

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARDS & RELATED BILLS

The cost of healthcare 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 establish prescription drug affordability boards (PDABs).<sup>1</sup> These boards are designed to address the increasing costs of prescription drug products. The diverse array of approaches employed by different state PDABs underscores the comprehensive nature of their approaches. These strategies encompass reviewing drug prices, implementing price controls, conducting data and reporting on pricing trends, drug markets, and policy strategies, and offering policy recommendations to improve consumer affordability. Currently, a noteworthy gap exists in the analysis of state adoptions and proposals of these boards. This resource serves as a detailed review of proposed PDAB bills and related drug affordability bills from 2017-2023, offering a comprehensive overview of the evolving landscape to better engage advocacy organizations, patients, providers for the challenges and opportunities that lie ahead in 2024.



# 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.<sup>2</sup> The price negotiated for Medicare by the Secretary of Health and Human Services is the MFP.<sup>3</sup> 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.<sup>4</sup> This allows Medicaid to negotiate with drug companies for supplemental rebates if drug spending exceeds certain thresholds.<sup>5</sup> These state Medicaid programs can also conduct pricing reviews or value assessments for high-cost drugs.<sup>6</sup>

## **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.<sup>7</sup>

## **Reference Pricing (RP)**

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

## **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.<sup>10</sup> The UPL does not dictate the manufacturer's pricing, but establishes an upper boundary on what a payer can charge for a drug.<sup>11</sup>

## **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.<sup>12</sup> 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.<sup>13</sup> 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 RELATED DRUG AFFORDABILITY BILLS (2019 – 2023)

<b>STATE</b>	<b>Massachusetts</b> <a href="#">HB 4000 - Section 46 of FY 2020 Budget</a>
<b>MODEL</b>	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.
<b>PLANS AFFECTED</b>	Medicaid
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability.
<b>DRUG SELECTION PROCESS</b>	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.
<b>PRICING CONSIDERATIONS</b>	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: <ol style="list-style-type: none"> <li>(1) The value, efficacy or outcomes of the drug;</li> <li>(2) Clinical efficacy and outcomes;</li> <li>(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;</li> <li>(4) The seriousness and prevalence of the disease or condition that is treated by the drug;</li> <li>(5) The extent of utilization of the drug;</li> <li>(6) The likelihood that the use of the drug will reduce the need for other medical care;</li> <li>(7) The number of manufacturers that produce the drug;</li> <li>(8) Whether there are pharmaceutical equivalents of the drug;</li> <li>(9) Analyses by independent third parties; and</li> <li>(10) Any information supplied by the manufacturer and other appropriate measures.</li> </ol>
<b>DRUGS COVERED</b>	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.
<b>STATUS</b>	Enacted. The 2023 Massachusetts Health Policy Commission <a href="#">annual report</a> 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 RELATED DRUG AFFORDABILITY BILLS (2019 – 2023)

STATE	<p><b>New York</b>  <a href="#">PHL § 280</a> (2017), <a href="#">SSL § 367-a</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"> <li>(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;</li> <li>(2) Significant and unjustified increases in the price of the drug;</li> <li>(3) Whether the drug may be priced disproportionately to its therapeutic benefits.</li> </ol>
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"> <li>(1) Publicly available information or information supplied to the department relevant to the pricing of the drug;</li> <li>(2) Information relating to value-based pricing;</li> <li>(3) The seriousness and prevalence of the disease or condition that is treated by the drug;</li> <li>(4) The extent of utilization of the drug;</li> <li>(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;</li> <li>(6) The likelihood that use of the drug will reduce the need for other medical care, including hospitalization;</li> <li>(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;</li> <li>(8) For generic drugs, the number of manufacturers that produce the drug;</li> <li>(9) Whether there are pharmaceutical equivalents to the drug; and</li> <li>(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;</li> <li>(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.</li> </ol>
DRUGS COVERED	<p>Drugs subject to price negotiations:</p> <ol style="list-style-type: none"> <li>(1) Drugs purchased by Medicaid that are contributing to spending that will exceed the state’s Medicaid drug cap (set annually);</li> <li>(2) Newly launched drugs considered to be “high cost”:</li> </ol> <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 <a href="#">\$500 million</a> in gross supplemental rebates.</p>

