

**2024**

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARDS UPDATES

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 steps to propose prescription drug affordability boards (PDABs).

These boards are designed to address the increasing costs of prescription drug products through a variety of mechanisms such as reviewing drug prices, implementing price controls, conducting data analysis, reporting on pricing trends, drug markets, and policy strategies, and offering policy recommendations to improve consumer affordability. This resource serves as a detailed review of the proposed PDAB legislation during the 2024 legislative sessions, offering a comprehensive overview of this evolving landscape. This resource aims to educate and empower advocacy organizations, patients, and providers on the various versions of PDAB legislation that may be seen in 2025.



# 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.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>Arizona</b> <a href="#">SB1533</a> (2024)
<b>MODEL</b>	UPL – Prescription Drug Affordability Division would set UPLs for specified prescription drugs; promote, study, and recommend consumer cost-saving mechanisms for prescription drugs; approve or deny prescription drug price increase requests; and ensure that proposed health insurance premium rates that are charged to the consumer accurately reflect the actuarial value of the prescription drug or related products, including any PBM rebates, carrier incentives, or other cost savings.
<b>PLANS AFFECTED</b>	State-sponsored and state-regulated plans.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges.
<b>DRUG SELECTION PROCESS</b>	Not included in bill; determined by the Department of Insurance and Financial Institutions.
<b>PRICING CONSIDERATIONS</b>	Not included in bill; determined by the Department of Insurance and Financial Institutions.
<b>DRUGS COVERED</b>	Not included in bill; determined by the Department of Insurance and Financial Institutions.
<b>STATUS</b>	Failed.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

STATE	<p><b>Connecticut</b>  <a href="#">SB5054</a> (2024)</p>
MODEL	<p>No specific approach adopted – The Board shall recommend potential cost containment strategies and tools prescription for drug products that have led or will lead to affordability challenges but has not provided or will not provide significant benefits to health or health outcomes.  MFP – The Board may use MFPs.</p>
PLANS AFFECTED	<p>Pending Board recommendations.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability or affordability challenges.  In determining whether a prescription drug product has led or will lead to an affordability challenge, the Board may consider the following factors:</p> <ol style="list-style-type: none"> <li>(1) The WAC;</li> <li>(2) The average monetary price concession, discount or rebate provided or expected to be provided to health plans in the state as reported by manufacturers and health plans, expressed as a percentage of the WAC for the prescription drug product under review;</li> <li>(3) The total amount of the price concession, discount or rebate the manufacturer provides to each PBM operating for the prescription drug product under review, as reported by manufacturers and 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 payors and PBMs for therapeutic alternatives;</li> <li>(6) The costs to health plans based on patient access consistent with FDA-labeled indications and recognized standard medical practice;</li> <li>(7) The impact on patient access resulting from the cost of the prescription drug product relative to health plan 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 may be quantified and compared to baseline effects of existing therapeutic alternatives;</li> <li>(10) The average patient copayment 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.</li> </ol>
DRUG SELECTION PROCESS	<p>In determining whether to conduct an affordability review, the Board shall consider input from relevant stakeholders and the average patient cost share of the selected prescription drug product.  In determining whether a prescription drug product has led or will lead to an affordability challenge, the Board shall examine any document and research related to the pricing of the prescription drug product, including:</p> <ol style="list-style-type: none"> <li>(1) Net average price in the state;</li> <li>(2) Market competition and context;</li> <li>(3) Projected revenue to the manufacturer;</li> <li>(4) The estimated value or cost effectiveness;</li> <li>(5) Whether and how the prescription drug product represents an innovative therapy or is likely to improve health or health outcomes for the target consumer; and</li> <li>(6) Any rebates, discounts, patient access programs or other cost mitigation strategies relevant to the prescription drug product.</li> </ol> <p><b>PROHIBITED FROM REVIEW:</b> Breakthrough drugs, orphan drugs, drugs with a new and unique mechanism of action for treating a medical condition or any other drug that represents a significant innovation or advance in therapy.</p>
PRICING CONSIDERATIONS	<p>In recommending cost containment strategy, the Board shall consider:</p> <ol style="list-style-type: none"> <li>(1) The cost of administering the drug;</li> <li>(2) The cost of delivering the drug to patients; and</li> <li>(3) other relevant administrative costs related to the drug.</li> </ol>
DRUGS COVERED	<p>The following drugs would be eligible for review:  Brand-name drugs with a launch WAC of \$30,000+ per year or course of treatment or with a WAC increase of \$3,000+ in any 12-month period;  Biosimilars with a launch WAC that is not at least 15% lower than the referenced brand biologic; and  Generic drugs with a WAC that increased by 200%+ in the preceding 12 months and that is \$100+ for:</p> <ol style="list-style-type: none"> <li>(1) A 30-day supply lasting 30 consecutive days based on the recommended dosage approved for labeling by the FDA;</li> <li>(2) A supply lasting a patient &lt; 30 days based on the recommended dosage approved for labeling by the FDA; or</li> <li>(3) One unit of the drug if the FDA-approved labeling does not recommend a finite dosage.</li> </ol>
STATUS	<p>Failed.</p>

