Annual Report: Policies and Options

PDAB Meeting

July 22, 2024

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Annual Report Overview

§ 21-2C-09 PDAB Reporting Requirements

On or before December 31, 2020, and each December 31 thereafter, the Board shall submit to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2-1257 of the State Government Article, a report that includes:

(1) Price trends for prescription drug products;

(2) The number of prescription drug products that were subject to Board review and the results of the review; and

(3) Any recommendations the Board may have on further legislation needed to make prescription drug products more affordable in the State.

Annual Report Options

1. Drug Price Transparency Program

- **Issue**: The net, market-clearing price of drugs is only known to PBMs and manufacturers - not to policymakers or the public. This lack of transparency can serve as an obstacle to effective market competition.

- **Potential policies**: Mirror federal provisions in the Internal Revenue Code, ERISA, and the PHS Act; require manufacturer reporting (e.g. Oregon); require wholesaler reporting (e.g. Maine); require hospital reporting on 340B program use; require pharmacy reporting to the State Actual Acquisition Cost (SAAC) survey

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2. Biosimilar Interchangeability

- **Issue**: Whereas small-molecule drugs are either categorized as brand name or generic, biologic products have three characterizations: reference, biosimilar, and interchangeable. For pharmacists to perform biologic product substitutions, a biosimilar must be FDA approved as interchangeable, which limits market competition. Note: the distinction between interchangeable and non-interchangeable biosimilars may change in the upcoming few years.

- **Potential policies**: New legislation that increases pharmacist scope of practice to allow pharmacists to substitute non-interchangeable biosimilars for biologic products; broaden allowable substitution list

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3. Device/Drug Combination Product Substitutability

- **Issue**: Some device/drug combinations (e.g., injectors and inhalers) cannot be substituted at the pharmacy level, even when they have the same active ingredient. This impedes patient access and competition.

- **Potential policies**: Study the obstacles to patient access regarding device/drug combination at the pharmacy, insurer, and prescriber levels; explore legislation options that would allow pharmacists broader authority to substitute drug/device combinations

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4. State Implementation of IRA Inflation Rebate

- **Issue**: The Inflation Reduction Act requires drug companies to pay rebates to Medicare if their drug price increases outpass the rate of inflation. These inflation-based rebates may help limit price increases and prevent the burden of price increases from falling on patients.

- **Potential policies**: Require manufacturers to pay inflation-based rebates on all drugs in Maryland if drug prices are increased more quickly than the rate of inflation

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5. State Application of IRA Drug Price Negotiation

- **Issue**: The Inflation Reduction Act allows for the Medicare to negotiate with manufacturers to establish a Maximum Fair Price for certain drugs. This Maximum Fair Price applies to Medicare enrollees only. Other patients may benefit from these negotiated Maximum Fair Prices.

- **Potential policies**: Explore the possibility for Maryland to expand the application of prices negotiated under the IRA to broader patient groups

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6. Fiduciary Duty to Customer

- **Issue**: There are a number entities in the supply chain that may engage in business practices that may be in their interest over the interest of their clients.

- **Potential policies**: Explore legislation that would establish a fiduciary duty between different stakeholders and their clients, including banning certain incentives

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7. Real-Time Benefit Tool Requirements

- **Issue**: Patients and prescribers make key treatment decisions, such as medication selection, during office and clinic visits. However, the out-of-pocket cost of drugs for patients at the pharmacy are rarely available ahead of time during these discussions. Affordability is a key factor and should be considered before prescriptions are written.

- **Potential policies**: Explore legislation that would require PBMs to implement real-time benefit tools to allow patients and prescribers to gather out-of-pocket cost information before prescriptions are written

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8. Out-of-Pocket Spending Smoothing Requirements

- **Issue**: Every January, patients begin a new benefit year. For many patients, that means they must pay a deductible before their insurance benefits begin. As part of the Inflation Reduction Act, the government implemented out-of-pocket spending smoothing for Medicare Part D beneficiaries. These requirements make it so that patients can smooth their costs over the 12 months, particularly for patients who will reach their out-of-pocket maximums.

- **Potential policies**: Add the same out-of-pocket cost smoothing requirements to regulated plans in Maryland.

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