



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

KEY STATE ACTIVITIES

JULY 20, 2023



Why Are We Here?



- ▶ MHCC advances health information technology (health IT) statewide to ensure that providers have the right information at the right time and place of care to improve treatment, prevent errors, and reduce health care costs
 - Health IT improves disease surveillance, increases health care knowledge, and informs best practice guidelines
- ▶ MHCC's plan for advancing health IT balances the need for information sharing with strong privacy and security policies

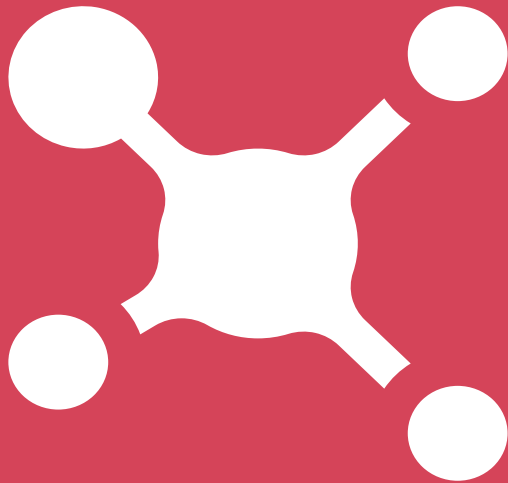
Source: MHCC's Strategic Report, 2023-2026



- ▶ Health Information Exchanges (HIEs) allow authorized users to securely and electronically access and share patient health information for clinical, quality improvement, and public health purposes
 - Range from regional, public entities (including State-Designated entities) and developers of health IT (e.g., electronic health record vendors)
- ▶ Maryland law (2011) requires MHCC to adopt regulations governing the privacy and security of protected health information (PHI) obtained or released through an HIE
 - COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information*, builds upon protections established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) in 2009
 - Entities operating in Maryland that meet the statutory definition of an HIE are required to register with MHCC annually; 16 HIEs are registered (see appendix)

HIE Regulations

Modernization Activities



- ▶ In August 2020, staff initiated modernization activities to align the regulations with federal policy (i.e., interoperability and information blocking provisions in the 21st Century Cures Act and the ONC Health IT Certification program final rule), and support legislation passed by the Maryland General Assembly in 2021 and 2022 (see appendix)
 - Stakeholders reviewed preliminary draft amendments to the regulations in June
- ▶ Activities to modernize the regulations will resume once emergency regulations to support the reproductive health services law are adopted



- ▶ Electronic Health Networks (EHNs) exchange electronic health care administrative transactions between payors and providers; EHNs verify the accuracy of claims data submitted, report on errors identified during the data cleaning process, and format transactions to align with HIPAA standards

- ▶ COMAR 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses*, requires government and private payors to accept transactions originating in Maryland only from MHCC Certified EHNs
 - EHNs must be accredited or certified by a nationally recognized organization where standards related to privacy and confidentiality, business practices, physical and human resources, technical performance, and security are evaluated

 - 29 EHNs are MHCC Certified (see appendix)



About the Law

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

Components



- ▶ Prohibits the disclosure of legally protected health care* by an HIE or EHN beginning December 1, 2023
- ▶ Defines:
 -  Legally Protected Health Care: All reproductive health services, medications, and supplies related to the provision of abortion care and other sensitive services
 -  Sensitive Health Services: Reproductive health services other than abortion care
- ▶ Establishes the Protected Health Care Commission (PHCC) to make recommendations regarding sensitive health services to the Secretary of Health in determining what is legally protected health care

**Includes the disclosure of 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*

Components *(Continued...)*



- ▶ 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



- ▶ Identify sensitive health services information by diagnosis, procedure, medication, or related codes where disclosure would create a substantial risk to patients or health care providers
 - May consult organizations with expertise in legal issues impacting providers of legally protected health care; consumer health privacy; health IT; and other related clinical, policy, or legal expertise
- ▶ Issue semi-annual reports to the Secretary of Health identifying sensitive health services and include an assessment of potential risks to patients and health care providers that would result from the disclosure of identified sensitive health services
- ▶ Within 60 days of receiving the PHCC's semi-annual report, the Secretary of Health will include findings and determinations in a written response to the PHCC, Senate Finance Committee, and House Health and Government Committee

