



Blueprint for Dispenser Reporting of Non-CDS Dispenses in Maryland

July 23, 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

In collaboration with stakeholders, MHCC implements program and initiatives that support diffusion of health information technology statewide



Background – Maryland Law

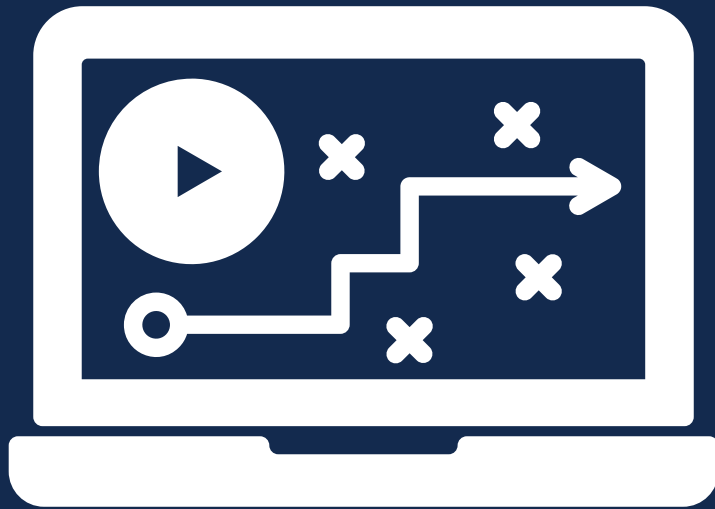
- ▶ [Chapter 296](#) (House Bill 1127), *Public Health – State Designated Exchange – Health Data Utility (2022)* aims to improve access to comprehensive medication histories for pharmacists and prescribers to support informed treatment and dispensing decisions
 - Requires dispensers to electronically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

Background – Maryland Law, *continued*



- ▶ The law requires prescription information to be electronically submitted in a manner that
 - Does not unduly increase the workload or expense on dispensers, and
 - Minimizes burden and duplication by being as compatible as possible with existing data submission practices

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
- ▶ Incomplete medical records can have far reaching consequences including misdiagnosis and inappropriate treatment, delays in care, and patient safety concerns

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



- ▶ [COMAR 10.25.18, Health Information Exchanges: Privacy and Security of Protected Health Information](#) (regulations) is the regulatory framework to support implementation of the law
 - Stakeholders have been engaged in discussions about amendments to support non-CDS reporting since the fall of 2022
 - Feedback helped shape the regulations, which were finalized in April 2025
- ▶ Regulation .13 is specific to non-CDS reporting
 - Requires dispensers to begin reporting non-CDS dispense information to CRISP by **September 1, 2025**
 - Requires MHCC to develop a dispenser data submission manual
 - Establishes a process for dispensers to request a waiver from reporting dispense information
 - Requires CRISP to make dispense information available

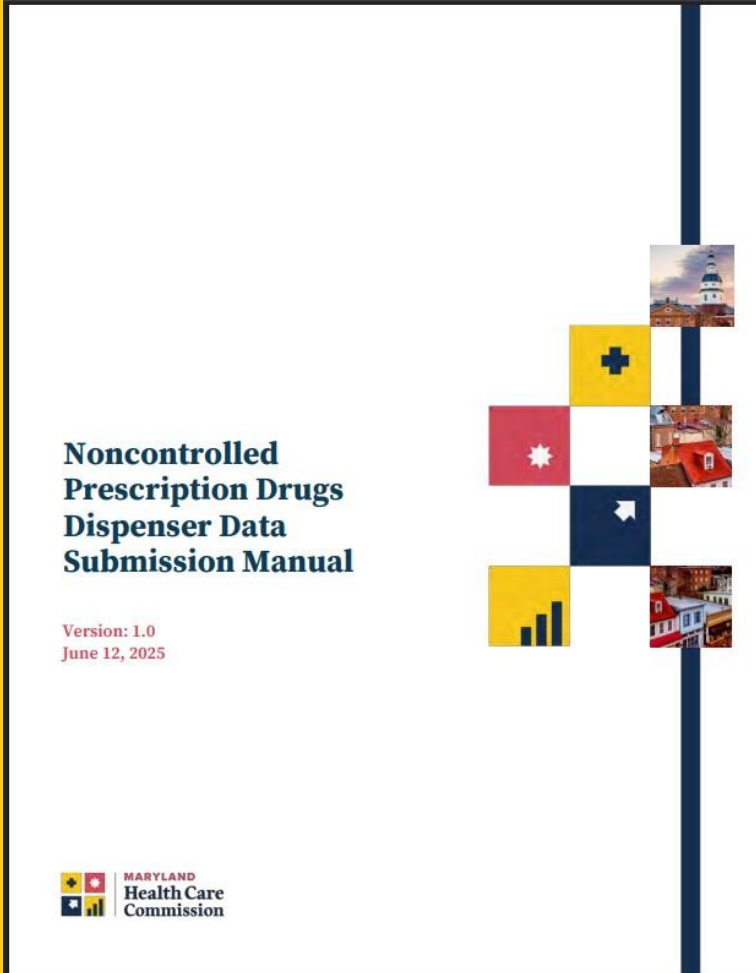
Who is Required to Submit Non-CDS Dispense Information?



