Noncontrolled Prescription Drugs Reporting

Frequently Asked Questions

March 2026

The Maryland Health Care Commission (MHCC) has compiled answers to frequently asked questions (FAQ) as it relates to reporting noncontrolled prescription drug (or non-CDS) dispense information to the State-Designated Health Information Exchange (CRISP). Maryland law requires dispensers to submit non-CDS dispense information to CRISP to support treatment, care coordination, and public health purposes. This FAQ serves as a resource for stakeholders, including pharmacists, pharmacies, and dispensing prescribers, and includes references to the relevant provisions in statute, regulation, and/or the *Noncontrolled Prescription Drugs Dispenser Data Submission Manual*. The information that follows does not constitute legal advice and should not be considered a substitute for a thorough review of Maryland law (Health General §19-145, Annotated Code of Maryland) and supporting regulations (COMAR 10.25.18).

Definitions

1. Who is considered a "dispenser"?

Individuals authorized by law to dispense non-CDS drugs to a patient, or a patient's agent in Maryland, including authorized nonresident pharmacies, are required to report non-CDS dispense information to CRISP. This includes pharmacies with a license from the Maryland Board of Pharmacy and dispensing prescribers with a dispensing permit from their respective Maryland health licensing board. Mail-order pharmacies with a license from the Maryland Board of Pharmacy must submit dispense information for non-CDS medications dispensed into Maryland. The following are exempt from the definition of "dispenser":

- A licensed hospital pharmacy that only dispenses prescription drugs for direct administration to an inpatient of the hospital
- An opioid treatment services program, as defined by COMAR 10.47.07.02
- A veterinarian licensed in Maryland
- A pharmacy issued a waiver permit under COMAR 10.34.17.03
- A pharmacy issued a waiver by the Department under COMAR 10.47.07.03G from reporting dispensing to hospice patients

See COMAR 10.25.18.02B(24)

2. What is a "dispense"?

"Dispense" has the meaning stated in Health Occupations Article, §12–101, Annotated Code of Maryland.

"Dispense" or "dispensing" means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient, or the patient's agent, and which entails:

1. Interpretation of an authorized prescriber's prescription for a drug or device;
2. Selection and labeling of the drug or device prescribed pursuant to that prescription; and
3. Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

See COMAR 10.25.18.02B(23) and *Health Occupations Article, §12–101(j), Annotated Code of Maryland*

3. What are noncontrolled prescription drugs?

A noncontrolled prescription drug means a prescription drug (including a compounded drug) that is not a controlled dangerous substance designated under Criminal Law Article, §5-401, Annotated Code of Maryland.

See Health General Article, §19-145(a)(3), Annotated Code of Maryland and Health General Article, §21-201(e), Annotated Code of Maryland and Health General Article, §21-220(a), Annotated Code of Maryland and *Noncontrolled Prescription Drugs Dispenser Data Submission Manual*, Appendix A.

Scope

4. What information does not have to be submitted to CRISP?

Dispensers do not need to submit the following information to CRISP:

- Prescription drug samples offered to patients
- Medications that are sold without a prescription (e.g., over-the-counter drugs); please note that drugs that could be sold over the counter but are dispensed with a prescription must be reported
- Controlled dangerous substances (CDS) designated under Criminal Law Article, §5-401, Annotated Code of Maryland required to be reported to the Maryland Prescription Drug Monitoring Program (PDMP)
- Information related to the direct administration of medications to patients
- Medical devices
- Clinical services
- Medications for pets

See COMAR 10.25.18.02B(54) and COMAR 10.25.18.02B(23) and Health Occupations Article, §12–102(d), Annotated Code of Maryland

5. Do veterinarians need to submit non-CDS dispense information?

Veterinarians are not required to submit non-CDS dispense information to CRISP.

See COMAR 10.25.18.02B(24)

6. Do hospitals need to submit non-CDS dispense information?

Hospitals with an outpatient/retail pharmacy and hospitals that dispense medications at discharge, such as "bridge" medications, are required to submit non-CDS dispense information to CRISP. Hospitals are not required to report medications directly administered to patients in the inpatient setting.

See COMAR 10.25.18.02B(24)

Timelines

7. When did non-CDS reporting begin?

On September 1, 2025, dispensers began submitting non-CDS dispense information to CRISP, consistent with specifications in the *Noncontrolled Prescription Drugs Dispenser Data Submission Manual*.

