

ENACTED RELATED DRUG PRICING LEGISLATION

The cost of health care within the United States has been a widespread concern among consumers, employers, and lawmakers. In response to these concerns, numerous states have taken measures to regulate drug prices. These diverse approaches include PDABs, as well as several non-PDAB alternatives. This resource provides an overview of related drug pricing legislation that does not directly create a PDAB. This resource is intended to inform patients, providers, caregivers, advocates and other stakeholders on the diverse approaches to prescription drug affordability reform.



TERMS

Average Wholesale Price (AWP)

Average suggested price paid by a retailer to buy a drug from a wholesaler, excluding price concessions, discounts, and rebates.

Average Sales Prices (ASP)

Refers to the average amount of money a company receives for selling a unit of a drug or biological product in the United States during a specific three-month period (calendar quarter). This is calculated by taking the total revenue from sales (excluding certain exempted sales) and dividing it by the total number of units of the drug or biological product sold during that quarter.

Federal Supply Schedule (FSS)

The drug pricing program used by federal agencies, U.S. territories, Indian tribes, and other specified entities to purchase supplies and services from outside vendors.

Maximum Fair Price (MFP)

The Inflation Reduction Act of 2022 introduced measures to allow Medicare to negotiate the price of prescription drugs for Medicare beneficiaries.² The price negotiated for Medicare by the Secretary of Health and Human Services is the MFP.³ Some states mandate their PDABs to use federally negotiated Medicare prices to establish a UPL for drugs subject to MFP. This enables states to apply to federally negotiated prices to state-regulated markets.

Medicaid Models

In Massachusetts and New York, Medicaid programs have enhanced negotiating authority.⁴ This allows Medicaid to negotiate with drug companies for supplemental rebates if drug spending exceeds certain thresholds.⁵ These state Medicaid programs can also conduct pricing reviews or value assessments for high-cost drugs.⁶

National Average Drug Acquisition Cost (NADAC)

The pricing benchmark calculated from the Centers for Medicare & Medicaid Services' (CMS) monthly surveys of retail pharmacies that reflects the average price pharmacies pay to acquire a drug from a wholesaler or manufacturer, excluding subsequent discounts or rebates from manufacturers to wholesalers or pharmacies.

Quality-Adjusted Life Year (QALY)

A metric for evaluating the effectiveness of medical treatments by calculating how different kinds of medical treatments lengthen and improve consumers' lives.⁷

Reference Pricing (RP)

A strategy that involves using international drug prices as benchmarks, or reference rates.⁸ The goal of RPs is to ensure that the maximum price paid for a drug is similar to its cost in other countries.⁹

State Actual Acquisition Cost (SAAC)

The state Medicaid agency's calculation of the actual acquisition cost, based on a survey of providers' actual prices paid to acquire drugs or products marketed or sold by specific manufacturers, when NADAC is unavailable.

Upper Payment Limit (UPL)

Represents the highest allowable reimbursement rate that purchasers within a specific state can provide for a prescription drug product.¹⁰ The UPL does not dictate the manufacturer's pricing, but establishes an upper boundary on what a payer can charge for a drug.¹¹

Wholesale Acquisition Cost (WAC)

Represents an approximation of the manufacturer's list price for a pharmaceutical drug when sold to wholesalers, pharmacies or direct buyers.¹² It doesn't account for any discounts, rebates, or other price concessions that are offered by manufacturers. The WAC serves as a benchmark or reference price for the medication.¹³ It's important to note that this price is not the actual amount paid by wholesalers, pharmacies and other direct purchasers, who benefit from rebates and other price concessions offered by manufacturers.



ENACTED DRUG PRICING LEGISLATION RELATED TO PDABs

STATE	Massachusetts HB 4000 - Section 46 of FY 2020 Budget
MODEL	Medicaid Drug Negotiations - The Massachusetts Executive Office of Health and Human Services may directly negotiate supplemental rebate agreements with manufacturers. If an agreement cannot be reached, and the drug exceeds certain costs, the executive office may identify a proposed value and provide interested persons an opportunity to present data, views or arguments as to the proposed value of the drug.
PLANS AFFECTED	Medicaid
DEFINITION OF AFFORDABILITY	Does not define affordability.
DRUG SELECTION PROCESS	Prior to seeking a supplemental rebate agreement with a manufacturer, the executive office must consider a drug's actual cost to the state and whether the manufacturer is providing significant discounts relative to other drugs covered by Medicaid.
PRICING CONSIDERATIONS	A proposed supplemental rebate must maximize value to the state, and a proposed supplemental rebate or proposed value for a drug, may be based on: <ul style="list-style-type: none"> (1) The value, efficacy or outcomes of the drug; (2) Clinical efficacy and outcomes; (3) Information relating to the pricing of the drug, including but not limited to information relating to prices paid by other developed nations, the drug's net price to the Medicaid program as compared to its therapeutic benefits; (4) The seriousness and prevalence of the disease or condition that is treated by the drug; (5) The extent of utilization of the drug; (6) The likelihood that the use of the drug will reduce the need for other medical care; (7) The number of manufacturers that produce the drug; (8) Whether there are pharmaceutical equivalents of the drug; (9) Analyses by independent third parties; and (10) Any information supplied by the manufacturer and other appropriate measures.
DRUGS COVERED	The executive office may identify a proposed value of the drug, if it is covered by Medicaid and projected to exceed a post-rebate cost per utilizer of \$25,000 per year or a post-rebate aggregate annual cost to Medicaid of \$10 million.
STATUS	Enacted. The 2023 Massachusetts Health Policy Commission annual report suggested that the state should build on the state Medicaid's successful drug pricing negotiation process by exploring expansion of the drug pricing review authority to other state and commercial payers in order to strengthen price negotiations.