- ▶ **Dispenser**: a person or entity authorized by law to dispense a non-CDS to a patient or a patient's agent in the State, including a nonresident pharmacy
- ▶ The following dispensers are **not** subject to the reporting requirement
 - A licensed hospital pharmacy that only dispenses for direct administration
 - An opioid treatment services program, as defined by COMAR 10.27.07.02
 - A veterinarian licensed in Maryland
 - A pharmacy (with a waiver permit under COMAR 10.34.17.03) that provides pharmaceutical specialty services exclusively to persons living in assisted living facilities, comprehensive care facilities, or development disabilities facilities
 - A pharmacy issued a waiver by the Department under COMAR 10.47.07.03G from reporting dispenses to hospice inpatients



Noncontrolled Prescription Drug Dispenser Data Submission Manual



- ▶ The [dispenser manual](#) provides technical guidance to dispensers required to report to CRISP, and includes
 - Non-CDS information 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
- ▶ Aligns, to the extent possible, with the *Maryland PDMP Data Submitter User Guide*



A Multi-Stakeholder Approach

- ▶ Since 2022, stakeholder collaborations have guided iterative development of the dispenser manual
 - Representatives from ~17 dispensing organizations, Nebraska and Maryland PDMPs, and technology vendors including CRISP and Leap Orbit
- ▶ Preliminary planning began with the Noncontrolled Prescription Drugs Workgroup, which convened about six times (October 2022 to February 2023)
- ▶ Select dispensers (chain and independent pharmacies) reviewed and provided feedback on informal drafts of the dispenser manual in summer 2024, fall 2024, and spring 2025
- ▶ The manual was published on May 2nd in Volume 52, Issue 9 of the Maryland Register for a 20-day public comment period; no comments were received



Dispenser Manual – Key Components

At a Glance



- ▶ Dispensers will utilize **RxGov** for non-CDS dispense reporting, the same platform required by the PDMP for CDS reporting
- ▶ Data must be submitted in the same **(ASAP) format**
- ▶ **One file** with dispense information for both CDS and non-CDS drugs may be submitted
- ▶ Reporting must occur **daily**



Zero Reports



- ▶ If a dispenser has no non-CDS dispensing transactions to report for the day, the dispenser must submit a zero report
- ▶ Dispensers must submit a non-CDS zero report even if they reported CDS dispense information to the PDMP
- ▶ The dispenser manual provides further guidance on how to submit zero reports



Waiver Requests



Waiver Request Process

- ▶ The regulations ([COMAR 10.25.18.13F](#)) allow dispensers to request a time-limited waiver from non-CDS reporting
- ▶ Dispensers must attest to meeting one of the following conditions for a waiver request to be considered:
 - Economic hardship
 - Technology limitations that are not reasonably within the dispenser's control
 - Dispensing less than 100 non-CDS prescription drugs annually
 - Other circumstances determined by the Commission to be extenuating
- ▶ A waiver request may be submitted on behalf of multiple pharmacies or dispensing prescribers
- ▶ Receipt of a complete [waiver request form](#) starts the review process, **please ensure all information is accurate and complete**



CRISP

Non-Controlled Medications and CRISP

Maia Gottlieb, MPH – Behavioral Health Lead





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

Note: If submitters have sufficient reason why they are not able to submit right now, they submit a waiver for the year through MHCC. If a waiver is accepted, no agreement is required.

