DRAFT FINAL AMENDMENTS

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

MARCH 20, 2025

State Law 2021

- Chapter 798 (House Bill 1375), *Health Information Exchanges - Electronic Health Information - Sharing and Disclosure*
  - Requires the State-designated Health Information Exchange (HIE) to develop and maintain a centralized consent management application (CMA) allowing persons to opt-out and opt-in from having their protected health information (PHI) shared or disclosed by HIEs operating in the State
  - HIEs operating in the State must update their systems based on the CMA to obtain the opt-out status of a consumer before sharing or disclosing their PHI

State Law 2022

- Chapter 296 (House Bill 1127), *Public Health – State Designated Exchange – Health Data Utility*
  - Establishes a health data utility (HDU), operated by the State-designated HIE, to assist with public health interventions, advance health equity, facilitate data exchange between public health officials and providers, and enhance interoperability
  - Requires dispensers* to submit information of non-controlled prescription drugs (non-CDS) to the State-designated HIE
  - Requires the State-designated HIE to establish a Consumer Advisory Council (CAC) with select members to share perspectives of individual and organizations with an interest in protecting consumers as it relates to the delivery of services by the State-designated HIE

**Dispenser means a person authorized by law to dispense non-CDS to a patient or a patient's agent in the State*

Regulations

- COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information,* is the regulatory framework to support implementation of State law
- Informal comments to draft amendments received in May 2024 informed proposed permanent regulations approved at the October 2024 Commission meeting
- The regulations were published in the Maryland Register on December 2, 2024; an opportunity for public comment was open through January 2, 2025
  - Staff considered roughly 39 comments with some recurring themes from five organizations and made seven non-substantive changes
  - Comments that did not result in a change included: clarification of regulatory interpretations, technical matters that do not require granularity in regulation, and assurances that can be obtained via third-party risk management

Public Comment Themes

Resulted in changes to the regulations:

- CMA implementation processes and timeline
- Non-CDS implementation timeline and data retention
- Data sharing for public health purposes

Amendments Based on Public Comments

Consent Management Application

- Clarifies that the State-designated HIE shall inform a person of interest of the types of electronic health information that may be shared or disclosed by the State-designated HIE – regulation .03 D (1) (c)
- Extends the timeline for the State-designated HIE to make the CMA available, from six to 12 months of the regulation effective date – regulation .03 D (2)
- Shortens the timeline for HIEs to connect to the CMA, from 18 to 12 months – regulation .03 D (4) (b) (i)
- Clarifies that HIEs shall continue accepting opt-out and opt-in requests from health care consumers directly – regulation .03 D (7)

Dispenser Reporting of Non-CDS

- Clarifies the State-designated HIE must not retain non-CDS information for patients who opt-out of the State-designated HIE – regulation .13 E (1) (d)
- Specifies the date (January 1, 2026) that the State-designated HIE must make patient-specific non-CDS dispense information available – regulation .13 E (4)
- Clarifies that non-CDS data provided by the State-designated HIE to select entities for public health purposes may only be provided as allowed by applicable law – regulation .13 E (5)

Commission Action Items

- 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 with an effective date of April 14, 2025

Appendix

All Proposed Amendments

Consent Management Application

- Adds a "consent management application" definition and clarifies the meaning of "opt out" to be inclusive of consumer requests via the CMA – regulation .02 B (12) & (57)
- Lists the required CMA components that CRISP must develop and the implementation timeline – regulation .03 D (1), (2), & (3)
- Requires HIEs to connect to the CMA and describes how connectivity must be established and maintained – regulation .03 D (4) & (5)
- Adds a requirement for HIEs to link to CRISP's website with information on using the CMA to opt out and back into data sharing and to continue managing local opt outs – regulation .03 D (6) & (7)
- Requires CRISP to notify MHCC if the CMA is not operational and when services resume – regulation .03 D (8)
- Adds exceptions to complying with §D(3) and clarifies that requirements are in addition to restrictions of certain information (e.g., Part 2) – regulation .03 D (9) & (10)

Dispenser Reporting of Noncontrolled Prescription Drugs

- Includes dispensers as part of the scope of Chapter 18 – regulation .01 B (4)
- Adds definitions for "dispense," "dispenser," and "noncontrolled prescription drugs" – regulation .02 B (23), (24), & (54)
- Adds a regulation requiring dispenses to report each noncontrolled prescription drugs dispenses to CRISP – regulation .13 A
- Requires MHCC to develop a *Noncontrolled Prescription Drugs Dispenser Data Submission Manual* (manual) annually and describes specific information to be included in the manual, timing and frequency of reporting, certain technical specifications, processes for requesting public comments and Commission approval, and processes for making the manual available to the public and notice of any updates – regulation .13 B & C
- Reporting deadlines and procedures for CRISP to accept and disclose dispense information – regulation .13 D & E
- Procedures for dispenser to request a waiver from reporting – regulation .13 F

Operation of the Health Data Utility

- Adds definitions for “Health Data Utility,” “improvement of patient safety,” “state health improvement program”– regulation .02 B (37), (46), & (78)
- Adds a regulation requiring CRISP to operate as an HDU and implement the CMA in accordance with regulation .03 D – regulation .14 A & B
- Explains protocols for disclosures of clinical information or electronic health care transactions by CRISP and requires CRISP to be designated as a reporting entity to the Maryland Medical Care Data Base – regulation .14 C
- Requires collaboration between CRISP and certain State agencies on data uses pertaining to a State health improvement program, mitigation of a public health emergency, improvement of patient safety; and any other public health priorities identified by the Secretary – regulation .14 D
- Requires CRISP to establish a Consumer Advisory Council that includes certain representation and adheres to the Maryland Open Meetings Act – regulation .14 E