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

STATE	<p><b>Connecticut</b> SB8 (2024)</p>
MODEL	<p>UPL – The Board could recommend UPLs for prescription drug products that have led or will lead to affordability challenges for the health care system in the state or patients, including, but not limited to, drugs needed to address significant public health priorities. This bill would also direct the director of the Office of Health Strategy to establish a Canadian prescription drug importation program. MFP – Board <b>must</b> consider MFP when establishing UPL.</p>
PLANS AFFECTED	<p>All state-sponsored and state-regulated plans; ERISA plans may opt-in.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability or affordability challenges. In determining whether a prescription drug product has led or will lead to an affordability challenge, the Board may consider the following factors:</p> <ol style="list-style-type: none"> <li>(1) The WAC;</li> <li>(2) The average monetary price concession, discount or rebate provided or expected to be provided to health plans in the state as reported by manufacturers and health plans, expressed as a percentage of the WAC for the prescription drug product under review;</li> <li>(3) The total amount of the price concession, discount or rebate the manufacturer provides to each PBM operating for the prescription drug product under review, as reported by manufacturers and 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 payors and PBMs for therapeutic alternatives;</li> <li>(6) The costs to health plans based on patient access consistent with FDA-labeled indications and recognized standard medical practice;</li> <li>(7) The impact on patient access resulting from the cost of the prescription drug product relative to health plan 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 may be quantified and compared to baseline effects of existing therapeutic alternatives;</li> <li>(10) The average patient copayment 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.</li> </ol>
DRUG SELECTION PROCESS	<p>In determining whether to conduct an affordability review, the Board shall consider input from relevant stakeholders and the average patient cost share of the prescription drug product. In determining whether a prescription drug product has led or will lead to an affordability challenge, the Board shall examine any document and research related to the pricing of the prescription drug product, including:</p> <ol style="list-style-type: none"> <li>(1) Net average price in the state;</li> <li>(2) Market competition and context;</li> <li>(3) Projected revenue to the manufacturer</li> <li>(4) The estimated value or cost effectiveness</li> <li>(5) Whether and how the prescription drug product represents an innovative therapy or is likely to improve health or health outcomes for the target consumer; and</li> <li>(6) Any rebates, discounts, patient access programs or other cost mitigation strategies relevant to the prescription drug product.</li> </ol>
PRICING CONSIDERATIONS	<p>In recommending a UPL, the Board shall consider:</p> <ol style="list-style-type: none"> <li>(1) The cost of administering the drug; (2) The cost of delivering the drug to patients; and (3) other relevant administrative costs related to the drug.</li> </ol>
DRUGS COVERED	<p>The following drugs would be eligible for review: Brand-name drugs with a launch WAC of \$30,000+ per year or course of treatment or with a WAC increase of \$3,000+ in any 12-month period; Biosimilars with a launch WAC that is not at least 15% lower than the referenced brand biologic; and Generic drugs with a WAC that increased by 200%+ in the preceding 12 months and that is \$100+ for:</p> <ol style="list-style-type: none"> <li>(1) A 30-day supply lasting 30 consecutive days based on the recommended dosage approved for labeling by the FDA; (2) A supply lasting a patient &lt; 30 days based on the recommended dosage approved for labeling by the FDA; or (3) One unit of the drug if the FDA-approved labeling does not recommend a finite dosage.</li> </ol>
STATUS	<p>Failed.</p>