ENACTED DRUG PRICING LEGISLATION RELATED TO PDABs

STATE	New Jersey S1615 (2023)
MODEL	No specific approach adopted. The Drug Affordability Council is required to formulate legislative and regulatory policy recommendations to lower the cost of prescription drug products that the council determines have led or will lead to an affordability challenge for the state health care system and for New Jersey patients.
BOARD MEMBERSHIP	The Council consists of five public members and three alternate public members all appointed by the Governor. These appointments are made directly by the Governor, upon recommendation from the President of the Senate, or upon recommendation from the Speaker of the General Assembly.
OPPORTUNITIES FOR ENGAGEMENT	The Council must provide an opportunity for public comment at each open meeting.
PLANS IMPACTED	Not applicable. This Council focuses on understanding the broader landscape of prescription drug costs. Currently, it does not have a mandate to establish UPLs.
FUNDING	\$1,500,000 appropriated from the general fund to the Division of Consumer Affairs in the Department of Law and Public Safety to implement the provisions of this act.
IMPLEMENTATION TIMELINE	January 2024 – Deadline to appoint council members (No members were appointed as of this deadline). February 2024 – Council required to hold its first meeting within 30 days following appointment of all council members (Meeting was not held because no Members were appointed in January 2024).
CURRENT STATUS	March 2024 – Appointments made .
DRUG SELECTION PROCESS	Not applicable. This Council focuses on understanding the broader landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs to review.
TYPE OF DRUG ELIGIBLE FOR SELECTION	Not applicable. This Council focuses on understanding the broader landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs to review.
DEFINITION OF AFFORDABILITY	Does not define affordability or affordability challenges.
AFFORDABILITY REVIEW	Not applicable. This Council focuses on understanding the broader landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs or conduct affordability reviews.
SETTING UPLS	Not applicable. This Council focuses on understanding the broader landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs or establish UPLs.



ENACTED DRUG PRICING LEGISLATION RELATED TO PDABs

STATE	<p>New York PHL § 280 (2017), SSL § 367-a (2022)</p>
MODEL	<p>Medicaid Drug Negotiations– New York’s Medicaid program is authorized to negotiate with drug manufacturers for supplemental rebates if spending on a drug is expected to exceed the Medicaid drug cap or if a newly launched drug is “high cost.”</p>
PLANS AFFECTED	<p>Medicaid</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability; defines “high cost” drug (see Drugs Covered column)</p>
DRUG SELECTION PROCESS	<p>In determining whether to recommend a target supplemental rebate for a drug, the drug utilization review board shall consider the actual cost of the drug to the Medicaid Program, including federal and state rebates, and may consider, among other things:</p> <ol style="list-style-type: none"> (1) The drug’s impact on the Medicaid drug spending growth target and the adequacy of capitation rates of participating Medicaid Managed Care plans and the drug’s affordability and the value to the Medicaid program; (2) Significant and unjustified increases in the price of the drug; (3) Whether the drug may be priced disproportionately to its therapeutic benefits.
PRICING CONSIDERATIONS	<p>In formulating a target rebate amount for a drug, the drug utilization review board may consider:</p> <ol style="list-style-type: none"> (1) Publicly available information or information supplied to the department relevant to the pricing of the drug; (2) Information relating to value-based pricing; (3) The seriousness and prevalence of the disease or condition that is treated by the drug; (4) The extent of utilization of the drug; (5) The effectiveness of the drug in treating the conditions for which it is prescribed, or in improving a patient’s health, quality of life, or overall health outcomes; (6) The likelihood that use of the drug will reduce the need for other medical care, including hospitalization; (7) The average wholesale price, WAC, retail price of the drug, and the cost of the drug to the Medicaid program minus rebates received by the state; (8) For generic drugs, the number of manufacturers that produce the drug; (9) Whether there are pharmaceutical equivalents to the drug; and (10) Information supplied by the manufacturer, if any, explaining the relationship between the pricing of the drug and the cost of development of the drug and/or the therapeutic benefit of the drug, or that is otherwise pertinent to the manufacturer’s pricing decision; (11) Any such information provided shall be considered confidential and shall not be disclosed by the drug utilization review board in a form that identifies a specific manufacturer or prices charged for drugs by such manufacturer.
DRUGS COVERED	<p>Drugs subject to price negotiations:</p> <ol style="list-style-type: none"> (1) Drugs purchased by Medicaid that are contributing to spending that will exceed the state’s Medicaid drug cap (set annually); (2) Newly launched drugs considered to be “high cost”: <p>Brand-name drug or biologic with a launch WAC of \$30,000+/year or course of treatment or a WAC increase of \$3,000+ in any 12-month period; biosimilar drugs that has a launch WAC that is not at least 15% lower than the referenced biologic; generic drugs with a WAC of \$100+ for a 30-day supply or course of treatment.</p>
STATUS	<p>Since 2018, New York Medicaid has negotiated more than 50 supplemental rebates, resulting in over \$500 million in gross supplemental rebates.</p>

