

MARYLAND REGISTER

Proposed Action on Regulations

Comparison to Federal Standards Submission and Response

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In accordance with Executive Order 01.01.1996.03 and memo dated July 26, 1996, the attached document is submitted to the Department of Business and Economic Development for review.

The Proposed Action is not more restrictive or stringent than corresponding federal standards.

COMAR Codification: 10.25.18.01, .02, .03, .04, .10, .11 and .12

Corresponding Federal Standard:

U.S. Department of Health and Human Services (HHS), Confidentiality of Substance Use Disorder Patient Records, 42 Code of Federal Regulations (CFR) Part 2, effective March 21, 2017

Discussion/Justification:

Health-General Article §§4-301, 4-302, 19-101, and 19-143, (2011) requires the Maryland Health Care Commission to adopt regulations for the privacy and security of protected health information obtained or released through a health information exchange. The requirements in regulations for the use of sensitive health information must align with the U.S. Department of Health and

Human Services (HHS) Confidentiality of Substance Use Disorder Patient Records regulations found in 42 CFR Part 2 (Part 2). HHS updated these regulations, effective March 21, 2017. Amendments to the current regulations COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information are required in order to be consistent with Part 2.

TO BE COMPLETED BY DBED

-Agree

-Disagree

Comments:

Name:

Date:

-Submit to Governor's Office

Governor's Office Response

Comments:

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	05/02/2018	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 6/8/2018

2. COMAR Codification

Title Subtitle Chapter Regulation

10 25 18 01, .02, .03, .04, .10, .11 and .12

3. Name of Promulgating Authority

Maryland Health Care Commission

_ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

11. Certificate of Authorized Officer

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Suellen Wideman, Assistant Attorney General, (telephone #410-764-3326) on February 15, 2018. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Robert E. Moffit, Ph.D.

Title

Chair

Telephone No.

410-764-3460

Date

February 15, 2018

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

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

Authority: Health-General Article, §§4-301, 4-302.2, 4-304, 19-101, and 19-143, Annotated Code of Maryland

Notice of Proposed Action

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The Maryland Health Care Commission proposes to amend Regulations .01, .02, .03, .04, .10, .11 and .12 under COMAR 10.25.18 Health Information Exchanges: Privacy and Security of Protected Health Information.

This action was considered by the Commission at an open meeting held on February 15, 2018, notice of which was given through publication in the Maryland Register, pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to amend the regulations that govern the operation of Health Information Exchanges (HIEs) in Maryland. These amendments are designed to support the electronic exchange of sensitive health information (SHI) for treatment while ensuring appropriate confidentiality protections for information that might

identify an individual, directly or indirectly. The amendments include provisions that allow HIEs to exchange SHI through electronic transmission other than by point-to-point (secure email). These regulations are aimed at ensuring that patients whose health care records include SHI (such as a substance use disorder) have the ability to participate in, and benefit from electronic health information exchanged through HIEs operating in Maryland. COMAR 10.25.18.03D includes a non-substantive change regarding requirements that went into effect on June 19, 2017.

Comparison to Federal Standards

There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

Estimate of Economic Impact

I. Summary of Economic Impact.

The amended regulations provide requirements for the private and secure exchange of SHI accessed, used, or disclosed through a HIE. The initial economic impact on certain entities is expected to be moderate; however, building trust in HIE is essential to ensure that the potential benefits of reduced health care cost may be realized.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
<hr/>		
A. On issuing agency:		
Maryland Health Care Commission	(E+)	Within Budget
B. On other State agencies:		
Other State Agencies	NONE	
C. On local governments:		
Local Governments	NONE	
	Benefit (+) Cost (-)	Magnitude
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D. On regulated industries or trade groups:		
(1) Regulated Industries and Trade Groups	(+)	Moderate
(2) Regulated Industries and Trade Groups	(-)	Moderate
E. On other industries or trade groups:		
Other Industries or trade groups	NONE	
F. Direct and indirect effects on public:		
Direct Indirect Effects on Public	(+)	Moderate

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The MHCC is the State agency responsible for advancing health information technology throughout Maryland. The chapter requires MHCC to monitor compliance with the regulations. The MHCC can support this chapter using current staff within the MHCC's budget.

B. Other State agencies do not meet the definition of an HIE, as defined in COMAR 10.25.18.02B; as such, there is no impact on State agencies.