# ENACTED RELATED DRUG AFFORDABILITY BILLS (2019 – 2023)

<b>STATE</b>	Ohio <a href="#">HB166</a> (2019)
<b>MODEL</b>	<p>No specific approach adopted.</p> <p>The prescription drug transparency and affordability advisory council was tasked with providing recommendations regarding Ohio's best path forward for:</p> <ol style="list-style-type: none"> <li>(1) Achieving prescription drug price transparency in Ohio;</li> <li>(2) Establishing new payment models or other avenues to create the most affordable environment for purchasing prescription drugs;</li> <li>(3) Leveraging Ohio's purchasing power across all state agencies, Boards, commissions, and similar entities;</li> <li>(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;</li> <li>(5) Identifying which critical outcomes can be measured and used to improve this state's system of purchasing affordable prescribed drugs;</li> <li>(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.</li> </ol>
<b>PLANS AFFECTED</b>	N/A
<b>DEFINITION OF AFFORDABILITY</b>	N/A
<b>DRUG SELECTION PROCESS</b>	N/A
<b>PRICING CONSIDERATIONS</b>	N/A
<b>DRUGS COVERED</b>	<p>Dec. 2019 - Appointments must be made.</p> <p>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:</p> <ol style="list-style-type: none"> <li>(1) How the state can best achieve prescription drug price transparency;</li> <li>(2) New payment models or other avenues to create the most affordable environment for purchasing prescription drugs;</li> <li>(3) Leveraging the state's purchasing power across all state agencies, Boards, commissions, and similar entities;</li> <li>(4) Creating efficiencies across different healthcare systems, such as hospitals, the criminal justice system, treatment and recovery support programs, and employer-sponsored health insurance, to reduce duplicative service delivery across these systems, ensure that patients receive high quality and affordable prescription drugs, and support quality care and outcomes;</li> <li>(5) Which critical outcomes can be measured and used to improve the state's system of purchasing affordable prescribed drugs;</li> <li>(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.</li> </ol> <p><a href="#">2020 Report</a></p>
<b>STATUS</b>	Enacted. Council submitted recommendations in <a href="#">2020 Report</a> .

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD BILLS (2023)

<b>STATE</b>	<b>Connecticut</b> <a href="#">HB6830</a>
<b>MODEL</b>	No specific approach adopted, but may recommend additional legislation. Board would monitor prescription drug pricing in the state and conduct annual reviews of prescription drug product usage to identify any prescription drug products that may create affordability challenges. May recommend any legislation to make prescription drugs more affordable.
<b>PLANS AFFECTED</b>	All state-regulated plans.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges.
<b>DRUG SELECTION PROCESS</b>	Not included in bill.
<b>PRICING CONSIDERATIONS</b>	Not included in bill.
<b>DRUGS COVERED</b>	Not included in bill.
<b>STATUS</b>	In committee.
<b>FUNDING</b>	Not included in bill.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD BILLS (2023)

<b>STATE</b>	<b>Michigan</b> <a href="#">SB0483</a> / <a href="#">SB0484</a>
<b>MODEL</b>	UPL – Board could establish UPLs for prescription drugs that may create affordability challenges for healthcare systems in the state and patients.
<b>PLANS AFFECTED</b>	All state-regulated plans.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges.
<b>DRUG SELECTION PROCESS</b>	In selecting one or more prescription drug products for an affordability review, the Board shall consider any information that a manufacturer chooses to provide to the Board and all of the following factors, to the extent practicable: <ul style="list-style-type: none"> <li>(1) The WAC;</li> <li>(2) The average monetary concession, discount or rebate that the manufacturer provides or is expected to provide to health insurers and PBMS, as a percent of the WAC;</li> <li>(3) The price of therapeutic alternatives;</li> <li>(4) The average monetary concession, discount, or rebate that another manufacturer provides or is expected to provide to health insurers or PBMs for therapeutic alternatives;</li> <li>(5) The cost to health insurers based on patient access;</li> <li>(6) The impact on patient access resulting from the cost of the prescription drug relative to insurance benefit design;</li> <li>(7) The value of drug-specific patient access programs that are supported by the manufacturer;</li> <li>(8) The relative financial impact to health, medical, or social service costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;</li> <li>(9) The average patient co-pay or other cost-sharing for the prescription drug product in this state; and</li> <li>(10) Any other factor established by the Board by rule.</li> </ul>
<b>PRICING CONSIDERATIONS</b>	In establishing a UPL, the Board shall consider all of the following: <ul style="list-style-type: none"> <li>(1) Relevant administrative costs related to supplying or stocking the prescription drug product;</li> <li>(2) The impact of a UPL on 340B Program entities;</li> <li>(3) UPL must not include professional dispensing fees; and</li> <li>(4) If the Board considers the estimated cost effectiveness, must use a cost-effectiveness analysis that weighs the value of all additional lifetime gained equally for any individual, no matter the severity of illness, age, or preexisting disability, and must not use a cost-per-quality adjusted life year.</li> </ul>
<b>DRUGS COVERED</b>	The following drugs would be eligible for review: Brand-name drug or a biologic with WAC of \$60,000.00+/year or course of treatment or has a WAC increase of \$3,000+ in any 12-month period; Biosimilar with a WAC that is not at least 15% lower than the referenced brand biologic; Generic with a WAC that is \$100+ for: <ul style="list-style-type: none"> <li>(1) a 30-day supply based on FDA-approved recommended dosage labeling; or</li> <li>(2) a supply lasting &lt; 30 days based on FDA-approved recommended dosage labeling; or</li> <li>(3) one unit of the drug if FDA does not recommend a finite dosage; and Increased by 200%+ during the preceding 12 months ; Other prescription drugs products that may create affordability challenges for healthcare systems in this state and to patients.</li> </ul>
<b>STATUS</b>	Passed Senate. In House Committee.
<b>FUNDING</b>	The state treasurer shall deposit money and other assets from any source into a prescription drug affordability fund created within the state treasury.