Agreement Options



- *Participation Agreement*
 - Allows for users to submit data and have clinical access
 - Requires a panel for access; CRISP developing a process to automate panel creation for pharmacies using pharmacy NPI
- *Connection Agreement*
 - Allows for dispensers to submit data
- *Waiver*
 - If a dispenser receives a waiver from the state and is not submitting data, no agreement is necessary

Accessing the Data



- Clinical CRISP users will be able to see dispensed medication data in the “Dispensed Medication” tab
- This is **not** PDMP data, and will be displayed and permissioned separately
- This will go live later in 2025

Accessing the Data - Mockup



← HIE InContext
Gilbert Grape
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

Method to submit agreement



- If you want to sign a Participation Agreement (PA) or Connection Agreement (CA):
 - Please email CRISP Support at support@crisphealth.org with the subject line: Pharmacy Onboarding for Non-CDS – [Agreement Name of your choosing]
 - Once you've emailed us, we will send the appropriate form and instructions for signature.
 - We can send samples for review, but please reach out to us directly to complete the agreement

Data Submission Overview



- Dispensers that are currently submitting PDMP data can simply start including non-controlled data as well, starting **today**
- Existing methods of submission will remain the same – SFTP and manual options
- The dispenser portal will separate controlled from noncontrolled data based on NDC number – reporters will **not** need to submit separate files
- Manual error correction will have to be done separately – in the PDMP and noncontrolled portals respectively
- *New* non-controlled dispensers will be required to register with RxGov and begin submitting data

Submission Webinar



Tuesday July 29th, 1pm

https://crisphealth.zoom.us/webinar/register/WN_ew_qgA77Se_aXYqDoTCxBbQ

Ready to submit?



- Let us know! We're happy to work with you on piloting your data and providing feedback on your submissions
- <https://rxgovmd.oneleap.io/>

Benefits to Sharing Non-CDS Medication



- More holistic view of medication history of patients
- More immediate than claims data
- More accurate than patient reported data

Contact



- support@crisphealth.org
- maia.gottlieb@crisphealth.org
- alicia.rego@crisphealth.org

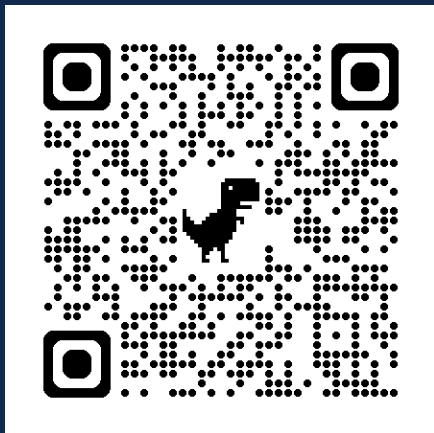




More Information

MHCC has a dedicated non-CDS webpage with information on the law, supporting regulations, the dispenser manual, and online form to request a waiver

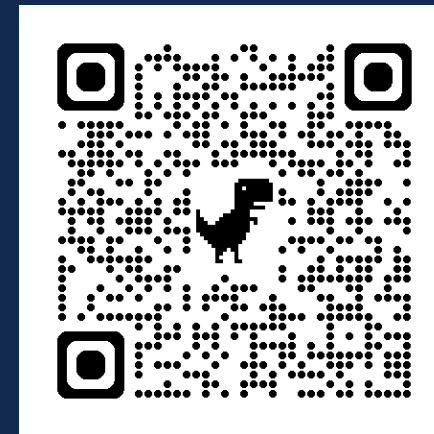
For non-CDS reporting requirements questions, please contact MHCC at mhcc.noncds@maryland.gov



CRISP is hosting the ***Non-CDS Data Submission webinar*** on July 29th at 1pm

During this webinar, CRISP will talk through the technical process for submitting dispense data

Questions for CRISP should be directed to support@crisphealth.org





THANK YOU!