See COMAR 10.25.18.13F

8. How often are dispensers required to submit non-CDS dispense information?

Dispensers must minimally submit non-CDS dispense information to CRISP daily and no later than the end of the next business day after the prescription is sold. Daily reporting includes the submission of a zero report on days when no prescriptions are dispensed.

See Noncontrolled Prescription Drugs Dispenser Data Submission Manual, page 5

Data Submission

9. What is the required format to submit non-CDS dispense information?

All dispense information must be submitted using a transmission standard developed by the American Society for Automation in Pharmacy (ASAP). Dispensers must minimally use ASAP version 4.2B, or they may use the newer 5.0 version. The *Noncontrolled Prescription Drugs Dispenser Data Submission Manual* provides detailed technical guidance, including a list of required fields based on ASAP version 4.2B. For questions and technical support submitting dispense information, contact Leap Orbit at rxgovsupport@leaporbit.com.

10. How should medications dispensed for pets be distinguished in data submissions?

If a dispenser includes dispense information for pet medications in its data file, the species code PAT20 with the value '02' is required. Dispensers have the option to omit dispenses for pet medications from the data file.

See Noncontrolled Prescription Drugs Dispenser Data Submission Manual, page 20

11. Are there different reporting requirements for non-CDS dispense information compared to CDS?

Some fields in ASAP version 4.2B have different validation requirements for non-CDS dispenses. Validation rules for non-CDS can be found in Appendix A of the *Noncontrolled Prescription Drugs Dispenser Data Submission Manual*. Fields with a validation status different than the PDMP are highlighted in yellow.

See Noncontrolled Prescription Drugs Dispenser Data Submission Manual, page 35

12. What is the process for dispensers to submit zero reports?

Zero reports can be submitted via SFTP or manually in the RxGov portal. For more information on submitting zero reports via SFTP, refer to Appendix B of the *Noncontrolled Prescription Drugs Dispenser Data Submission Manual*. For more information on submitting zero reports manually in RxGov portal, refer to Section VII, "Zero Reports," on pages 31-32 of the *Noncontrolled Prescription Drugs Dispenser Data Submission Manual*.

Dispensers must submit a non-CDS zero report even if CDS dispense information is reported to the Maryland PDMP. Please refer to the dispenser manual for more information.

See Noncontrolled Prescription Drugs Dispenser Data Submission Manual, pages 31 and 32

Dispenser Waiver of Compliance

13. Who can request a waiver from submitting non-CDS dispense information?

Dispensers seeking a waiver from non-CDS reporting must minimally meet one of the following conditions:

- Economic hardship
- Technology limitations that are not reasonably within the dispenser's control
- Dispensing less than 100 non-CDS drugs annually
- Other circumstances determined by the Commission to be extenuating

Dispensers other than veterinarians who exclusively dispense prescriptions for pets may request a waiver from reporting.

See COMAR 10.25.18.13F

14. What is the process for dispensers to request a waiver?

A waiver request form is available on MHCC's website and must be completed and submitted to MHCC for consideration. A waiver request may be submitted on behalf of multiple pharmacies or dispensing prescribers. The MHCC will review waiver requests and provide a response within 45 days.

See COMAR 10.25.18.13F

Viewing Dispense Information for Clinical Care

15. Who can view patients' prescription history?

Authorized users with an active CRISP Participation Agreement may securely access dispense information to facilitate patient care.

16. How do users access dispense information?

Patient specific dispense information can be viewed in CRISP (via the Portal or InContext) by navigating to the Medication Management tab. For technical support regarding access to dispense information and other clinical data, contact CRISP Support at support@crisphealth.org.

Additional Resources

Webinar: *Blueprint for Dispenser Reporting of Non-CDS Dispenses in Maryland* (July 23, 2025)

Webinar: *Non-CDS Data Submission* (July 29, 2025)

MHCC Non-CDS webpage

CRISP Non-CDS webpage

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

About MHCC

The Maryland Health Care Commission is an independent regulatory agency that promotes informed decision-making, improves access, and enhances accountability in the State's health care system. Learn more by visiting mhcc.maryland.gov or searching MHCCMD on Facebook or X (Twitter).