MDH regarding the scope of legally protected health information

Note: A copy of the comments received were included in the meeting materials



Summary of Comments



Comments Expressing Support

- ▶ Establishes data privacy protections that do not exist at the federal level in a post-Dobbs environment
- ▶ Provides confidentiality for Maryland providers and patients traveling to Maryland for certain services
- ▶ Offers reassurance to providers and patients seeking abortion related care from facing retribution in the form of criminal and civil penalties



Comments Suggesting Technical Changes



- ▶ Include an exemption process for EHNs – *COMAR 10.25.07*
 - **The disclosure of legally protected health information is permitted for the adjudication of claims [defined under regulation .02B(1)]**
- ▶ Only withdraw an EHN’s certification if the EHN ‘knowingly’ disclosed legally protected health information – *COMAR 10.25.07.09*
 - **Language currently exists, the regulations state that a person who “knowingly” violates the law is subject to a fine based on certain circumstances [.09C(1)-(3)]**
- ▶ Define when and how to collect and manage consent – *COMAR 10.25.07.09 and COMAR 10.25.18.02*
 - **The law and regulations provide the legal framework for EHNs and HIEs; processes to obtain and manage consent are handled by vendors in collaboration with their clients**
- ▶ Clarify the definition of an HIE – *COMAR 10.25.18.01*
 - **Changes to the regulation would require amendments to the statutory definition [Md. Code Ann., Health-Gen §4-301(i)]**

Comments Suggesting Technical Changes *(Continued...)*



- ▶ Allow health care providers to have access to patients' complete medical record in an emergency – *COMAR 10.25.18.04*
 - **The law does not permit the disclosure of legally protected health information in an emergency; regulation .11 allows HIEs to develop and implement emergency access policies and procedures and specifies the conditions for disclosing information in an emergency**
- ▶ Develop compatible technological solutions that do not create undue burden on providers – *COMAR 10.25.18.04*
 - **Software development decisions are handled by vendors in collaboration with the clients; approaches vary**

No changes to the regulations were made; implementation guidance was made available to EHNs and HIEs

Questions



Commission Action



Two Motions

- ▶ Staff requests the Commission approve amendments to COMAR 10.25.07 as final regulations
- ▶ Staff requests the Commission approve amendments to COMAR 10.25.18 as final regulations

Note: If approved, final regulations are anticipated to be published in the Maryland Register in May



Appendix



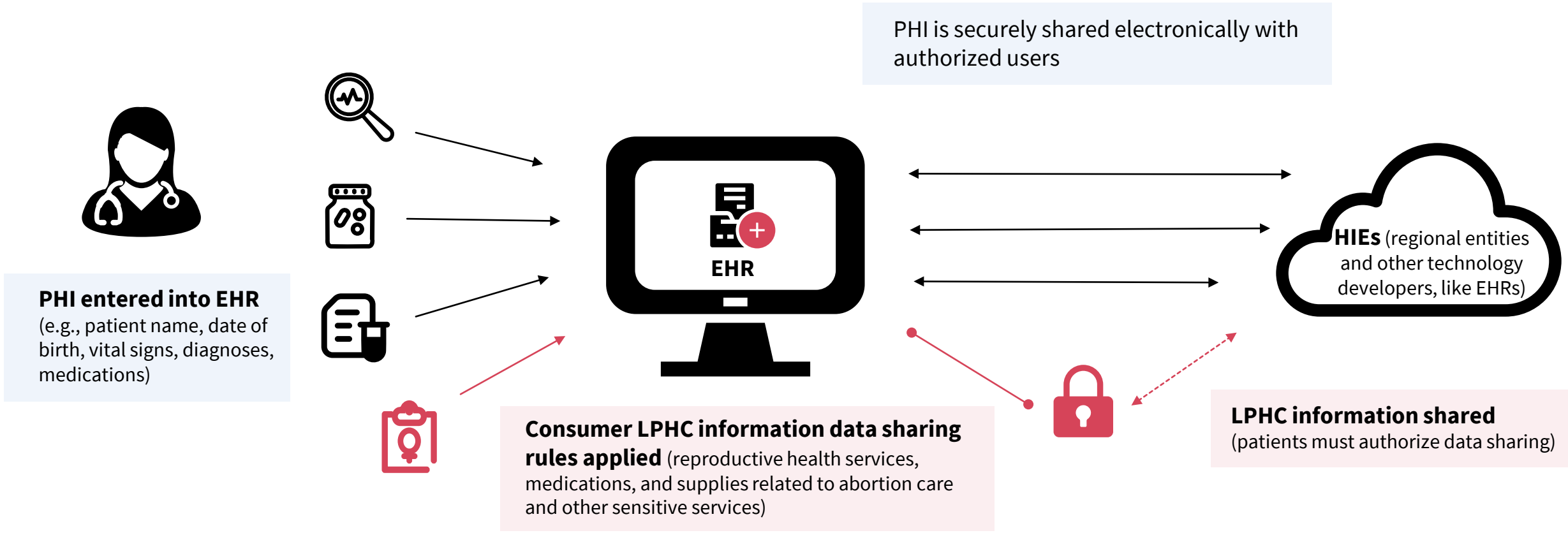
Chapter 296 (House Bill 812), *Health – Reproductive Health Services – Protected Information and Insurance Requirements*

Chapter 296 (2023)



- ▶ Requires the Maryland Department of Health (MDH) to adopt emergency regulations within 90 days after the effective date to restrict the disclosure of abortion care and other sensitive health services information
- ▶ Requires MHCC to adopt emergency regulations within nine months after the effective date to restrict data sharing of patients who have obtained legally protected health care
- ▶ Allows fines for noncompliance beginning June 1, 2024 (not to exceed \$10,000 per day)
- ▶ Mandates MHCC to report on implementation of the law in 2024 and 2025
- ▶ Establishes the Protected Health Care Commission to make recommendations regarding sensitive health services to the Secretary of Health in determining what is legally protected health care

Legally Protected Health Care (LPHC)



Workflow Scenario