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

STATE	<p><b>Illinois</b>  <a href="#">HB4472/SB3108</a> (2024)</p>
MODEL	<p>UPL – Board could set UPLs for prescription drug products that may create affordability challenges for the State health care system or patients, including, but not limited to, drugs to address public health emergencies.  MFP – Board required to use MFPs when establishing UPLs.</p>
PLANS AFFECTED	<p>State-regulated health plans.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability or affordability challenges.  <b>PROHIBITED FROM USING:</b> Board prohibited from using QALY, or similar measure, that discounts the value of life because of an individual's disability or age</p>
DRUG SELECTION PROCESS	<p>The Board shall determine whether to conduct an 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, stakeholder input, and other information decided by the Board.</p>
PRICING CONSIDERATIONS	<p>Does not specify, however, prohibited from using QALY, or similar measure, that discounts the value of life because of an individual's disability or age.</p>
DRUGS COVERED	<p>The following drugs would be eligible for review:  Brand-name drugs with a WAC of \$60,000+ per year or course of treatment if less than a year, or with a WAC increase of \$3,000+ in any 12-month period;  Biosimilars with a launch WAC that is not at least 20% lower than the referenced brand biologic and that have been suggested for review by the members of public, medical professionals, and other stakeholders;  Generic drugs with a WAC that increased by 200%+ in the preceding 12 months and that is \$100+ for a 30-day supply or course of treatment lasting &lt; 30 days; and  Other prescription drug products that may create affordability challenges for the State health care system or patients, including, but not limited to, drugs to address public health emergencies.</p>
STATUS	<p>Failed.</p>