PHCC – Membership



- ▶ The Attorney General or their designee
- ▶ MHCC Executive Director or their designee
- ▶ Specific appointments from the Secretary of Health (all must be residents of the State; see appendix for more information on the organizations that follow)
 - Licensed physician nominated by the American College of Obstetricians and Gynecologists
 - Licensed clinician who provides reproductive health care nominated by the Reproductive Health Access Project
 - Certified nurse-midwife nominated by the Maryland affiliate of the American College of Nurse Midwives
 - A representative of Physicians for Reproductive Health
 - Two consumer representatives with expertise in consumer data privacy
 - An individual with expertise in health information



Emergency Regulations

Targets



- ▶ Update COMAR 10.25.18 and COMAR 10.25.07 to support the law; propose draft amendments to the regulations for release for a 30-day informal comment period at the September Commission meeting
- ▶ Finalize COMAR 10.25.18 and COMAR 10.25.07 and present as final regulations at the November Commission meeting



Federal Initiative – Proposed Alterations to HIPAA to Support Reproductive Health Care Privacy

Note: Comment period for a Notice of Proposed Rulemaking released in April concluded in June

U.S. Department of Health and Human Services

Proposed Rule Takeaways

- ▶ Alters the current Privacy Rule standards by prohibiting uses and disclosures of PHI by a covered entity and their business associates relating to criminal, civil, or administrative investigations into or proceedings against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, including abortion-related care, that is lawful
- ▶ Introduces a new category of PHI related to reproductive health care, defined to include care, services, or supplies related to the reproductive health of the individual
- ▶ Strengthens privacy protections for reproductive health information in direct response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* (June 2022)
- ▶ Prevents an individual's information from being disclosed to investigate, sue, or prosecute an individual, a health care provider, or certain individuals for seeking, obtaining, providing, or facilitating legal reproductive health care, including abortion
- ▶ Requires a regulated entity that receives a request for PHI potentially related to reproductive health care to obtain a signed attestation that the use or disclosure is not for a prohibited purpose

