

## **Noncontrolled Prescription Drugs Reporting**

### ***Dispenser Waiver Request***

#### **Overview**

Maryland [law](#) (2022) requires dispensers, as defined in [COMAR 10.25.18.02B\(24\)](#), to electronically submit certain noncontrolled prescription drug information to the State-Designated Health information Exchange (“CRISP”). CRISP is required to make noncontrolled prescription drug information available for treatment and care coordination purposes. [COMAR 10.25.18.13](#), *Noncontrolled Prescription Drugs Dispenser Reporting*, supports implementation and compliance with the law. Section F of the regulation includes a process for dispensers to request a time-limited waiver from reporting noncontrolled prescription drugs under certain conditions. The Maryland Health Care Commission (“MHCC” or “Commission”) will review and provide a response after receipt of complete information from a dispenser requesting a waiver. For more information, visit MHCC’s website [here](#).

#### **Who is Required to Submit Dispense Information**

All dispensers who dispense noncontrolled prescription drugs in or into Maryland are required to report dispense information to CRISP by September 1, 2025. Dispenser means a person or entity authorized by law to dispense a noncontrolled prescription drug 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 and do not need to submit a waiver request:

- A licensed hospital pharmacy that only dispenses a monitored prescription drug 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 under [Agriculture Article, Title 2, Subtitle 3](#), Annotated Code of Maryland;
- A pharmacy that has been issued 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, and developmental disabilities facilities; and
- A pharmacy issued a waiver by the Department under [COMAR 10.47.07.03G](#) from reporting dispensing to hospice inpatients.

## Conditions for Requesting a Waiver

Dispensers of noncontrolled prescription drugs may seek a waiver based on:

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

## How to Submit a Waiver Request

**Pharmacies:** A pharmacy that holds a pharmacy license from the Maryland Board of Pharmacy may submit a waiver request. A waiver request may be submitted on behalf of all pharmacy locations that dispense in or into Maryland. Respondents who submit a request on behalf of pharmacies with multiple locations are required to submit a [Supplemental Form](#) (Tab B) along with the completed waiver request form.

**Dispensing Prescribers:** Dispensing prescribers who hold a dispensing permit from their respective Maryland licensing board may submit a waiver request. A waiver request may be submitted on behalf of multiple dispensing prescribers. Respondents who submit a request on behalf of multiple dispensing prescribers are required to submit a [Supplemental Form](#) (Tab C) along with the completed waiver request form.

**A waiver request must be submitted online [here](#).** Submission of a complete waiver request, including the supplemental form if required, starts the review process by MHCC. Please ensure all information is accurate and complete.

Please note, all information submitted in a waiver request is subject to the Maryland Public Information Act ("PIA"), General Provisions Article ("Gen. Prov.") [§§ 4-101 to 4-601 \(2014\)](#). The Maryland PIA requires that MHCC deny a request for disclosure of any of its records that contain confidential commercial or financial information or trade secrets (see Gen. Prov. §4-335). Therefore, it is important to clearly identify any information that is believed to fall within the meaning of [Gen. Prov. § 4-335](#) and should be withheld by MHCC in response to any PIA requests.

## Questions

Please direct any questions regarding regulatory requirements for reporting noncontrolled prescription drugs and the waiver request process to [mhcc.noncds@maryland.gov](mailto:mhcc.noncds@maryland.gov).

# Dispenser Waiver Request Form

## Section I: Contact

Name of the individual submitting this waiver request:

Salutation:

Title:

Phone number:

Email address:

Select the category of dispenser requesting a waiver:

- Pharmacy (proceed to Section II)
- Dispensing Prescriber (proceed to Section III)

## Section II: Pharmacy Request

1. Is this waiver request on behalf of a pharmacy with one or multiple locations authorized to dispense noncontrolled prescription drugs in Maryland?

- Single location
- Multiple locations

### Single Location:

2. Pharmacy name:
3. Pharmacy address (include city and zip code):
4. The MHCC would like to understand the volume of noncontrolled prescription drugs dispensed in or into Maryland in the past 12 months. Please consider providing the estimated number for the pharmacy requesting a waiver.

### Multiple Locations:

5. Provide the pharmacy names and respective addresses for each location. *Note: Individuals submitting a request on behalf of a pharmacy with multiple locations are required to complete the [Supplemental Form](#) to provide information for each location. Please review the instructions tab before filling out the form. Once completed, email the form to [mhcc.noncds@maryland.gov](mailto:mhcc.noncds@maryland.gov).*
6. The MHCC would like to understand the volume of noncontrolled prescription drugs dispensed in or into Maryland in the past 12 months. Please consider providing the estimated number for the pharmacies requesting a waiver (total).

### Section III: Dispensing Prescriber Request

1. Is this waiver request on behalf of an individual or multiple dispensing prescribers authorized to dispense noncontrolled prescription drugs in Maryland?

Individual

Multiple

#### Individual Dispensing Prescriber:

2. Dispenser name:
3. Maryland licensing board that issued a dispensing permit:
4. Name of business(es) where the dispenser practices:
5. Address (include city and zip code):
6. The MHCC would like to understand the volume of noncontrolled prescription drugs dispensed in or into Maryland in the past 12 months. Please consider providing the estimated number for the dispensing prescriber requesting a waiver.

#### Multiple Dispensing Prescribers:

7. Name of business(es) where the dispensers practice:
8. Provide the names, the respective Maryland licensing board(s) that granted a dispensing permit pharmacy, and respective address for each dispensing prescriber. *Note: Individuals submitting a request on behalf of multiple dispensing prescribers are required to complete the [Supplemental Form](#) to provide information for each dispenser requesting a waiver. Please review the instructions tab before filling out the form. Once completed, email the form to [mhcc.noncds@maryland.gov](mailto:mhcc.noncds@maryland.gov).*
9. The MHCC would like to understand the volume of noncontrolled prescription drugs dispensed in or into Maryland in the past 12 months. Please consider providing the estimated number for the dispensing prescribers requesting a waiver (total).

### Section IV: Reason for Waiver

1. Select the reason(s) for seeking a waiver.
  - Economic hardship
  - Technology limitations not reasonably within the dispenser's control

- Dispensing less than 100 noncontrolled prescription drugs annually
- Other extenuating circumstances (please specify below)

Provide a detailed explanation of the extenuating circumstances necessitating a waiver.

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**Section V: Attestation**

NOTE: The individual submitting this request for a waiver is authorized and attests to the accuracy of the information provided.

*By completing the application, I attest that the information provided is true and accurate to the best of my knowledge and belief. I also attest that I will immediately inform the Commission if the circumstances necessitating a waiver no longer exist, as required by COMAR 10.25.18.13F(5).*