



## **Standing Orders and Opioid Overdose Reversal Drugs**

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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/SB 0408 (Chapters 849 and 850 of the Acts of 2024) 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 FDA 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 opioid overdose reversal drugs (OORD) approved by the Federal Food and Drug Administration (FDA). 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.

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 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 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](#) (“Standing Order for Naloxone Dispensing by Pharmacies”) 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 2025, the OORDs currently approved by the FDA for use are *Naloxone* and *Nalmefene*.<sup>1</sup>

### Naloxone

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 (U.S. Food and Drug Administration). Naloxone has demonstrated effectiveness in reducing the risk of opioid overdose death in community settings. 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>2</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>3</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>4</sup> When compared to naloxone, nalmefene has a longer half-life and has a high affinity for the opioid receptor.<sup>5</sup> As highlighted in a 2025 publication in the *International Journal of Drug Policy* that explored the evidence for and risks vs. benefits of use of nalmefene in the community setting, the use of nalmefene may result in more severe and prolonged

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<sup>1</sup> U.S. Food and Drug Administration (FDA). (2025). *Approved Drug Products with Therapeutic Equivalence Evaluations 45th Edition (Orange Book)*. Rockville, MD: FDA.  
<https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>

<sup>2</sup> Giglio R.E., Li, G., DiMaggio, C.J. (2015). Effectiveness of bystander naloxone administration and overdose education programs: a meta-analysis. *Inj Epidemiol*, 2(1):10. <http://doi.org/10.1186/s40621-015-0041-8>.

<sup>3</sup> Maryland Addiction Consultation Service. undated. Evidence brief: 4 mg Naloxone is the most evidence-based treatment for opioid overdose reversal.

<https://www.marylandmacs.org/media/som/microsites/macs/documents/Nalmefene-Evidence-Brief-Final.pdf>

<sup>4</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.  
<https://doi.org/10.1080/15563650.2023.2283391>

<sup>5</sup> Edinoff, A. N., Nix, C. A., Reed, T. D., Bozner, E. M., Alvarez, M. R., Fuller, M. C., Anwar, F., Cornett, E. M., Kaye, A. M., & Kaye, A. D. (2021). Pharmacologic and clinical considerations of Nalmefene, a long duration opioid Antagonist, in opioid overdose. *Psychiatry International*, 2(4), 365-378.  
<https://doi.org/10.3390/psychiatryint2040028>

withdrawal symptoms than naloxone due to its long-acting nature and high receptor bonding affinity.<sup>6</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. 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.

### **Conclusion**

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.

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<sup>6</sup> Navin, M.C., Fink, L.R., Rieder, T.R. (2025). Stronger isn't always better: Nalmefene in community overdose response and the false promise of quick-fix public health solutions, *International Journal of Drug Policy*, 145, 2025, 104945. <https://doi.org/10.1016/j.drugpo.2025.104945>.