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD BILLS (2023)

STATE	<p><b>New Jersey</b> A1747 / S329</p>
MODEL	<p>No specific approach adopted but could draft a plan to establish UPLs. Board would study policy options that are being used in other states and countries to lower the list price of pharmaceutical drug products, including establishing UPLs, and if the Board determines that it is in the best interests of the state to establish a process for establishing UPLs for prescription drug products that it determines have led or will lead to an affordability challenge, the Board shall draft a plan of action for implementing the recommended action.</p>
PLANS AFFECTED	<p>State-employee plans.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability or affordability challenges.</p>
DRUG SELECTION PROCESS	<p>Board shall determine whether to conduct a cost review for each identified prescription drug product by seeking input from the Board about the product and considering the average cost share of the product, including any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in the state, market competition and context, projected revenue, and the estimated value or cost-effectiveness of the prescription drug product.</p> <p>In determining whether a prescription drug product has led or will lead to an affordability challenge, <b>the Board shall consider the following factors:</b></p> <ol style="list-style-type: none"> <li>(1) The WAC and any other relevant prescription drug cost index;</li> <li>(2) The average manufacturer price concession, discount, or rebate provided to health plans and PBMs, expressed as a percent of the WAC;</li> <li>(3) The price of therapeutic alternatives;</li> <li>(4) The average manufacturer price concession, discount, or rebate provided to health benefits plans and PBMs for therapeutic alternatives;</li> <li>(5) The costs to health benefits plans based on patient access;</li> <li>(6) The effects on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;</li> <li>(7) The current or expected value of manufacturer drug-specific patient access programs that are supported by the manufacturer;</li> <li>(8) The financial effects on health, medical, and social service costs as can be quantified and compared to the baseline effects of existing therapeutic alternatives;</li> <li>(9) The average patient copay or other cost-sharing;</li> <li>(10) Any additional factors established by the Board by regulation.</li> </ol> <p>If the Board is unable to determine whether a prescription drug product will produce or has produced an affordability challenge, <b>the Board may consider the following factors:</b></p> <ol style="list-style-type: none"> <li>(1) The manufacturer's research and development costs, in proportion to the manufacturer's sales in the state;</li> <li>(2) The portion of direct-to-consumer marketing costs specific to the prescription drug product under review that are eligible for favorable federal tax treatment in the most recent tax year, multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales in the U.S. for the product;</li> <li>(3) Gross and net manufacturer, PBM, and wholesale distributor revenues for the prescription drug product under review for the most recent tax year;</li> <li>(4) Any additional factors proposed by the manufacturer and appropriate health benefits plan carriers, wholesale distributors, and PBM that the Board considers relevant; and</li> <li>(5) Any additional factors that the Board establishes by regulation.</li> </ol>
PRICING CONSIDERATIONS	<p>The Board's plan of action shall include the criteria the Board will use to establish UPLs, which must include consideration of:</p> <ol style="list-style-type: none"> <li>(1) The cost of administering the drug product;</li> <li>(2) The cost of delivering the prescription drug to consumers;</li> <li>(2) Other relevant administrative costs related to the prescription drug product.</li> </ol>
DRUGS COVERED	<p>The Board shall use information and data collected to identify prescription drug products that are:</p> <p>Brand name drugs or biologics with a launch WAC of \$30,000+/year or course of treatment or a WAC increase of \$3,000+ in any 12-month period, or over any course of treatment that is &lt; 12 months; Biosimilars with a launch WAC that is not at least 15% lower than the referenced brand-name biological product; Generic drugs with a WAC that is \$100+ for:</p> <ol style="list-style-type: none"> <li>(1) a 30-day supply based on based on FDA-approved recommended dosage labeling; or</li> <li>(2) a supply lasting &lt; 30 days based on FDA-approved recommended dosage labeling; or</li> <li>(3) one unit of the drug, if FDA does not recommend a finite dosage; and Increased by 200%+ during the preceding 12 months; Any other prescription drugs that the Board determines may create affordability issues for the state healthcare system and New Jersey patients.</li> </ol>
STATUS	<p>In Committee.</p>
FUNDING	<p>Appropriates \$1,000,000.</p>



