



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*

DRAFT EMERGENCY REGULATIONS

SEPTEMBER 21, 2023

Overview

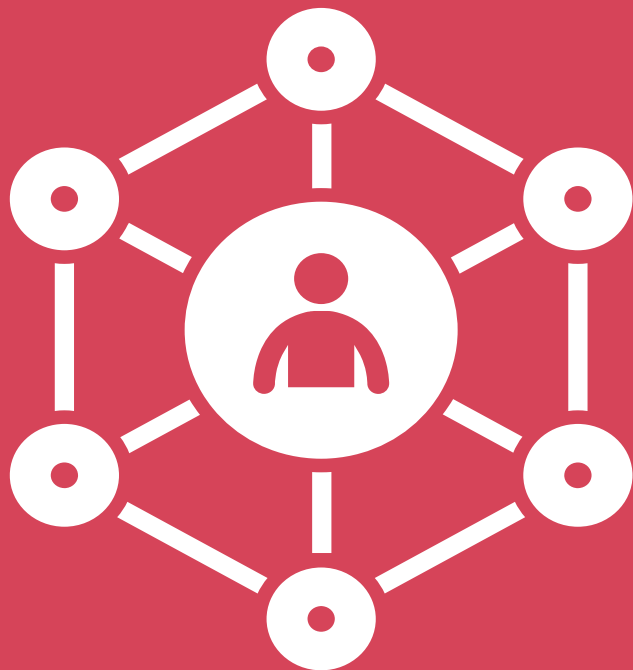


- ▶ During the 2023 legislative session, the Maryland General Assembly passed Chapter 249 (House Bill 812), *Health – Reproductive Health Services – Protected Information and Insurance Requirements*
 - Establishes protections for the disclosure of legally protected health care* by health information 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) (*see appendix for more information*)
- ▶ MHCC is required to adopt emergency regulations within nine months (March 2024) to support implementation
 - Requires amending Chapter 7 and 18 of the Code of Maryland Regulations (COMAR)

**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*



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*)



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*)



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

Draft Emergency Regulations



Background



- ▶ 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*)



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

Regulation .01 Scope and Purpose



- ▶ 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



- ▶ 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



- ▶ 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



- ▶ 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



- ▶ 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



Summary of Amendments to COMAR 10.25.07, *Certification of Electronic Health Networks and Medical Care Electronic Claims Clearinghouses*



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*



Next Steps

Timeline – Anticipated



- ▶ 2023
 - Request informal comments through October
 - Incorporate feedback and present proposed emergency regulations at the December 21st Commission meeting
- ▶ 2024
 - Publish emergency regulations in Maryland Register in Q1 (adoption period up to 180 days)
 - Present proposed permanent changes to Chapters 7 and 18 incorporating changes as a result of the emergency regulations in March



The End





Appendix



Chapter 296 (House Bill 812), *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

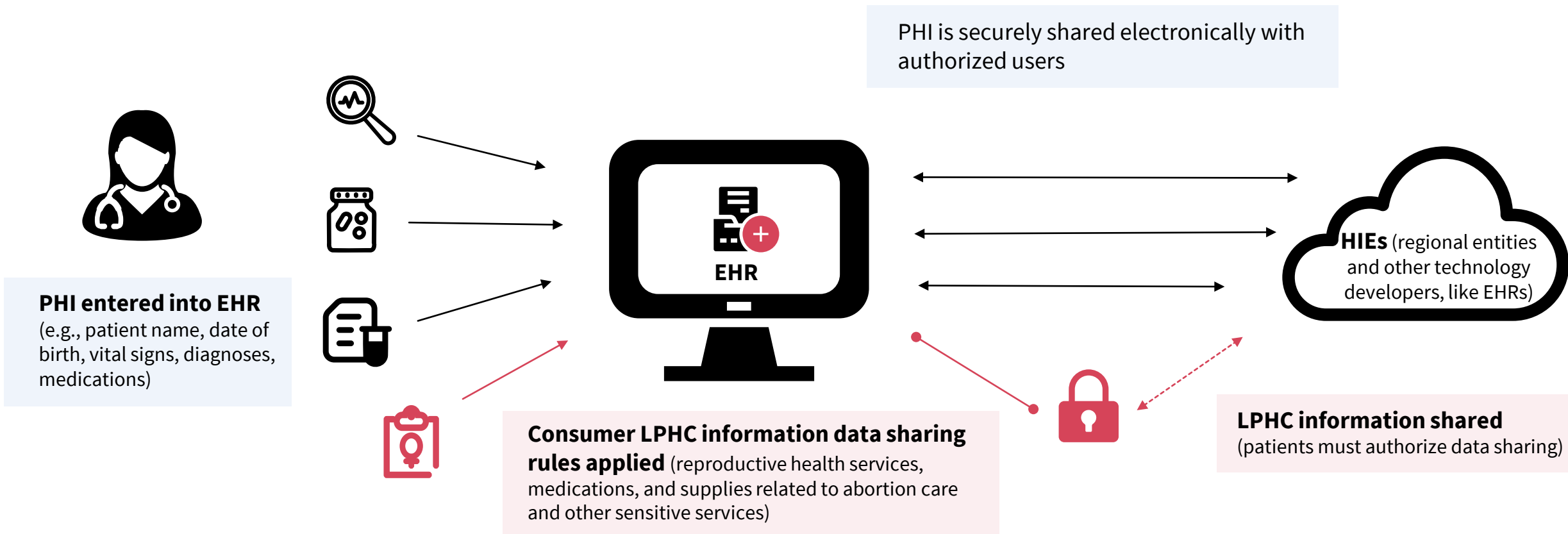
**Includes the disclosure of mifepristone data, the diagnosis, procedure, medication, and related codes for abortion care, and other sensitive health services as determined by the Secretary of Health and Protected Health Care Commission*

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

Legally Protected Health Care (LPHC) Information



Workflow Scenario



- ▶ 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 (*see appendix for more information*)
 - 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

PHCC Membership *(Continued)*



- ▶ **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 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



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.



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.		



Chapter 18 Modernization Efforts

Modernization



- ▶ August 2020 – Activities began to align the regulations with federal policy (21st Century Cures Act and ONC Health IT Certification program final rule); Post & Schell, P.C. was competitively selected to assist with development of draft amendments
- ▶ 2021 and 2022 – Legislation passed by the General Assembly required amendments to the regulations; the legislation revised the definition of an HIE and requires CRISP to operate a health data utility (HDU), among other things
- ▶ June 2023 – Stakeholders reviewed preliminary draft amendments; staff received about 150 comments from 10 organizations
- ▶ Modernization activities have slowed as staff shifted attention to developing draft emergency regulations as required by House Bill 812 (2023)

Modernization *(Continued)*



- ▶ 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*

Modernization 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

Modernization 2022 Legislation



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

- ▶ Establishes a HDU to be 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