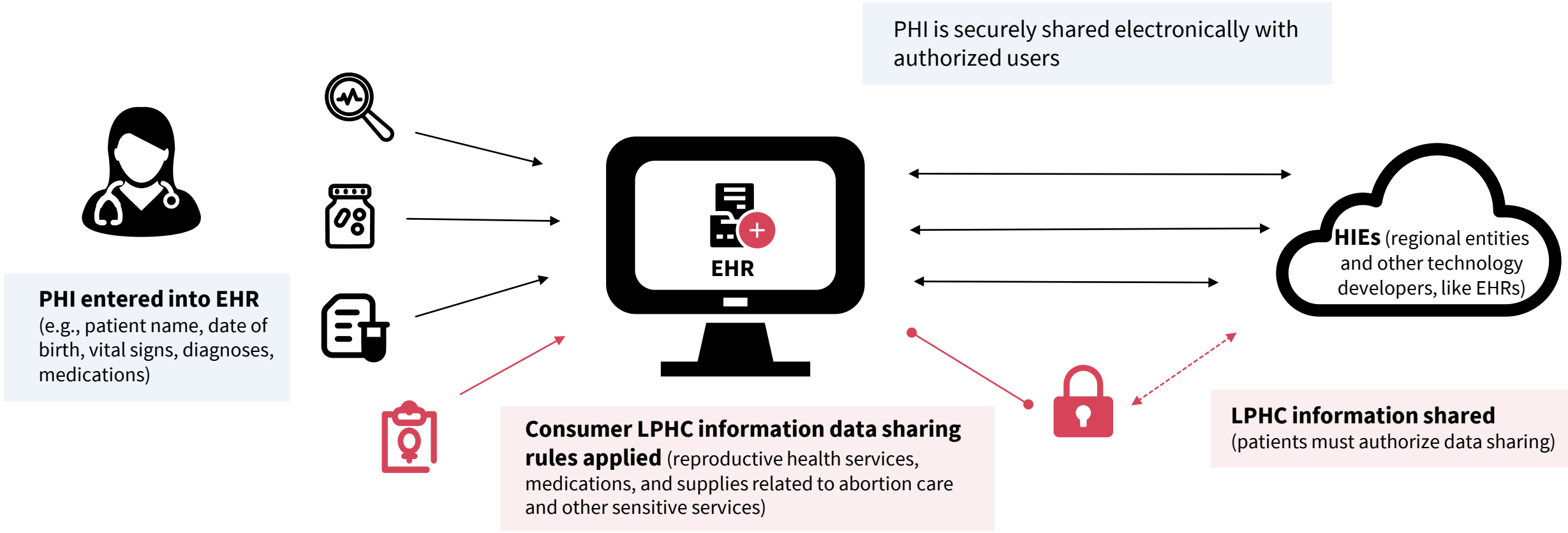
The End





Appendix

Legally Protected Health Care (LPHC) Information



Workflow Scenario

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. |

Modernizing COMAR 10.25.18



Approach

- ▶ Align with federal interoperability and information blocking provisions in the 21st Century Cures Act and the ONC Health IT Certification Program final rule
- ▶ Support legislation passed by the Maryland General Assembly
 - 2021
 - Chapter 790 (HB 1022), *Public Health - State Designated Exchange – Clinical Information*
 - Chapter 798 (HB 1375), *Health Information Exchanges - Electronic Health Information - Sharing and Disclosure*
 - 2022
 - Chapter 296 (HB 1127), *Public Health - State Designated Exchange - Health Data Utility*
 - Chapter 718 (HB 213), *Health Information Exchanges - Definition and Privacy Regulations*

Modernizing COMAR 10.25.18

2021 Legislation



Chapter 790 (HB 1022), *Public Health - State Designated Exchange - Clinical Information*

- ▶ Requires nursing homes to electronically submit clinical information to the State-Designated HIE
- ▶ Authorizes the State-Designated HIE to provide health information to health care providers, health information exchange users, and State and federal officials to facilitate a state health improvement program, mitigate a public health emergency, and to improve patient safety
- ▶ Provides for the protection of health information by limiting redisclosure of financial information, restricts information from individuals who have opted-out of information sharing, and restricts data from health care providers that possess sensitive health care information

Chapter 798 (HB 1375), *Health Information Exchanges - Electronic Health Information - Sharing and Disclosure*

- ▶ Requires the State-Designated HIE to develop and maintain a consent management utility (CMU) allowing persons to opt-out of having their electronic health information shared or disclosed by an HIE
- ▶ Requires the State-Designated HIE to provide the opt-out status of a person, on receipt of an electronic request from an HIE, before sharing or disclosing a person's electronic health information

Modernizing COMAR 10.25.18

2022 Legislation (Continued...)



Chapter 296 (HB 1127), *Public Health - State Designated Exchange - Health Data Utility*

- ▶ Establishes a health data utility (HDU) operated by the State Designated HIE
- ▶ Requires dispensers to submit certain data to the HDU
- ▶ Requires the HDU to make select information available to providers and health officials for public health interventions and health equity

Chapter 718 (HB 213), *Health Information Exchanges - Definition and Privacy Regulations*

- ▶ Aligns the definition of HIE with the federal definition
- ▶ Prohibits the regulations governing the privacy and security of PHI obtained or released through an HIE from sharing or disclosing electronic health information for certain purposes

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. | | |

PHCC Membership



- ▶ **American College of Obstetricians and Gynecologists:** A professional membership organization for obstetrician–gynecologists that produces practice guidelines for health care professionals and educational materials for patients, provides practice management and career support, and facilitates programs and initiatives to improve women’s health, and advocates for members and patients
- ▶ **Reproductive Health Access Project:** Trains, supports, and mobilizes primary care clinicians to ensure equitable access to sexual and reproductive health care, including abortion; a 501(c)(3) nonprofit organization
- ▶ **American College of Nurse Midwives:** A professional association representing certified nurse-midwives and certified midwives; sets the standard for excellence in midwifery education and practice and strengthens the capacity of midwives in developing countries
- ▶ **Physicians for Reproductive Health:** Organizes, mobilizes, and amplifies the voices of medical providers to advance sexual and reproductive health, rights, and justice; programs combine education, advocacy, and strategic communications to ensure access to abortion care and equitable, comprehensive health care; a 501(c)(3) nonprofit organization