

Non-CDS Medications



Resources



<https://www.crisphealth.org/applications/prescription-drug-monitoring-program-pdmp/non-cds-medication-data/>

Overview

Clinical Benefits

Registration

Reporting

Documentation

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Overview

The Maryland Health Care Commission (MHCC) and CRISP are beginning collection of non-controlled substances (“non-CDS”) in accordance with Maryland House Bill 1127 Public Health – State Designated Exchange – Health Data. CRISP, in partnership with Leap Orbit, has built an infrastructure to receive, process, store and deliver non-CDS data. **Dispensers will be required to begin reporting non-CDS data starting September 1st, 2025.**

Through the contract between CRISP and Leap Orbit, dispense data will be securely collected and stored using RxGov. This is a web-based program that does not require additional hardware or software.

Clinical Benefits

Through this new infrastructure, CRISP clinical users will be able to review data on all medications a patient has received – not just controlled substances. This will help providers stay properly informed about their patient when prescribing, as well as monitor whether a prescription has been filled by the

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Speakers



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Improving Access to Medication History: Non-CDS Medications

Policy Framework – Maryland Health Care Commission

May 13, 2025

About the Maryland Health Care Commission



The Maryland Health Care Commission (MHCC) is an independent regulatory agency whose mission is to plan for health system needs, promote informed decision-making, increase accountability, and improve access in a rapidly changing health care environment.

Various programs and initiatives support diffusion of health information technology statewide, among other things.



National Perspective

- ▶ Medication errors rank as the most frequent and avoidable source of patient harm
 - ▶ Adverse drug events cause more than 1.5 million emergency department visits annually across the country¹
 - ▶ An estimated 44,000 to 98,000 hospital deaths are attributed to preventable adverse drug events²
- ▶ Medical costs for treating drug-related injuries occurring in hospitals amount to \$3.5 billion a year (not accounting for lost wages and productivity)³
- ▶ 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. Committee on Quality of Health Care in America: Institute of Medicine. To err is human: building a safer health system. Washington, D.C.: *National Academy Press*; 2000.

3. Institute of Medicine. Preventing medication errors. Washington, DC: *National Academy Press*; 2007.



Maryland Law

- ▶ [Chapter 296](#) (House Bill 1127), *Public Health – State Designated Exchange – Health Data Utility* (2022) aims to improve access to comprehensive medication histories for pharmacists and prescribers to support informed treatment and dispensing decisions as well as patient care coordination
- ▶ Requires dispensers to electronically submit information on noncontrolled prescription drugs (non-CDS) dispensed in or into Maryland to CRISP
- ▶ Non-CDS data will be made available for:
 - Public health purposes;
 - Quality improvement purposes; and
 - Treatment and care coordination of a patient for authorized users



Regulations



COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information (regulations) is the regulatory framework to support implementation of Chapter 296