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>Iowa</b> <a href="#">SF2238/HF2408</a> (2024)
<b>MODEL</b>	UPL – Board would submit UPL recommendations for prescription drug products that may create affordability challenges for the state health care system and for patients.
<b>PLANS AFFECTED</b>	Not applicable. This Board focuses on understanding the broader landscape of prescription drug costs and formulating recommendations. Currently, it can only recommend UPLs be set by the General Assembly it cannot itself impose a UPL. .
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges. In determining whether a prescription drug may create affordability challenges for the state health care system and for patients, 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, or is expected to provide, to PBMs and health plans expressed as a percentage of the WAC cost for the prescription drug product under review;</li> <li>(3) The price of therapeutic alternatives;</li> <li>(4) The average monetary concession, discount, or rebate the manufacturer provides, or is expected to provide, to health plan payors and PBMs for therapeutic alternatives;</li> <li>(5) The cost to health plans based on patient access consistent with FDA label indications and recognized standard medical practice;</li> <li>(6) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;</li> <li>(7) The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer;</li> <li>(8) The relative financial impacts to the costs of health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives;</li> <li>(9) The average patient copay or other cost sharing for the prescription drug product in the state;</li> <li>(10) Any information a manufacturer chooses to provide</li> <li>(11) Any other factors as determined by the Board through rules adopted by the Board.</li> </ol>
<b>DRUG SELECTION PROCESS</b>	In determining whether to conduct an affordability review, the Board shall consider stakeholder council input and the average patient cost share of the prescription drug product.
<b>PRICING CONSIDERATIONS</b>	If the Board finds that spending on a prescription drug has led or will lead to affordability challenges for the state health care system and for patients, the Board shall establish UPL recommendations for the General Assembly after consideration of the cost of administering the prescription drug production, the cost of delivery the prescription drug product to consumers, and other relevant administration costs related to the prescription drug.
<b>DRUGS COVERED</b>	The following drugs are eligible for review: 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; Biosimilars with a WAC that is not at least 15% lower than the referenced brand biologic; and Generic drugs with a WAC that increased by 200%+ over the preceding 12-month period and that is \$100+ for: <ol style="list-style-type: none"> <li>(1) a 30-day supply or less, based on FDA-approved recommended dosage labeling; or</li> <li>(2) one dose if FDA labeling does not recommend any finite dosage;</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.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>Kentucky</b> HB823 (2024)
<b>MODEL</b>	No specific approach proposed, but the Board would issue a report on whether the state should pass legislation to expand the authority of the Board to set UPLs and develop a plan for establishing them.
<b>PLANS AFFECTED</b>	Public employee health plans.
<b>DEFINITION OF AFFORDABILITY</b>	<p>Does not define affordability or affordability challenges.</p> <p>In determining whether a prescription drug product has imposed costs that create a significant affordability challenge for the state health care system or patients, the Board shall consider the following factors:</p> <ol style="list-style-type: none"> <li>(1) The number of residents in this state prescribed the drug;</li> <li>(2) The price of the drug, including WAC and any other relevant prescription drug cost index for the drug;</li> <li>(3) The relevant factors contributing to the price of the drug, including the WAC, discounts, rebates, or other price concessions;</li> <li>(4) The price and availability of therapeutic alternatives to the drug that are sold in this state;</li> <li>(5) The relevant factors contributing to the price paid for the therapeutic equivalents of the drug, including the WAC, discounts, rebates, or other price concessions for the therapeutic equivalent;</li> <li>(6) The cost to health insurance contracts, policies, certificates, or plans based on patient use of the drug that is consistent with the labeling approved by the FDA; and recognized standard medical practice;</li> <li>(7) The impact on patient access to the drug based on standard prescription drug benefit designs in health insurance contracts, policies, certificates, and plans offered in this state;</li> <li>(8) The dollar value and accessibility of patient assistance programs offered by the manufacturer of the drug;</li> <li>(9) The relative financial impacts to health, medical, or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives;</li> <li>(10) The effect of the price of the drug on Kentucky consumers' access to the drug;</li> <li>(11) The average patient copayment or other cost sharing that is associated with the drug and typically required pursuant to health insurance policies, certificates, plans, and contracts issued by insurers in the state;</li> <li>(12) The impact on safety net providers if the drug is available through Section 340B of the Public Health Service Act;</li> <li>(13) Orphan drug status;</li> <li>(14) Input from patients, caregivers, and individuals who possess scientific and medical training related to the condition or disease treated by the prescription drug; and</li> <li>(15) Any other information that a manufacturer, insurer, PBM, other administrator of pharmacy benefits, or other entity chooses to provide to the Board.</li> </ol>
<b>DRUG SELECTION PROCESS</b>	<p>Board shall determine whether to conduct a cost review after evaluating:</p> <ol style="list-style-type: none"> <li>(1) the class of the drug; (2) the availability of any therapeutically equivalent prescription drugs, and (3) aggregated data, and considering: (4) input about the drug from stakeholders, (5) the average patient's out-of-pocket cost for the drug, and (6) any other criteria established by the Board in administrative regulation.</li> </ol>
<b>PRICING CONSIDERATIONS</b>	Not included in bill; determined by Board.
<b>DRUGS COVERED</b>	<p>The following drugs would be eligible for review:</p> <p>Brand-name drugs or a biologics with WAC of \$30,000.00+/year or course of treatment or has a WAC increase of 10%+ in any 12-month period;</p> <p>Biosimilars with a WAC that is not at least 15% lower than the referenced brand biologic;</p> <p>Generics with a WAC that increased by 200%+ during the preceding 12 months and 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 (2) one dose of the drug if FDA labeling does not recommend any finite dosage</li> </ol>
<b>STATUS</b>	Failed.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

