



# ***Final Draft Noncontrolled Prescription Drug Dispenser Data Submission Manual***

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**JUNE 12, 2025**

# Background - State Law



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



# Drivers for the Law – National Perspective

- ▶ Medication discrepancies and adverse drug events pose significant challenges to patient safety and the delivery of high-quality care
  - Adverse drug events cause more than 1.5 million emergency department visits annually across the country<sup>1</sup>
  - The American Society for Pharmacovigilance estimates that adverse drug events account for over 250,000 deaths a year<sup>2</sup>
- ▶ Incomplete medical records can have far reaching consequences including misdiagnosis and inappropriate treatment, delays in care, and patient safety concerns

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

2. American Society for Pharmacovigilance. (2025, March 24). *America's Silent Epidemic Worsens: Adverse Drug Events Now the Third Leading Cause of Death* [Press Release].

# Expanding Access to Dispense Information



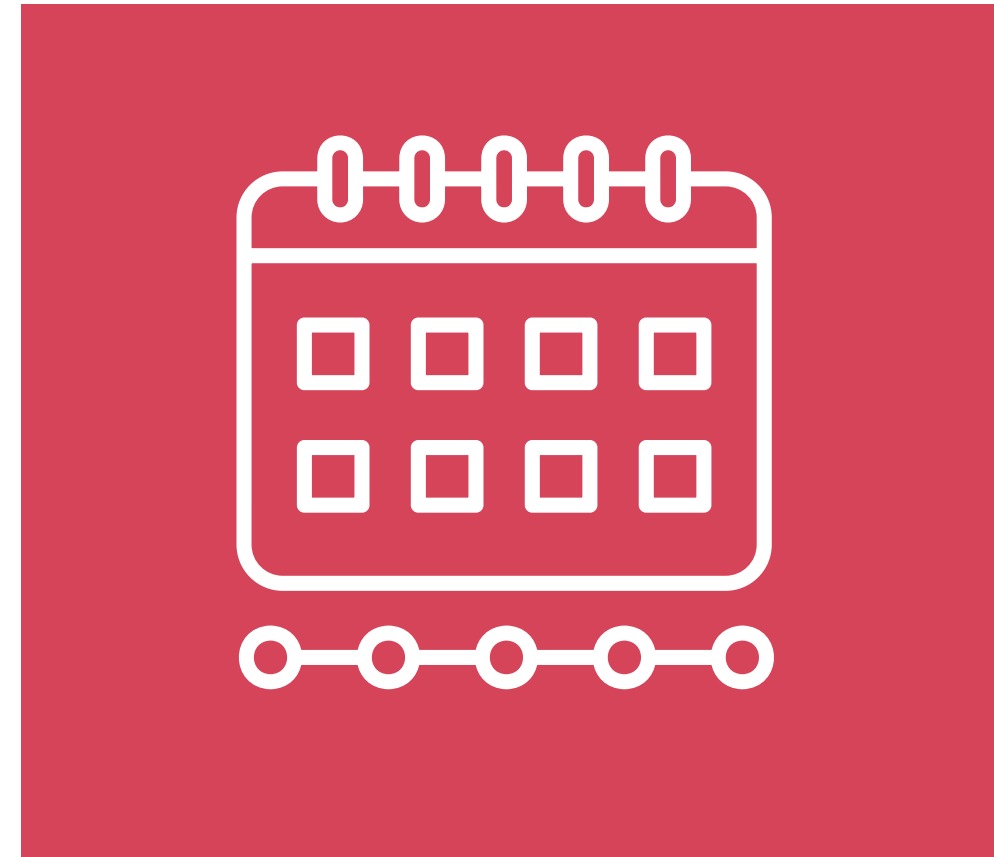
- ▶ The Maryland Prescription Drug Monitoring Program (PDMP) currently makes dispense information for controlled dangerous substances (CDS) available to assist:
  - Providers in care delivery and clinical-decision making
  - Public health and safety authorities with reducing the misuse, abuse, and diversion of prescription drugs
- ▶ More complete patient medication history with information on non-CDS dispenses supports care delivery and public health goals



# Regulations



- ▶ COMAR 10.25.18.13, *Noncontrolled Prescription Drugs Dispenser Reporting*, is the regulatory framework to support implementation of the law
- ▶ Dispensers are required to begin reporting non-CDS dispense information to CRISP by September 1, 2025
- ▶ The MHCC must develop a *Noncontrolled Prescription Drug Dispenser Data Submission Manual* (dispenser manual) that aligns, to the extent possible, with the Maryland PDMP submission process
  - The Commission must approve the dispenser manual annually after a 20-day public comment period



# Awareness Building



- ▶ Educational efforts to inform dispensers of non-CDS reporting requirements and the availability of non-CDS dispense information alongside clinical data within CRISP have commenced
  - Partners including professional associations, licensing boards, chain and independent pharmacies, technology vendors who support reporting to PDMPs on behalf of dispensers, CRISP, and the Maryland PDMP
  - Outreach efforts include a non-CDS flyer with answers to frequently asked questions; dedicated webpage on MHCC's website for non-CDS reporting; webinars (planned); conference presentations; and other communications via email and social media
- ▶ Planning activities are underway to inform patients about the benefits of making non-CDS dispense information available to care teams



# Overview of the Draft Dispenser Manual

# Development



- ▶ A multi-stakeholder approach guided iterative development of the draft dispenser manual
  - Included representatives from ~17 dispensing organizations, Nebraska and Maryland PDMPs, and technology vendors including CRISP and Leap Orbit
- ▶ Preliminary planning began in October 2022; a workgroup convened about six times through February 2023
- ▶ Stakeholders, including chain and independent pharmacies, reviewed and provided feedback on informal drafts of the dispenser manual in summer 2024, fall 2024, and spring 2025
- ▶ The draft dispenser manual was published in the Maryland Register on May 2<sup>nd</sup>; the public comment period ended on May 22<sup>nd</sup>
  - No public comments were received

# Key Components



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 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 CDS and non-CDS drugs

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



# Commission Action Item

- ▶ Staff requests the Commission approve the *Noncontrolled Prescription Drug Dispenser Data Submission Manual* as final

*Note: The final dispenser manual will be posted on MHCC's website and made available to dispensers*

