Draft *Noncontrolled Prescription Drug Dispenser Data Submission Manual*

APRIL 17, 2025

Background - State Law

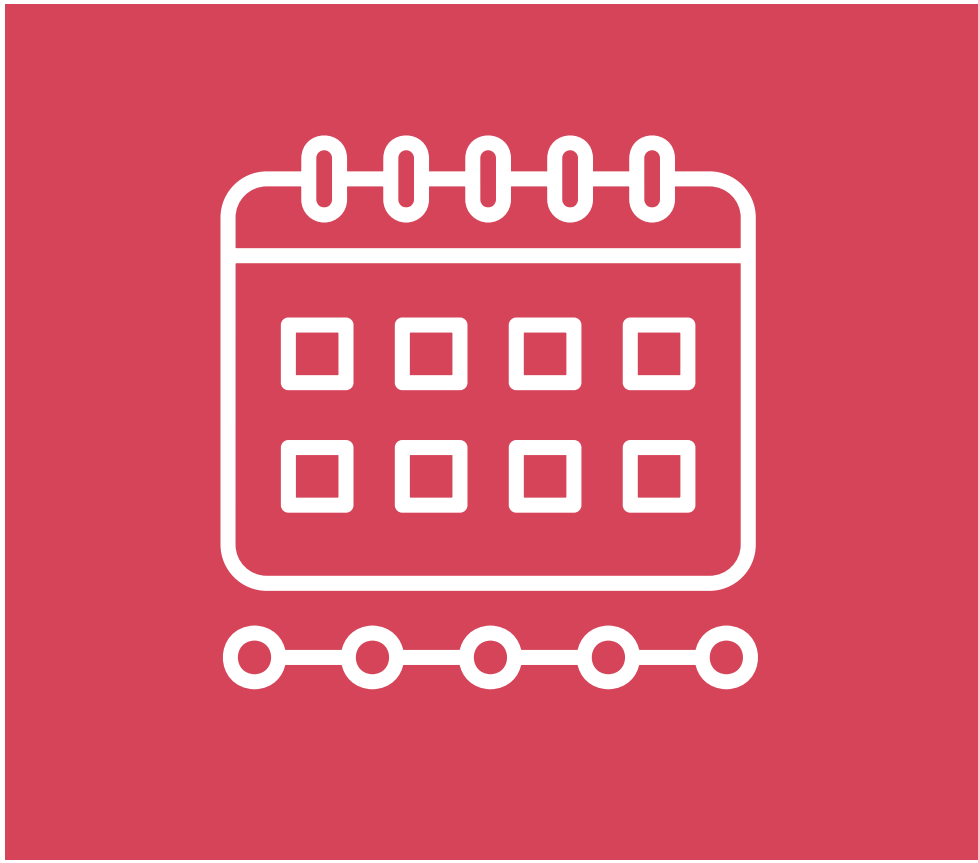
- Chapter 296 (House Bill 1127), *Public Health – State Designated Exchange – Health Data Utility*
  - Requires dispensers submit information to the State-Designated health information exchange (CRISP) after dispensing a noncontrolled prescription drug (non-CDS)
  - CRISP will make prescription drug information available for purposes of:
    - Treatment and care coordination of a patient
    - Public health and quality improvement

Regulations

- COMAR 10.25.18, *Health Information Exchanges: Privacy and Security of Protected Health Information,* is the regulatory framework to support implementation of Chapter 296
- The regulations require MHCC develop a *Noncontrolled Prescription Drug Dispenser Data Submission Manual* (dispenser manual)
- The dispenser manual must align, to the extent possible, with the Maryland Prescription Drug Monitoring Program (PDMP) *Data Submitter Guide* and minimally specify the:
  - Data that must be submitted to CRISP and in what format
  - Timeframe and frequency of data submission
  - Electronic reporting specifications (e.g., encryption, file layout)
  - Process for dispensers unable to submit data due to mechanical, electrical, or other technical failure

Regulations (*continued…*)

- The Commission must approve the dispenser manual annually after a 20-day public comment period
  - The draft dispenser manual will be posted on MHCC's website and the Maryland Register in May (anticipated)
  - Staff will consider any comments received and make changes, as appropriate
  - The draft dispenser manual will be presented to the Commission for approval in June (anticipated)



Note: Dispenser reporting of non-CDS prescription drugs begins September 1, 2025 (COMAR 10.25.18.13)

Overview of the Draft Dispenser Manual

To be posted online for public comment

Components

The dispenser manual provides technical guidance for non-CDS reporting in alignment with the PDMP submission process for controlled dangerous substances

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

Where: Reporting will occur using the RxGov platform

What: Data must be submitted in the same (ASAP) format

How: Dispensers will be able to submit one file with dispense information for both controlled dangerous substances and non-CDS drugs

When: Dispensers must report daily, including submission of a 'zero report'

Stakeholder Engagement

- A multi-stakeholder approach guided iterative development of the draft dispenser manual
  - Included representatives form ~17 dispensing organizations and technology vendors, Nebraska and Maryland PDMP, CRISP, and Leap Orbit (CRISP's technology vendor)
- Preliminary planning began with the Noncontrolled Prescription Drugs Workgroup, which convened about six times (October 2022 to February 2023)
- Stakeholders, including dispensers (chain and independent pharmacies), reviewed and provided feedback on informal drafts of the draft dispenser manual in summer 2024, fall 2024, and spring 2025

Commission Action Items

- Staff requests the Commission approve posting the draft dispenser manual for a 20-day public comment period

Note: If approved, the manual is anticipated to be published in the May 2nd issue of the Maryland Register; the final draft manual will be presented at the June 12th meeting of the Commission