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD BILLS (2023)

STATE	<b>New Mexico</b> <a href="#">HB51</a>	<b>Rhode Island</b> <a href="#">HB5507</a>
MODEL	No specific approach adopted. Board would conduct a study of the state and national prescription drug market and recommend strategies for lowering the cost of prescription drugs. Must submit to the legislative finance committee and the legislative health and human services committee a report that includes price trends for prescription drug products and recommendations for legislation necessary to lower the cost of prescription drugs.	No specific approach adopted, but may adopt UPLs. Creates prescription drug advisory board designated to investigate and comprehensively evaluate drug prices and possible ways to reduce them in order to make them more affordable, including whether to subject a prescription drug product to a cost review and vote on whether to recommend a UPL on purchases and payor reimbursements of prescription drug products.
PLANS AFFECTED	Not included in bill.	All state-regulated plans.
DEFINITION OF AFFORDABILITY	Not included in bill.	Does not define affordability.
DRUG SELECTION PROCESS	Not included in bill.	The Board may adopt rules and regulations to carry out the provisions of this chapter.
PRICING CONSIDERATIONS	Not included in bill.	The Board may adopt rules and regulations to carry out the provisions of this chapter.
DRUGS COVERED	Not included in bill.	The Board may adopt rules and regulations to carry out the provisions of this chapter.
STATUS	Failed.	In committee.
FUNDING	\$750,000 is appropriated from the general fund for 2024 to establish the Board and cover operational costs. The Board shall be funded by an annual assessment on manufacturers, wholesale drug distributors, or PBMs.	Does not address funding.

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD BILLS (2023)

<b>STATE</b>	Vermont <a href="#">S98</a>
<b>MODEL</b>	UPL – Authorize and directs the Green Mountain Care Board to evaluate the costs of certain high-cost prescription drugs and recommend methods for addressing those costs, including setting limits on what Vermonters would be expected to pay for some high-cost drugs. MFP – The Board must not create a UPL that differs from the Medicare MFP.
<b>PLANS AFFECTED</b>	All state-regulated plans.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges.
<b>DRUG SELECTION PROCESS</b>	The Board shall determine whether to conduct a full affordability review for the proposed prescription drugs after compiling preliminary information about the cost of the product, patient cost sharing for the product, health plan spending on the product, and stakeholder input and other information decided by the Board. Information used to conduct the review may include any document or research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, patient assistance programs specific to the product, estimated or actual manufacturer produce price concessions in the market, net product cost to state payers, and other information as determined by the Board.
<b>PRICING CONSIDERATIONS</b>	The Green Mountain Care Board may adopt rules to carry out its duties. <b>PROHIBITED FROM USING:</b> QALY, or similar measure, to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability.
<b>DRUGS COVERED</b>	The following drugs are eligible for review: Brand-name drugs or biologics with a WAC of \$60,000+/year or per course of treatment or a WAC increase of \$3,000+ in any 12-month period; Biosimilar drugs with a WAC that is not at least 20% lower than the brand-name biologic reference product generic drugs; Generics with a WAC of \$100+ for a 30-day supply or for a course of treatment that increased by 200%+ during the immediately preceding 12-month period; Any other prescription drug products that the Board determines may create affordability challenges for the state's healthcare system and for patients.
<b>STATUS</b>	In committee.
<b>FUNDING</b>	Does not address funding.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD BILLS (2023)