ENACTED DRUG PRICING LEGISLATION RELATED TO PDABs

STATE	<p>Ohio HB166 (2019)</p>
MODEL	<p>No specific approach adopted.</p> <p>The Prescription Drug Transparency and Affordability Advisory Council required to provide recommendations for:</p> <ol style="list-style-type: none"> (1) Achieving prescription drug price transparency in Ohio; (2) Establishing new payment models or other avenues to create the most affordable environment for purchasing prescription drugs; (3) Leveraging Ohio's purchasing power across all state agencies, boards, commissions, and similar entities; (4) Creating efficiencies across different healthcare systems, to reduce duplicative service delivery, ensure patients receive high-quality and affordable prescription drugs, and support quality care and outcomes; (5) Identifying which critical outcomes can be measured and used to improve this state's system of purchasing affordable prescribed drugs; and (6) Examining how federal, state, and local resources are being used to optimize outcomes and identify where resources can be better coordinated or redirected to meet the needs of consumers.
BOARD MEMBERSHIP	<p>The Council includes 14 Members.</p> <p>Five Members are from State agencies including:</p> <ol style="list-style-type: none"> (1) The Director of Administrative Services; (2) The Director of Health; (3) The Medicaid Director; (4) The Director of Mental Health and Addiction Services; (5) The Administrator of Workers' Compensation; <p>Nine additional individuals are appointed by the Governor, the Senate President, and the Speaker of the House of Representatives. Additional appointees must be working to address prescription drug availability and affordability in any of the following areas:</p> <ol style="list-style-type: none"> (1) Insurance; (2) Local, state, and federal government service; (3) Private industry; (4) Organizations of faith; (5) Health care providers; (6) Consumer organizations; (7) Prescription drug manufacturers; (8) Prescription drug wholesale distributors; (9) Pharmacists; (10) Business organizations; (11) Individuals concerned about mental health or substance abuse matters; and (12) Advocates for individuals struggling to afford prescription drugs.
OPPORTUNITIES FOR ENGAGEMENT	<p>Council Membership may include representation from consumer organizations.</p> <p>Policies and procedures for engaging with the Council and commenting on Council activities have not yet been developed.</p>
PLANS IMPACTED	<p>Not applicable. This Council focuses on understanding the broader landscape of prescription drug costs and formulating recommendations. Currently, it does not have a mandate to establish UPLs.</p>
FUNDING	<p>Funded by the Ohio Department of Administrative Services.</p>

ENACTED DRUG PRICING LEGISLATION RELATED TO PDABs

STATE	Ohio cont. HB166 (2019)
IMPLEMENTATION TIMELINE	Apr. 2020 – Must submit a report to the Governor, the General Assembly and the Chairperson of the Joint Medicaid Oversight Committee, which must include recommendations on all of the following: <ol style="list-style-type: none"> (1) How the state can best achieve prescription drug price transparency; (2) New payment models or other avenues to create the most affordable environment for purchasing prescription drugs; (3) Leveraging the state's purchasing power across all state agencies, boards, commissions, and similar entities; (4) Creating efficiencies across different healthcare systems, to reduce duplicative service delivery, ensure that patients receive high-quality and affordable prescription drugs, and support quality care and outcomes; (5) Which critical outcomes can be measured and used to improve the state's system of purchasing affordable prescribed drugs; and (6) How federal, state, and local resources are being used to optimize these outcomes and identify where the resources can be better coordinated or redirected to meet the needs of consumers in the state.
CURRENT STATUS	2020 Report Will continue to meet quarterly.
DRUG SELECTION PROCESS	Not applicable. This Council focuses on understanding the larger landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs to review.
TYPE OF DRUG ELIGIBLE FOR SELECTION	Not applicable. This Council focuses on understanding the larger landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs for affordability reviews.
DEFINITION OF AFFORDABILITY	Not applicable. This Council focuses on understanding the larger landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs or conduct affordability reviews.
AFFORDABILITY REVIEW	Not applicable. This Council focuses on understanding the larger landscape of prescription drug costs. Currently, it does not have a mandate to select specific drugs or conduct affordability reviews.
SETTING UPLS	Not applicable. This Council focuses on understanding the larger landscape of prescription drug costs and spending in the state. Currently, Council it does not have a mandate to select specific drugs or establish UPLs.



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