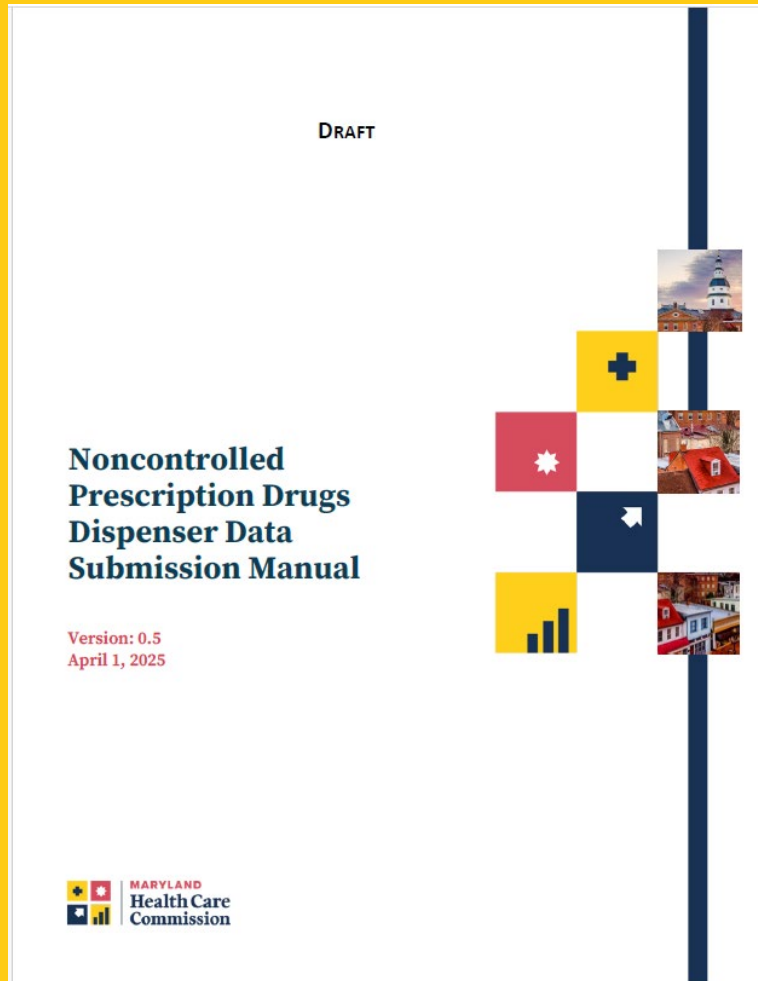
- ▶ Dispenser reporting of non-CDS dispense information begins **September 1, 2025** (COMAR 10.25.18.13)

Why Does Access to Non-CDS Dispense Information Matter?



- ▶ Medication discrepancies and adverse drug events pose significant challenges to patient safety and the delivery of high-quality care
- ▶ The Maryland Prescription Drug Monitoring Program (PDMP) makes dispense information for controlled dangerous substances 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
- ▶ Expanding access to a more complete patient medication history with information on non-CDS dispenses supports care delivery and public health goals

Noncontrolled Prescription Drug Dispenser Data Submission Manual



- ▶ Regulations require the MHCC to develop a *Noncontrolled Prescription Drugs Dispenser Data Submission Manual* (dispenser manual)
- ▶ The dispenser manual must align, to the extent possible with the Maryland PDMP *Data Submitter User 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)
 - Processes for dispensers unable to submit data due to mechanical, electrical, or other technical failure

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



Manual Development

- ▶ A multi-stakeholder approach guided iterative development of the draft dispenser manual
- ▶ 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

Outreach

- ▶ Partnering with CRISP and others to inform dispensers of the upcoming reporting requirements

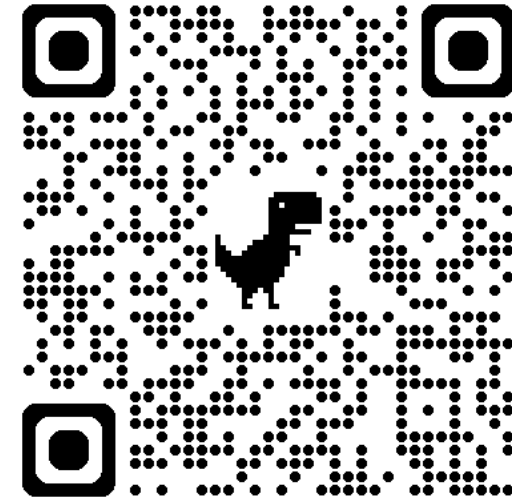




Thank you!



For questions, about the regulatory requirements for non-CDS, please contact MHCC at mhcc.noncds@maryland.gov



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Noncontrolled Medications and CRISP

Maia Gottlieb, MPH – Behavioral Health Lead, CRISP



● What is CRISP's role?