C. Local governments do not meet the definition of an HIE, as defined in COMAR 10.25.18.02B; as such, there is no impact on local governments.

D(1). The regulations are essential to ensuring the privacy, confidentiality, and security of particularly sensitive patient information exchanged electronically. The regulations ensure positive changes to the industry, increase control of health care consumers, and improve consumer trust in electronic HIE.

D(2). The regulations are expected to have a moderate financial impact on organizations that meet the definition of an HIE as defined in COMAR 10.25.18.02B.

E. The regulations are not expected to have an impact on other industries and trade groups.

F. The regulations are expected to have a positive impact on the public. These regulations are necessary to ensure that robust protections are in place for the electronic exchange of SHI. They also provide health care consumers control over their electronic health information and allow HIEs flexibility in terms of the methods of exchanging SHI in a private and secure manner.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Angela Evatt, Chief, Health Information Exchange, Center for Health Information Technology, Maryland Health Care Commission, 4160 Patterson Avenue, or call 410-764-3574, or email to angela.evatt@maryland.gov, or fax to 410-358-1236. Comments will be accepted through July 9 at 4:30 p.m. A public hearing has not been scheduled.

Open Meeting

Final action on the proposal will be considered by the Maryland Health Care Commission during a public meeting to be held on September 20, 2018 at 1:00 p.m., at 4160 Patterson Avenue, Room 100, Baltimore, MD 21215.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 19

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

Maryland Health Care Commission
Special Funds

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The regulations are expected to have minimal or no economic impact on small businesses. Typically small businesses may provide tertiary services to HIEs but are not the organization that meets the definition of an HIE as defined in COMAR 10.25.18.02B.

G. Small Business Worksheet:

Attached Document:

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 25 MARYLAND HEALTH CARE COMMISSION

Chapter 18 Health Information Exchanges: Privacy and Security of Protected Health Information

Authority: Health-General Article, §§4-301, 4-302.2, 4-304, 19-101, and 19-143, Annotated Code of Maryland

.01 Scope and Purpose.

A. (text unchanged)

(1) A health information exchange, as defined in Regulation [.02B(25)].02B(28) of this chapter;

(2)–(3) (text unchanged)

C. –D. (text unchanged)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)–(9) (text unchanged)

(10) “Care management organization”, in the context of secondary use, means any entity that:

(a)–(b) (text unchanged)

(c) Is operating [under the] *in accordance with* Maryland's All-Payer Model [Contract approved by] or successor agreement between the [federal Center] Centers for Medicare and Medicaid [Innovation] Services and the State of Maryland;

(d) (text unchanged)

(11)—(23) (text unchanged)

(24) "*Granular patient consent*" means expressed preferences made by a health care consumer regarding the disclosure, access, and use of the patient's protected health information according to the type of information, type of provider, purpose, or circumstance communicated by the health care consumer to the HIE through reasonable means specified by the HIE, which shall include paper and electronic means.

[(24)] (25)—[(35)] (36) (text unchanged)

(37) "*Nationally recognized standards*" means technical standards for the exchange, integration, sharing or retrieval of electronic health information considered reliable by the health IT industry nationally.

[(36)] (38)—[(38)] (40) (text unchanged)

[(39)] (41) "Part 2" means the federal Confidentiality of [Alcohol and Drug Abuse Patient Records regulations found in 42 CFR Part 2.] *Substance Use Disorder Patient Records final rule, 82 Fed. RE. 6052-01 (Jan. 18, 2017); 42 CFR §2.1-2.67 (2017).*

[(40)] (42)—[(44)] (46) (text unchanged)

[(45)] (47) "Person in interest" means any of the following, but does not include a participating organization:

(a)—(d) (text unchanged)

(e) If [§B(43)(d)] §B(45)(d) of this regulation does not apply to a minor:

(i)—(ii) (text unchanged)

(f) (text unchanged)

[(46)] (48)—[(63)] (65) (text unchanged)

.03 Rights of a Health Care Consumer Concerning Information Accessed, Used, or Disclosed Through an HIE.

