



**Standing Orders and Opioid Overdose Reversal Drugs Report 2024**

**Report Required by SB 408/HB 411 (Ch 849 and 850 of the Acts of 2024)**

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## **Executive Summary**

The Maryland Department of Health strives to provide opioid overdose reversal drugs (OORDs) as part of a broader harm reduction strategy. The Maryland Statewide Naloxone Standing Order is a critical part of this strategy.

[House Bill 0411/Senate Bill 0408](#) requires that the Maryland Department of Health (MDH) report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, on:

1. Current opioid overdose reversal drugs approved by the Federal Food and Drug Administration (FDA); and
2. For any current opioid overdose reversal drug approved by the federal Food and Drug Administration, whether the Department has added the drug to a standing order, and if not, the reasons why the drug has not been added.

Pursuant to this mandate, this report provides an overview of the Maryland Statewide Naloxone Standing Order and the OORDs currently approved by the FDA; their inclusion or lack of inclusion in the Maryland Statewide Naloxone Standing Order; and for those OORDs that are not included, the reasons why the drug has not been added.

## **Introduction and Overview**

Standing orders are written instructions for the prescribing and dispensing of an OORD approved by the federal Food and Drug Administration. Unlike a typical prescription, a standing order is not person-specific and allows dispensing to any individual who meets the requirements detailed in the prescriber’s written instruction. Although the legal authority to issue state- or jurisdiction-wide standing orders is limited to prescribers employed by state or local public health authorities, the prescribers issue these orders under their own license rather than as an order, or policy, of the health department as an agency.

The Maryland Department of Health strives to provide opioid overdose reversal drugs (OORDs) as part of a broader harm reduction strategy. Health-General Article §13-3106, Annotated Code of Maryland, authorizes a licensed healthcare practitioner with prescribing authority who is employed by MDH or a local health department to prescribe and dispense OORDs by issuing a standing order.

The first “statewide standing order” was issued in 2015 by Dr. Howard Haft, Deputy Secretary for Public Health Services, allowing any Maryland-licensed pharmacist to dispense naloxone to individuals who had been trained on opioid overdose recognition and response through the Maryland Overdose Response Program (ORP). Subsequent statewide standing orders have been issued by Dr. Jinlene Chan, Deputy Secretary for Public Health Services (2021 and 2022), and, most recently, Dr. Laura Herrera Scott, Secretary of Health (2023 and 2024). These standing orders have continued to authorize dispensing of Naloxone formulations by pharmacists throughout Maryland while expanding (in accordance with changes to the authorizing statute) the range of individuals eligible to be dispensed naloxone.

The current Maryland Statewide Naloxone Standing Order<sup>1</sup> authorizes pharmacists to dispense unlimited naloxone prescriptions and refills, and devices for its administration to any individual in the state. The order guides pharmacists on the most commonly used naloxone dosages and formulations and considerations for selecting the appropriate product for their patients. The accompanying Guidance for Pharmacy Dispensing includes additional information on the ORP, legal requirements, and protections, instructions for billing Medicaid and other insurers, and links to additional educational resources.

## **Current United States Food and Drug Administration,(FDA) -Approved OORDs and the Maryland Statewide Naloxone Standing Order**

As of 2024, the OORDs currently approved by the FDA for use are *Naloxone* and *nalmefene*.

### *Naloxone*

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<sup>1</sup> Maryland Department of Health. Information for Pharmacists. The Overdose Response Program. <https://health.maryland.gov/pha/NALOXONE/Pages/Statewide-Standing-Order.aspx>

Naloxone is an opioid antagonist widely available in multiple FDA-approved formulations and dosing. Naloxone inhaled versions are available in single-use products ranging from 2mg to 10mg per dose and are also available as an injectable product<sup>2</sup>. Naloxone has demonstrated effectiveness in reducing the risk of opioid overdose death. For nearly 20 years, overdose education and naloxone distribution programs have successfully trained nonmedical community members on opioid overdose recognition and response using naloxone nationally and in Maryland.<sup>3</sup>

Naloxone is included in the Maryland Statewide Naloxone Standing Order. The Maryland Statewide Naloxone Standing Order provides flexibility in dosing and formulation understanding the expertise and clinical judgment of the pharmacist to provide patients with naloxone taking into consideration the lowest effective dose patient preference and insurance coverage options.<sup>4</sup>

### Nalmefene

Nalmefene is an opioid antagonist available on the market as a prefilled, single-dose inhaled or injected product. The American College of Medical Toxicology and the American Academy of Clinical Toxicology released a joint statement in 2023 opposing the utilization of nalmefene as an overdose reversal agent in community-based settings until additional studies supporting its utility can be conducted.<sup>5</sup> When compared to naloxone, nalmefene has a longer half-life and has a high affinity for the opioid receptor<sup>6</sup>. There is concern that in the community setting, compared to naloxone, the use of nalmefene may result in more severe and prolonged withdrawal symptoms due to its long-acting nature and high receptor bonding affinity<sup>7</sup>. As a result, patients may endure severe withdrawal symptoms for a longer period.

Currently, nalmefene is not included in the Maryland Statewide Naloxone Standing Order as there have been no community-based intervention trials with nalmefene nasal spray and no direct comparisons to naloxone in the community setting addressing these concerns. Despite its exclusion from the Maryland Statewide Naloxone Standing Order, nalmefene can be prescribed by individual providers directly to patients and the standing order does not preclude pharmacies from dispensing nalmefene with a valid prescription.

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<sup>2</sup> FDA lists all approved products in its Orange Book. Multiple manufacturers and products are available at each dose. See details at <https://www.fda.gov/media/71474/download?attachment>

<sup>3</sup> Giglio, RE, et.al. "Effectiveness of bystander naloxone administration and overdose education programs: a meta-analysis." *Injury Epidemiology* (2015) 2:10

<sup>4</sup> <https://www.marylandmacs.org/media/som/microsites/macsdocuments/Nalmefene-Evidence-Brief-Final.pdf>

<sup>5</sup> Stolbach, A. I., Mazer-Amirshahi, M. E., Nelson, L. S., & Cole, J. B. (2023). American College of Medical Toxicology and the American Academy of Clinical Toxicology position statement: nalmefene should not replace naloxone as the primary opioid antidote at this time. *Clinical Toxicology*, 61(11), 952-955.

<sup>6</sup> Edinoff et al. Pharmacologic and Clinical Considerations of Nalmefene, a Long Duration Opioid Antagonist, in Opioid Overdose. *Psychiatry Int.* 2021, 2(4), 365-378;

<https://doi.org/10.3390/psychiatryint2040028>

<sup>7</sup> New Drug Approval 217470 Opvee 3mg/0.1mL. <https://www.fda.gov/media/171603/download>

## **Conclusions**

The Department remains committed to the utilization of data and research to make determinations about the inclusion of OORDs in the Maryland Statewide Naloxone Standing Order as well as in the continued use of the Maryland Statewide Naloxone Standing Order as part of its broader harm reduction strategy.