



DEPARTMENT OF HEALTH

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

February 15, 2024

The Honorable Joseline A. Peña-Melnyk
Chair, House Health and Government Operations Committee
241 House Office Building
Annapolis, MD 21401-1991

RE: House Bill 736 – Health Insurance and Maryland Medical Assistance Program – Coverage – Opioid Reversal Drugs and Products

Dear Chair Beidle and Committee Members:

The Maryland Department of Health (the Department) respectfully submits this letter of information for House Bill (HB) 736 – *Health Insurance and Maryland Medical Assistance Program – Coverage – Opioid Reversal Drugs and Product*.

HB 736 requires the Maryland Medical Assistance Program (Medicaid) to cover nonprescription naloxone hydrochloride and any other Food and Drug Administration (FDA) approved drug or product used for the complete or partial reversal of an opioid overdose. The bill also prohibits imposing a co-payment or co-insurance requirement that exceeds \$10.

Federal Requirements

Under federal statute, Medicaid may only receive federal matching funds and federal rebates in certain circumstances. Drugs that meet the definition of a “covered outpatient drug” as defined in 42 C.F.R. §447.502 are eligible for federal matching dollars. A covered outpatient drug must meet the definition of a prescribed drug in 42 CFR §440.120; be approved by the FDA; be dispensed upon prescription; and the manufacturer has entered a rebate agreement with the Centers for Medicaid and Medicare Services (CMS).

Medicaid may also cover OTC drugs that do not meet the definition of a covered outpatient drug (a.k.a., prescribed drugs) when prescribed by a physician or other authorized prescriber, dispensed by a pharmacist, and included in the Medicaid State Plan. A standing order can satisfy the requirement for a prescription.

Based on claims and cost data from Quarter 2 of Fiscal Year 2024, MDH estimates Medicaid covers 53,000 prescriptions for overdose reversal drugs in a year, amounting to \$3.2 million prior to rebates and \$2.7 million after rebates.

Maryland Medicaid currently covers both prescription naloxone for Medicaid participants and OTC Narcan with a prescription from an authorized prescriber. In order to receive naloxone, a Medicaid participant must have a prescription and go to a pharmacy counter. Claims need to be submitted by a pharmacy provider to Medicaid for processing using the NCPDP Transaction Standard.

The Department has a standing order in place for naloxone. The standing order authorizes Maryland-licensed pharmacists to dispense naloxone in several different formulations, but not every opioid reversal drug available on the market. The standing order satisfies the Medicaid requirement to have a prescription.

Medicaid notes that the standing order would need to be updated to enable Medicaid to receive federal match when covering all FDA-approved opioid reversing drugs that are rebate eligible as required by HB 736. Updates would also be needed as new opioid reversal drugs come to market.

Medicaid's co-pay structure complies with HB 736's requirements. The co-pay for Medicaid participants is \$1 for preferred brand and all generic drugs and \$3 for non-preferred brand drugs. This co-pay is waived for pregnant women and children. If a participant cannot afford to pay a pharmaceutical co-pay, the pharmacist is required to dispense medication without collecting a co-pay.

If the intent of HB 736 is to enable participants to be able to buy naloxone at a retail checkout counter, Medicaid does not have existing infrastructure to operationalize payment for this situation and anticipates substantial financial impact. In addition to the operational challenges this would pose, Medicaid cannot claim federal match for outpatient drugs covered without a prescription. Both operational costs and drug costs would require 100% State general funds.

Naloxone purchased from a store shelf through a retail checkout counter is not currently eligible for coverage by Medicaid. As stated previously, in order to receive federal funds and drug rebates for OTC drugs, Medicaid must require a prescription and the purchase must be made through the pharmacy counter.

If a prescription is not required, as would be the case if a person checked out at a standard register, State-only funds must be used. These drugs would no longer be eligible for federal funding match or drug rebates. This could result in costs in excess of \$3.2 million in State general funds in drug costs alone. Retailers would have great discretion in setting prices of OTC drugs and the Department would not have the ability to set reimbursement amounts, potentially substantially increasing the fiscal impact of HB 736.

Medicaid would also need to establish a new unit to process submissions of receipts for OTC naloxone by consumers, which would require the hiring of new staff, and creation of a new process for reimbursement. 100% State general funds would have to be used to fund the new unit.

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 or (410) 260-3190.

Sincerely,

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

Laura Herrera Scott
Secretary