AIMEDALLIANCE

ENACTED RELATED DRUG PRICING LEGISLATION

2025

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 state 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: (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. As of July 1, 2024, MassHealth had active supplemental rebate agreements with 27 manufacturers covering 72 drugs.

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. The majority of 2025 was devoted to finalizing the establishment of the Board, reviewing manufacturer reporting, and assessing various implementation approaches.
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	**New York** PHL § 280 (2017), SSL § 367-a (2022)
MODEL	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."
PLANS AFFECTED	Medicaid
DEFINITION OF AFFORDABILITY	Does not define affordability; defines "high cost" drug (see Drugs Covered column)
DRUG SELECTION PROCESS	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: (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	In formulating a target rebate amount for a drug, the drug utilization review board may consider: (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	Drugs subject to price negotiations: (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": 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 lunch 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.
STATUS	As of 2018, New York Medicaid had negotiated more than 50 supplemental rebates, resulting in over $500 million in gross supplemental rebates. Since the implementation of the NYRx program, the self-imposed Drug Cap has impeded the ability of DOH to directly negotiate additional savings via supplemental rebate negotiations and/or Drug Utilization Review Board (DURB) referrals.

ENACTED DRUG PRICING LEGISLATION RELATED TO PDABs

STATE	Vermont SB98 (2023)
MODEL	No specific approach adopted. Requires the existing Green Mountain Care Board to explore and create a framework and methodology for implementing a program to regulate the cost of prescription drugs for Vermont consumers and Vermont's health care system.
BOARD MEMBERSHIP	In addition to members of the existing Board, creates permanent classified positions on Board to lead the exploration, development, and implementation of the prescription drug regulation program. Members reappointed with Governor approval and Senate consent. Resigning members replaced by Governor with Senate approval (Committee nomination process required in certain circumstances).
OPPORTUNITIES FOR ENGAGEMENT	Pending Board plan development Jan. 2026.
PLANS IMPACTED	Pending Board plan development Jan. 2025.
FUNDING	For FY 2025, $245,000 is appropriated to the Board from the Evidence-Based Education and Advertising Fund. These funds are intended to allow the Board to contract with experts on prescription drug-related issues. The expenses and cost of operating the Board, including research and analysis, shall be funded by manufacturers fees of 1.75% of the previous calendar year's prescription drug spending. The Board will be funded for 2026 through a combination of a general fund appropriation ($80,000) and the GMCB Billback Regulatory Fund ($120,000).
IMPLEMENTATION TIMELINE	Jan. 15, 2025 – Board shall provide its preliminary plan for implementing a program to regulate the cost of prescription drugs in Vermont, and any proposals for legislative action needed to implement the program. Jan. 15, 2026 – The Board shall provide its final plan for implementing a program to regulate the cost of prescription drugs in Vermont, along with proposals for addressing any additional identified legislative needs.
CURRENT STATUS	In January 2025, the Board released its Preliminary Report on Implementing a Vermont Prescription Drug Cost Regulation Program. It expects to issue recommendations in January 2026 that build on the state's existing infrastructure.
DRUG SELECTION PROCESS	Pending Board plan development Jan. 2026.
TYPE OF DRUG ELIGIBLE FOR SELECTION	Pending Board plan development Jan. 2026.
DEFINITION OF AFFORDABILITY	Pending Board plan development Jan. 2026.
AFFORDABILITY REVIEW	Pending Board plan development Jan. 2026.
SETTING UPLS	Pending Board plan development Jan. 2026.

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