A.—D. (text unchanged)

D. [Within 6 months of the effective date of this regulation an] An HIE shall:

(1)—(2) (text unchanged)

E.—H. (text unchanged)

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

A. Consistency with disclosure requirements under federal and State law.

(1) A person shall comply with all relevant State and federal laws, including [but not limited to] 42 CFR Part 2, concerning the access, use, or disclosure of sensitive health information through an HIE and maintenance of such information by an HIE. [Until the Commission issues regulations governing the access, use, or disclosure of sensitive health information through an HIE or maintenance of such information by an HIE, all sensitive health information shall only be transmitted via point-to-point transmission.]

(2) If federal or State law requires written consent or authorization for access, use, or disclosure of sensitive health information, a person [shall:] *shall*

[(a) Obtain] *obtain* consent or authorization consistent with the applicable law prior to the access, use, or disclosure of sensitive health information to and through an HIE to an authorized [recipient; and] *recipient*.

[(b) Use only point-to-point transmission to allow access to, use, or disclosure of the sensitive health information through an HIE.]

(3) Notwithstanding [§A(2)(a)] §A(2) of this regulation, an HIE may transmit sensitive health [information via point-to-point transmission:] *information:*

(a) (text unchanged)

(b) In an emergency, [as defined by Health-General Article, §4-301(d), Annotated Code of Maryland,] if a health care provider makes a professional determination that an immediate disclosure is necessary to provide for the emergency health care needs of a patient or recipient.

(4) *An HIE shall use only point-to-point transmission to allow access, use, or disclosure of the sensitive health information through an HIE, unless the HIE implements:*

(a) *Nationally recognized standards that support control by the health care consumer over the electronic exchange of the patient's sensitive health information consistent with the privacy and consent directives made by the health care consumer;*

(b) *Electronic exchange controls and processes that:*

(i) *Support granular patient consent for the electronic transmission of sensitive health information consistent with applicable State and federal laws concerning the access, use, or disclosure of sensitive health information, including applicable standards and technical requirements in accordance with Part 2;*

(ii) *Assure that the health care consumer's granular consent controls remain associated with the sensitive health information and are adhered to as the information is transmitted through, maintained, or disclosed by the HIE.*

(c) *Health care consumer educational content that:*

(i) *Is developed and established in coordination with MHCC and stakeholders;*

(ii) *Is kept current; and*

(iii) Receipt of which shall be acknowledged by the health care consumer as part of the granular consent process.

[(4)] (5) (text unchanged)

B. Procedure for disclosing or re-disclosing of Part 2 health information.

(1) (text unchanged)

(2) A participating organization that receives Part 2 information may not re-disclose such information without appropriate patient consent or authorization, as [otherwise] permitted by *applicable federal and State laws and [these] regulations*.

(3) (text unchanged)

.10 Requirements for Accessing, Using, or Disclosing of Data Through an HIE for Secondary Use.

A. Population Care Management.

(1)–(3) (text unchanged)

(4) *An HIE shall not disclose a patient's sensitive health information for population care management purpose unless permitted by applicable federal and State laws and regulations.*

B. Research.

(1)–(8) (text unchanged)

(9) *An HIE shall not disclose a patient's sensitive health information for research purpose unless permitted by applicable federal or State laws and regulations.*

C. (text unchanged)

.11 Requirements for Accessing, Using, or Disclosing of Data Through an HIE in an Emergency.

A. (text unchanged)

B. If an HIE's emergency access policy allows the disclosure of information during an emergency, the HIE shall:

(1) Only disclose information to the requesting health care provider if the following conditions are met:

(a)–(b) (text unchanged)

(c) Information available through the HIE may be relevant to the treatment needed by the patient in the specific emergency; [and]

(d) The participating organization has an established policy that describes the requirements and attestation process for emergency [access.] *access; and*

(e) *Disclosure of information available through the HIE is not in violation of applicable federal and State laws and regulations related to sensitive health information.*

(2)–(6) (text unchanged)

.12 Requirements for Providing Health Care Consumers Electronic Access to Their Health Information.

A. (text unchanged)

(1)–(8) (text unchanged)

(9) Establish processes and procedures that allow an individual to electronically access health information for a patient or patients:

(a) (text unchanged)

(b) For whom the patient has authorized such [access; and] *access*.

(10) Establish processes and procedures to confirm the authority of a person in interest, if not directly authorized by a patient, which must be satisfied as a condition to providing access to that person in [interest.] *interest; and*

(11) *Comply with applicable federal and State laws and regulations related to sensitive health information when disclosing such information to a health care consumer.*

B.–H. (text unchanged)