

**Department of Legislative Services**  
Maryland General Assembly  
2024 Session

**FISCAL AND POLICY NOTE**  
**First Reader**

Senate Bill 497  
Finance

(Senator Gile)

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**Health Insurance and Maryland Medical Assistance Program - Coverage -  
Opioid Reversal Drugs and Products**

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This bill requires insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers) that provide coverage for prescription drugs and the Maryland Medicaid program to cover nonprescription naloxone hydrochloride and any other drug or product approved by the U.S. Food and Drug Administration (FDA) for the complete or partial reversal of an opioid overdose. Coverage must be provided without imposing a copayment or coinsurance requirement that exceeds \$10 per package. **The bill takes effect January 1, 2025, and applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.**

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**Fiscal Summary**

**State Effect:** Minimal special fund revenue increase for the Maryland Insurance Administration (MIA) in FY 2025 only from the \$125 rate and form filing fee. Any additional workload on MIA can likely be handled with existing budgeted resources. Assuming the current process for coverage of naloxone under Medicaid satisfies the intent of the bill, Medicaid can implement any required administrative changes within existing budgeted resources, as discussed below. No impact on the State Employee and Retiree Health and Welfare Benefits Program, as discussed below.

**Local Effect:** Any fiscal impact on local governments that purchase fully insured health plans is anticipated to be minimal.

**Small Business Effect:** Minimal.

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## Analysis

### Current Law:

#### *Overdose Response Program*

The Maryland Department of Health (MDH) Overdose Response Program (ORP) allows for FDA-approved opioid overdose reversal drugs to be offered to specified individuals – free of charge – by multiple providers, programs, and entities. Subject to the limitations of the State budget, MDH must purchase and provide FDA-approved opioid overdose reversal drugs, at no cost, to the entities who may provide the reversal drugs only if MDH provides them. MDH may authorize private or public entities to conduct education and training on opioid overdose recognition and response that includes (1) education on recognizing the signs and symptoms of an opioid overdose; (2) training on responding to an opioid overdose, including the administration of FDA-approved opioid overdose reversal drugs; and (3) access to opioid overdose reversal drugs and the necessary supplies for the administration of the opioid overdose reversal drug. Individuals are not required to obtain the specified training and education on opioid overdose recognition and response from a private or public entity before a pharmacist may dispense an FDA-approved opioid overdose reversal drug.

#### *Standing Order for Opioid Overdose Reversal Drugs*

Maryland has a statewide standing order for opioid overdose reversal drugs that authorizes any Maryland-licensed pharmacist to dispense unlimited prescriptions and refills of naloxone and devices for its administration to any individual, as specified. A pharmacist must provide consultation with the individual regarding the naloxone dosage that is most appropriate, select and dispense two doses of naloxone, and provide directions for use. The standing order is set to expire June 30, 2024, at which time a new order will be issued. If a patient cannot afford naloxone or related copayments, or does not wish to use insurance coverage, pharmacists are instructed to refer them to ORP where they can obtain a naloxone kit free of charge.

#### *Medicaid Pharmacy Coverage Requirements*

Under federal law, state Medicaid programs may only receive federal matching funds and federal drug rebates for a covered outpatient drug. A covered outpatient drug must:

- meet the definition of a prescribed drug in federal regulations (42 CFR § 440.120);
- be FDA-approved;
- be dispensed upon prescription; and

- be from a manufacturer that has entered into a rebate agreement with the federal Centers for Medicare and Medicaid Services.

State Medicaid programs may also cover over-the-counter (OTC) drugs that do not meet the definition of a covered outpatient drug if the drug is:

- prescribed by an authorized prescriber (a standing order can satisfy the requirement for a prescription);
- dispensed by a pharmacist; and
- included in the Medicaid State Plan.

### *Insurance Coverage of Nonprescription Drugs*

Under the federal Patient Protection and Affordable Care Act, insurers may be required to cover certain OTC preventive medications without cost sharing; however, a patient must obtain a prescription. Examples of such medications include aspirin; bowel preparation; contraceptives; fluoride, folic acid, iron, and vitamin D supplementation; and tobacco cessation products. A patient obtains a prescription from their health care provider and is able to obtain the OTC medication using their insurance through the pharmacy counter.

### **State Fiscal Effect:**

#### *Medicaid*

Medicaid currently covers both prescription and OTC naloxone *with a prescription*. To receive naloxone, a Medicaid participant must have a prescription (or go through the standing order) and go to a pharmacy counter. Claims for OTC naloxone (and other FDA-approved drugs or products to reverse an opioid overdose) must be submitted by a pharmacy provider to MDH. Naloxone and similar drugs are considered specialty behavioral health drugs and are paid for on a fee-for-service basis. Medicaid participants pay a \$1 copayment for preferred brand-name drugs and all generic drugs, and a \$3 copayment for nonpreferred brand-name drugs. If a participant cannot afford the copayment, the pharmacist must dispense the medication without collecting a copayment.

Medicaid covers approximately 53,000 prescriptions for overdose reversal drugs annually at a cost of \$3.2 million prior to rebates and \$2.7 million after rebates.

MDH assumes that Medicaid could continue to allow participants to receive naloxone *through the pharmacy counter* and satisfy the requirements of the bill. If and when any additional FDA-approved drugs or products for the complete or partial reversal of an opioid overdose become available OTC, the statewide standing order would need to be updated

to continue to enable MDH to receive federal matching funds and federal rebates when covering those additional drugs or devices at the pharmacy counter. These updates could likely be handled with existing budgeted resources.

However, MDH advises that, if Medicaid must allow participants to purchase naloxone at a retail check-out counter, the department does not have a way to operationalize payment and anticipates substantial financial impact. Under this scenario, Medicaid expenditures (100% general funds) increase by a significant amount (as much as \$3.2 million annually in drug costs alone as Medicaid would be unable to claim federal matching funds or federal drug rebates for such products), plus additional significant but indeterminate expenses for establishment of a new unit to process submission of receipts for OTC naloxone by consumers.

The Department of Legislative Services advises that this analysis assumes that coverage of OTC naloxone under the bill will be processed through the pharmacy counter as is currently done by Medicaid and for those OTC products covered by insurers.

#### *Department of Budget and Management*

The Department of Budget and Management advises that there is no impact on the State Employee and Retiree Health and Welfare Benefits Program as coverage of OTC naloxone is already provided to members.

**Additional Comments:** In March 2023, FDA approved Narcan 4 milligram naloxone hydrochloride nasal spray as the first nonprescription naloxone product. The availability and price of this product is determined by the manufacturer. As of February 2024, the retail price of brand-name Narcan is \$45 for two doses. Generic naloxone nasal spray is available from Walgreens for \$40.

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### **Additional Information**

**Recent Prior Introductions:** Similar legislation has not been introduced in the past three years.

**Designated Cross File:** HB 736 (Delegate Vogel, *et al.*) - Health and Government Operations.

**Information Source(s):** U.S. Food and Drug Administration; Department of Budget and Management; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

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