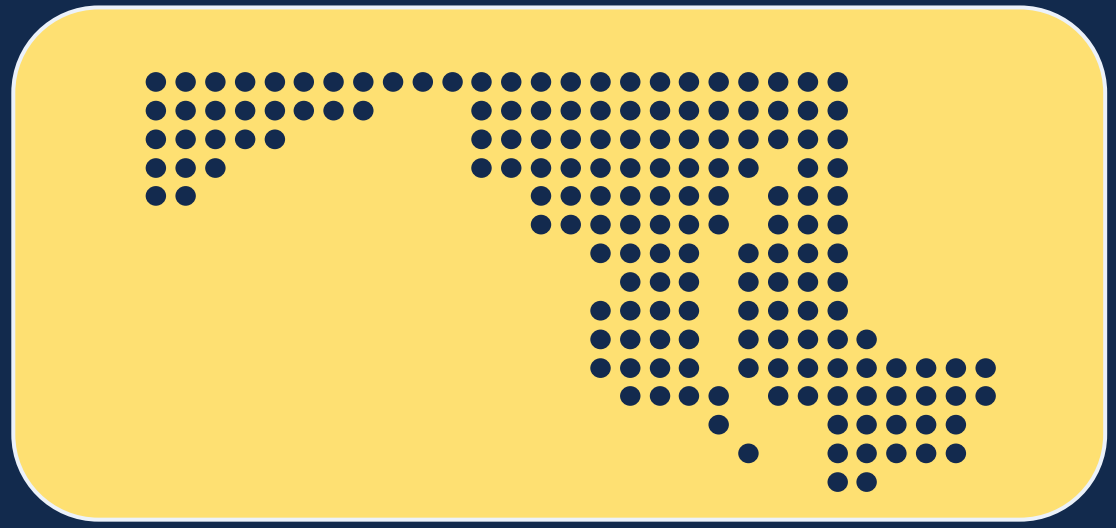


Draft – *Noncontrolled Prescription Drug Dispenser Data Submission Manual*

May 21, 2026

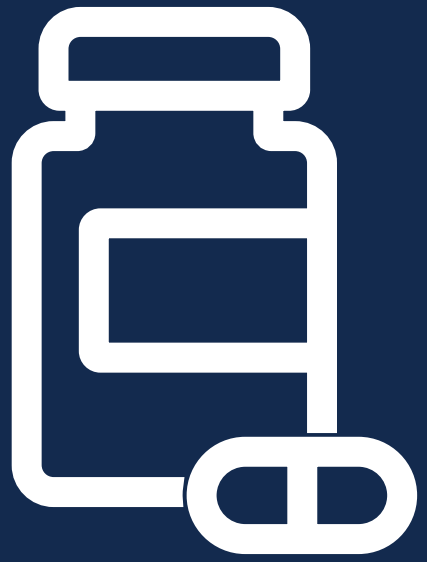
Presentation Overview

- Overview Maryland law (2022)
- Describe the annual requirement in regulation (COMAR 10.25.18.13) for updating the *Noncontrolled Prescription Drug Dispenser Data Submission Manual* (dispenser manual)
- Discuss non-controlled prescription drug (non-CDS) reporting drivers and stakeholder process

Background

- Legislation enacted in 2022 (Chapter 296, *Public Health – State Designated Exchange – Health Data Utility*) requires dispensers to submit non-CDS dispense information to CRISP
- The law requires CRISP to make non-CDS information available for:
  - Treatment and care coordination of a patient
  - Public health and quality improvement
- COMAR 10.25.18 is the supporting regulatory framework that operationalized non-CDS reporting
  - Dispenser reporting began in September 2025
- The regulations require MHCC to annually develop and approve the dispenser manual by June 1st
  - Version 1.0 was issued in June 2025

Non-CDS Reporting Drivers



- Access to comprehensive medication history is critical for informed clinical decisions
  - Incomplete medical records increase patient safety risks
- Medication errors rank as the most frequent and avoidable source of patient harm
  - Nationally, adverse drug events cause more than 1.5 million emergency department visits annually*

* Centers for Disease Control and Prevention, FastStats: Medication Safety Data., April 2024

Updating the Dispenser Manual

- **January 2026:** Staff, in collaboration with CRISP and stakeholders, began exploring potential updates to the dispenser manual
- **February 2026:** Select dispensers reviewed and expressed support for informal draft updates to the dispenser manual
  - Draft updates clarify certain processes for non-CDS reporting and are considered non-substantive
- **April 2026:** The dispenser manual with proposed updates was published in the Maryland Register with a public comment period from April 17 – May 7, 2026
  - No comments were received

2026 Draft Updates

Proposed Non-Substantive Changes

- ***Data Submitter Account***
  - Updated images and descriptions of how to set up and manage an account in the reporting platform (RxGov); *pages 6-13*
- ***Managing Error Corrections***
  - Added information about new functionality in RxGov that allows submitters to assign roles for staff and to review and manage errors; *pages 24-27*
- ***Required Information for Each Dispense Submitted***
  - Removed warnings for missing identifier in the RxNorm field and required an NDC for each dispense; *Appendix A, pages 43 and 46*
- ***Zero Reports***
  - Clarified instructions for submitting zero reports, including fields to complete and appropriate values; *Appendix B, page 49*

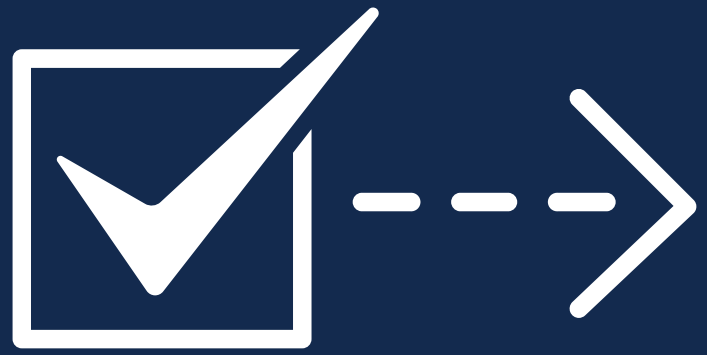
Commission Action

Dispenser Manual

Staff request the Commission approve the *Noncontrolled Prescription Drug Dispenser Data Submission Manual* as final

Commission Action

Consent Agenda



Staff recommends the Commission add a category to the Consent Agenda for future meetings to include non-substantive updates to MHCC's technical manuals, including the *Noncontrolled Prescription Drug Dispenser Data Submission Manual*

Thank you

Questions?

Appendix

Regulations

- COMAR 10.25.18.13, *Noncontrolled Prescription Drugs Dispenser Reporting,* requires MHCC to develop a dispenser manual that aligns, to the extent possible, with the dispenser submission process for the Maryland Prescription Drug Monitoring Program (PDMP)
- Regulations require the draft dispenser manual be posted in the Maryland Register for a 20-day public comment period before the Commission considers the manual for approval
- Existing regulations adopted by the Maryland Department of Health in 2014 established reporting requirements for the Maryland PDMP specific to controlled dangerous substances (CDS)
- The PDMP assists providers with the care delivery and clinical decisions, and public health and safety authorities with reducing the misuse, abuse, and diversion of CDS

Key Components of the Dispenser Manual

The **dispenser manual** provides technical guidance for non-CDS reporting, in alignment with the PDMP submission process for CDS

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 occurs in the RxGov platform

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

How: Dispensers may submit one file with dispense information for both CDS and non-CDS drugs

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