



Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 5, 2025

The Honorable Joseline A. Peña-Melnyk
Chair House Health and Government Operations Committee
Room 241, House Office Building
Annapolis, Maryland 21401

RE: House Bill (HB) 572 – Public Health - Opioid Overdose Reversal Drugs - Standing Orders – Letter of Opposition

Dear Chair Peña-Melnyk and Committee Members:

The Maryland Department of Health (Department) respectfully submits this letter of opposition for House Bill (HB) 572 – Public Health - Opioid Overdose Reversal Drugs - Standing Orders.

HB 572 would require health care providers, when writing standing orders for an opioid reversal drug, to allow an individual to choose any formulation of any opioid overdose reversal drug (OORDs) approved by the Food and Drug Administration (FDA).

While the Department acknowledges the intent of the legislation to expand access, the legislation is not required as an individual can currently request any formulation of opioid overdose reversal drugs approved by the FDA. The Department is dedicated to addressing the overdose crisis in Maryland and is actively providing overdose reversal medications via a statewide standing order, which includes all formulations of naloxone and technical support for pharmacists on how to educate individuals who access naloxone via the standing order on how best to utilize the medication, through the Overdose Response Program (ORP). In fiscal year 2024, we distributed more than 430,283 OORDs into the community.

MDH has concerns with the bill as currently drafted. Maryland's ORP, administered by the MDH Office of Harm Reduction, oversees the majority of community-level overdose education and naloxone distribution in the state. The program relies on licensed healthcare practitioners to issue standing orders that authorize non-medical staff—such as outreach workers and community health educators—to dispense naloxone. These standing orders allow prescribers to determine which formulations are most appropriate for the populations served, ensuring that individuals at risk of overdose receive products that are safe, effective, and easy to administer in high-stress situations.

By requiring that the end recipient be allowed to select any FDA-approved product, this bill undermines the prescriber's clinical authority and may compel harm reduction programs to distribute newer, more potent formulations that have limited real-world data on safety and

efficacy¹ when administered by non-medical personnel. Many prescribers who currently support ORP efforts may not be comfortable authorizing distribution of these products under their licenses, potentially leading them to withdraw from participation. Given that many prescribers serve in voluntary or unpaid roles, even a small reduction in participation could significantly impact the availability of standing orders across the state, threatening the operational integrity of ORP organizations.

MDH provides overdose reversal education technical assistance and distributes naloxone to community-based organizations at no cost to those organizations. Naloxone is a well-known opioid overdose reversal medication with a long-standing history of safe use in community-based settings through the Overdose Response Program (ORP). MDH has provided years of public health education to the community around the appropriate administration of this formulation in conjunction with the activation of the emergency medical system. The effectiveness of MDH's overdose education and naloxone distribution strategies (OEND), as described above, reflect best practice standards based on a large body of evidence within the scientific literature.²

HB 572, if passed as written, would require MDH to include novel formulations of overdose reversal medications approved by the FDA, which lack evidence of efficacy in community-based settings. New OORDs, namely nalmefene hydrochloride, have recently become available - however, in the case of nalmefene hydrochloride, clinicians have expressed concern about the use of the formulation in the community setting due to the increased likelihood of inducing opioid withdrawal and have urged further study of the formulation. This view has also been expressed by the American College of Medical Toxicology and the American Academy of Clinical Toxicology, which released a joint statement expressing concern about the utilization of nalmefene as an overdose reversal agent in community-based settings until additional studies supporting its utility can be conducted.³

The bill also affects standing orders for pharmacy dispensing issued by MDH and local health departments, including the statewide naloxone standing order issued by the MDH Secretary. To comply with the legislation, these standing orders would need to be reissued to cover all FDA-approved formulations, regardless of whether state or local public health officials determine them to be the most effective and accessible options.

Additionally, the bill creates potential conflicts with payer policies, particularly Maryland Medicaid's Preferred Drug List (PDL). Medicaid recipients who request an OORD that is not included on the PDL may face significant out-of-pocket costs, limiting access to overdose reversal medications and introducing new barriers for vulnerable populations. Expanding access to overdose reversal medications is a critical component of Maryland's harm reduction strategy, however HB 572 introduces logistical, financial, and clinical challenges that could reduce the effectiveness of current naloxone distribution efforts.

¹ <https://www.marylandmacs.org/media/som/microsites/macsd/documents/Nalmefene-Evidence-Brief-Final-1.pdf>

² Razaghizad, A., Windle, S. B., Filion, K. B., Gore, G., Kudrina, I., Paraskevopoulos, E., ... & Eisenberg, M. J. (2021). The effect of overdose education and naloxone distribution: an umbrella review of systematic reviews. *American journal of public health*, 111(8), e1-e12.

³ 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://www.marylandmacs.org/media/som/microsites/macsd/documents/Nalmefene-Evidence-Brief-Final-1.pdf>

Given these dynamics, MDH believes HB 572 would not be helpful to the state's efforts to reduce overdose mortality and may create additional harm. The newer formulations of overdose reversal agents should undergo additional study in community-based settings prior to being incorporated into public health strategy.

For these reasons, MDH respectfully urges an unfavorable report on House Bill 572. If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "LH Scott", is positioned above the typed name.

Laura Herrera Scott, M.D., M.P.H.
Secretary