STATE	<p><b>Michigan</b>  <a href="#">SB483</a>; <a href="#">SB484</a>; <a href="#">SB485</a> (2023)</p>
MODEL	<p>UPL – The Board may establish UPLs for prescription drugs that have led or will lead to affordability challenges for health care systems in the state or high out-of-pocket costs for patients in the state.</p>
PLANS AFFECTED	<p>All state-regulated health plans, including Medicaid.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability or affordability challenges.</p> <p>In determining whether a prescription drug has led or will lead to an affordability challenge, the Board shall consider:</p> <ol style="list-style-type: none"> <li>(1) Information that a manufacturer chooses to provide to the Board and all of the following factors, to the extent practicable:</li> <li>(2) The WAC;</li> <li>(3) The average monetary price concession, discount, or rebate that the manufacturer provides to health insurers and PBMs, expressed as a percent of the WAC;</li> <li>(4) The price at which therapeutic alternatives for the prescription drug product have been;</li> <li>(5) The average monetary concession, discount, or rebate that another manufacturer provides or is expected to provide to health insurers and PBMs for therapeutic alternatives;</li> <li>(6) The cost to health insurers based on patient access consistent with FDA-labeled indications or recognized standard medical practice;</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 impact to health, medical, or social service costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;</li> <li>(10) The average patient co-pay or other cost-sharing for the prescription drug product in this state; and</li> <li>(11) Any other factor established by the Board by rule.</li> </ol>
DRUG SELECTION PROCESS	<p>In determining whether to conduct a cost review, the Board shall consider input from the council and the average patient cost share for each prescription drug product.</p>
PRICING CONSIDERATIONS	<p>When establishing a UPL, the Board shall consider all the relevant administrative costs related to supplying or stocking the prescription drug product and the impact of a UPL on 340B Program entities.</p> <p><b>PROHIBITED FROM USING:</b> The Board is prohibited from using QALY, or similar measure, that discounts the value of life because of an individual's disability or age.</p>
DRUGS COVERED	<p>The following drugs would be eligible for review:</p> <p>Brand-name drug or a biologic with a WAC of \$60,000+/year or course of treatment or has a WAC increase of \$3,000+ in any 12-month period;</p> <p>Biosimilar with WAC that is not at least 15% lower than the referenced brand biologic; and</p> <p>A generic with a WAC that increased by 200%+ during the preceding 12-month period and that \$100+ for:</p> <ol style="list-style-type: none"> <li>(1) a 30-day supply that lasts 30 consecutive days based on FDA-approved recommended dosage labeling;</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 a finite dosage;</li> </ol> <p>A prescription drug product that may create affordability challenges for health care systems in this state and patients, including, but not limited to, a prescription drug product needed to address a public health emergency</p>
STATUS	<p><a href="#">SB0483</a> only passed in the Senate; failed. <a href="#">SB484</a> and <a href="#">SB485</a> both failed.</p>

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

STATE	<p><b>Nebraska</b>  <a href="#">LB833</a> (2024)</p>
MODEL	<p>UPL – Board would establish up to 12 UPLs annually (18 with demonstrated need) for prescription drugs that are unaffordable for Nebraska consumers.</p>
PLANS AFFECTED	<p>All state regulated health plans. Self-funded health benefit plans can opt-in to the program.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define unaffordable.          In determining whether a prescription is unaffordable to Nebraska consumers, the Board shall consider:</p> <ol style="list-style-type: none"> <li>(1) The WAC;</li> <li>(2) The cost and availability of therapeutic alternatives;</li> <li>(3) The effect of the price on Nebraska consumers' access to the prescription drug;</li> <li>(4) The relative financial effects on health, medical, or social services costs, as the effects can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug;</li> <li>(5) The patient copayment or other cost sharing that is associated with the prescription drug and typically required pursuant to health benefit plans issued by carriers in the state;</li> <li>(6) The impact on safety net providers if the prescription drug is available through the federal Public Health Service Act;</li> <li>(7) Orphan drug status;</li> <li>(8) Input from patients, caregivers and individuals who possess scientific or medical training related to a condition or disease treated by the prescription drug;</li> <li>(10) Any other information that a manufacturer, carrier, PBM, or other entity chooses to provide; and</li> <li>(11) Any other factors as determined by the Board.</li> </ol>
DRUG SELECTION PROCESS	<p>The Board shall determine whether to conduct an affordability review after:</p> <ol style="list-style-type: none"> <li>(1) Evaluating the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale;</li> <li>(2) Evaluating aggregated data;</li> <li>(3) Seeking and considering input from the advisory council about the prescription drug; and</li> <li>(4) Considering the average patient's out-of-pocket cost for the prescription drug.</li> </ol>
PRICING CONSIDERATIONS	<p>Methods set by Board, which must consider: (1) The cost of administering or dispensing the prescription drug; (2) The cost of distributing the prescription drug to consumers; (3) The status of the prescription drug on the drug shortage list published by the FDA; and (4) Other relevant costs related to the prescription drug.          In determining a UPL method, the Board shall not consider research or methods that employ QALY or similar measure that discounts the value of a life because of an individual's disability or age.</p>
DRUGS COVERED	<p>The following drugs would be eligible for review:          Any prescription drug that has a</p> <ol style="list-style-type: none"> <li>(1) A WAC of \$3,000+;</li> <li>(2) An WAC increase of \$300+ in the preceding 12 months;</li> <li>(3) An WAC increase of 200%+ in the preceding 12 months; or</li> <li>(4) A current WAC of \$30,000+ for a course of treatment per person per year;</li> </ol> <p>Any biosimilar drug with a launch WAC that is not at least 15% lower than the WAC of the corresponding biological product;          A generic drug with a WAC that increased by 200%+ in the preceding 12-month period and is \$100+ for:</p> <ol style="list-style-type: none"> <li>(1) a 30-day supply based on FDA-approved recommended dosage labeling;</li> <li>(2) a supply lasting &lt; 30 days based on FDA-approved recommended dosage labeling; or</li> <li>(3) one unit of the generic drug if FDA labeling does not recommend any finite dosage;</li> </ol>
STATUS	<p>Failed.</p>