- As the state designated HIE/HDU, CRISP is responsible for collecting non-controlled medication data
- Per CRISP policy, submitters are required to sign one of two agreements:
 - Standard Participation Agreement
 - Connection Agreement

Agreement Options

Participation Agreement

- Standard CSS agreement for all participants
- Allows users to have clinical access
- Requires a panel for access
- CRISP developing automation of panel creation for pharmacies

Connection Agreement

- New agreement type
- Allows for dispensers to submit data to CRISP
- No data visibility in CRISP allowed
- Can see submitted data via RxGov Portal

Note: If a dispenser receives a waiver from MHCC and is not submitting data, no agreement with CRISP is required

● **Non-CDS and CDS Submission:** *Similarities*

Noncontrolled medication submission is set up to align with controlled medication data submission, for ease of use for dispensers

- One file submission (CDS and non-CDS)
- Existing submission method (SFTP, file upload, or manual)
- Existing submission format (ASAP 4.2A, 4.2B, and 5.0 accepted)
- No additional registration required for current dispensers; existing registration applies to non-CDS

● **Non-CDS and CDS Submission: *Differences***

- The dispenser portal will separate controlled from noncontrolled data based on NDC number
- The two groups of medications are subject to slightly different validation rules
 - Ex. Noncontrolled dispenses can be sent with NPI *or* DEA
 - See dispenser manual for more details
- Manual error correction will be done separately – in the PDMP and noncontrolled portals respectively
- New reporting dispensers will have to register in the submission portal

● Accessing the Data

- Clinical CRISP users will be able to see dispensed medication data in the “Dispensed Medication” tab
- Users will only be able to see dispensed data for individuals on their panel
- This is **not** PDMP data, and will be displayed and permissioned separately



Accessing the Data - Mockup

Male | Jan 1, 1984

PDMP **DISPENSED MEDICATIONS** REPORTED MEDICATIONS

Medications

This is data from pharmacy dispenses. Not all pharmacies are sharing data yet and it may not reflect a patient's complete medication list. It also does not fulfill the obligation of users to check PDMP.

Medication	Dosage	Sig	Days Supply	Quantity Dispensed	Refills Remaining	Date Dispensed	Date Written	Prescriber	Pharmacy name
▼ Norvasc	10 MG	Take 1 tablet daily	30	30	0	1/17/2024	1/17/2024	Dr. Wong	WALGREEN CO.
	10 MG	Take 1 tablet daily	30	30	0	12/15/2023	12/12/2023	Dr. Wong	WALGREEN CO.
	10 MG	Take 1 tablet daily	30	30	0	11/15/2023	11/15/2023	Dr. Wong	Rite Aid
	5 MG	Take 1 tablet daily	30	30	0	10/16/2023	10/14/2023	Dr. Wong	CVS
Effexor XR	75 MG	Take 1 capsule by mouth once daily	30	30	30	1/17/2024	1/17/2024	WALGREEN CO.	WALGREEN CO.
	75 MG	Take 1 capsule by mouth once daily	30	30	30	12/15/2024	12/13/2024	Dr. Vargas	CVS
diazepam	5 MG	Take 1 tablet at bedtime	30	30	30	—	11/5/2024	WAL-MART PHARMACY	WALMART-PHARMACY

6210 Annapolis Rd, Landover Hills, MD 20784

Benefits to Non-CDS Medication Dispense Data

More
comprehensive
than other
clinical data

More
immediate
than claims
data

More
accurate
than patient
reported
data

Easy view of
changes to
medications
over time

● Questions?

- To begin onboarding, contact support@crisphealth.org
- With specific questions, contact:
 - Maia Gottlieb – maia.gottlieb@crisphealth.org
 - Alicia Rego – alicia.rego@crisphealth.org



CRISP

Chesapeake Regional Information
System for our Patients

Questions?

Please take our survey



Training materials, and
education flyers can be
found at:

<https://www.crisphealth.org/applications/prescription-drug-monitoring-program-pdmp/non-cds-medication-data/>

CRISP Support

support@crisphealth.org

877-952-7477