<b>STATE</b>	<b>Virginia</b> HB1596 / SB957
<b>MODEL</b>	UPL – Board would conduct affordability reviews of prescription drug products and establish UPLs for prescription drug products that create affordability challenges. No more than 12 UPLs may be set annually between Jan. 1, 2024 and Jan. 1, 2027. MFP – The Board must not establish a UPL amount greater than the Medicare MFP.
<b>PLANS AFFECTED</b>	All state-regulated plans.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges.
<b>DRUG SELECTION PROCESS</b>	In determining whether a prescription drug product has led or will lead to an affordability challenge, the Board shall consider the following factors: <ol style="list-style-type: none"> <li>(1) The WAC;</li> <li>(2) The average monetary price concession, discount, or rebate the manufacturer provides to health plans, expressed as a percentage of the WAC;</li> <li>(3) The total amount of the price concession, discount, or rebate the manufacturer provides to each PBM, expressed as a percentage of the WAC;</li> <li>(4) The price of therapeutic alternatives;</li> <li>(5) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payers and PBMs for therapeutic alternatives;</li> <li>(6) The cost to health plans based on patient access;</li> <li>(7) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;</li> <li>(8) The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;</li> <li>(9) The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;</li> <li>(10) The average patient copay or other cost-sharing;</li> <li>(11) Any information a manufacturer chooses to provide; and</li> <li>(12) Any other factors as determined by the Board through regulations adopted by the Board.</li> </ol>
<b>PRICING CONSIDERATIONS</b>	If the Board finds that the spending on a prescription drug product has led or will lead to an affordability challenge for the VA healthcare system or high out-of-pocket costs for citizens of VA, particularly patients experiencing physical and mental illnesses, communities affected by the opioid crisis, state and local governments, commercial health plans, healthcare providers, pharmacies and other stakeholders within the healthcare system, the Board shall establish an UPL amount after 219 considering: <ol style="list-style-type: none"> <li>(1) the cost administering the prescription drug product;</li> <li>(2) the cost of delivering the prescription drug product to customers; and</li> <li>(3) Other relevant administrative costs related to the prescription drug product.</li> </ol> <p><b>PROHIBITED:</b> Use QALY, or similar measure, to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability.</p>
<b>DRUGS COVERED</b>	The following drugs are eligible for review: Brand-name drugs or biologics with a WAC of \$60,000+/year or course of treatment or a WAC increase of \$3,000+ in any 12-month period; Biosimilars with a WAC that is not at least 20% lower than the referenced brand biologic, and that have been suggested for review by members of the public, medical professionals, or other stakeholders; Generic drugs with a WAC that is \$100+ for: <ol style="list-style-type: none"> <li>(1) a 30-day supply based on based on FDA-approved recommended dosage labeling; or</li> <li>(2) a supply lasting &lt; 30 days based on FDA-approved recommended dosage labeling; or</li> <li>(3) one unit of the drug if FDA labeling does not recommend any finite dosage; and Increased 200%+ in the previous 12 months.</li> </ol> Other prescription drug products that may create affordability challenges for the healthcare system in Virginia and high out-of-pocket costs for patients.
<b>STATUS</b>	Failed.
<b>FUNDING</b>	Funds appropriated special non-reverting fund to be known as the Prescription Drug Affordability Fund.

## REFERENCES

1. Colleen Becker, *Prescription Drug Trends: Pharmacy Benefit Manager Reform, Affordability Boards and More*, <https://www.ncsl.org/state-legislatures-news/details/prescription-drug-trends-pharmacy-benefit-manager-reform-affordability-boards-and-more#:~:text=Drug%20Affordability%20Boards&text=One%20idea%20gaining%20traction%20is,ways%20to%20reduce%20state%20spending>.
2. Juliette Cubanski, *FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, KFF, <https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program/>.
3. *Id.*
4. National Academy for State Health Policy, *New Legislative and Medicaid Models to Lower Drug Prices: 2022*, <https://nashp.org/toolkit-new-legislative-and-medicare-models-to-lower-drug-prices-2022/>.
5. *Id.*
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