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>Pennsylvania</b> SB696 (2023)
<b>MODEL</b>	No specific model – Board established to review high-cost prescription drug products and develop recommendations for addressing affordability burdens faced by residents, State and local government agencies, commercial health plans, health care providers, employers, pharmacies licensed in this state.
<b>PLANS AFFECTED</b>	Not applicable. This Board focuses on providing recommendations for future legislation that could apply to health plans. Currently, it does not have a mandate to establish UPLs.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges.
<b>DRUG SELECTION PROCESS</b>	Not applicable. This Board focuses on providing recommendations for future legislation that could apply to health plans. Currently, it does not have a mandate to select specific drugs to review.
<b>PRICING CONSIDERATIONS</b>	<p>To develop report, the Board shall consider the following information submitted by manufacturers:</p> <ol style="list-style-type: none"> <li>(1) The costs for the R&amp;D and manufacturing accrued by the manufacturer in the development of the drug;</li> <li>(2) The total costs of clinical trials and other regulatory costs accrued by the manufacturer;</li> <li>(3) The total costs of materials, manufacturing and distribution attributable to the drug for each of the previous three years;</li> <li>(4) The costs accrued by any other entity, including any amount from federal, state or other governmental programs or any form of subsidies, grants or other support;</li> <li>(5) Other costs to acquire the drug, including costs for the purchase of or leasing the rights to patents, licensing or acquisition of a corporate entity owning rights to the drug while in development;</li> <li>(6) The marketing and advertising costs accrued for the promotion of the drug directly to consumers for each of the previous three years, including costs associated with coupons or discounts, marketing and advertising costs accrued in the U.S. for promotion of the drug directly or indirectly to prescribers;</li> <li>(7) A five-year history of average WAC increases for the drug expressed as percentages, including the months each average WAC increase took effect;</li> <li>(8) The total profit attributable to the drug as represented in dollars and as a percentage of the total company profits for each of the previous three years;</li> <li>(9) The aggregate amount of all rebates that the manufacturer provided to all payers, including insurers and PBMs, within the previous 3 years;</li> <li>(10) A description of the manufacturer's patient prescription assistance programs available in the U.S., in the previous 3 years, including the amount of financial assistance, the amount of financial assistance provided to residents (including the average per capita), the eligibility and benefit structure of the patient prescription assistance programs, including coupons;</li> <li>(11) Payments or financial incentives provided to hospitals, health care providers or physicians, including speaking fees, dinners, research, consulting, charitable donations, grants or other incentives, discounts or rebates for the previous 3 years.</li> </ol>
<b>DRUGS COVERED</b>	The drug has an average WAC of at least \$5,000 annually or per course of treatment if less than a year, and which the average WAC has increased by 50%+ over the past 5 years or the average WAC has increased by 15%+ over the past 12 months.
<b>STATUS</b>	In committee. Legislative session ends 11/30/2024.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>Rhode Island</b> SB2719/HB8220 (2024)
<b>MODEL</b>	UPL-like limit – Drug cost review commission could establish level of reimbursement for the spending on the prescription drug product under review creates excess costs for payors and consumers, the Commission shall establish the level of reimbursement.
<b>PLANS AFFECTED</b>	All state-regulated plans, pharmacies, and administrating providers.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges. “Excess costs” means: Costs of appropriate utilization of a prescription drug product that exceed the therapeutic benefit relative to other therapeutic options/alternative treatments or that are not sustainable to public and private health care systems over a ten-year timeframe.
<b>DRUG SELECTION PROCESS</b>	In determining whether to conduct a cost review, the Commission shall consider public comments. In determining excess cost, the Commissioner shall consider: <ol style="list-style-type: none"> <li>(1) The price at which the prescription drug has been/will be sold in the state;</li> <li>(2) The average monetary price concession/discount/rebate the manufacturer provides to payors in the state/or is expected to provide to payors in the state;</li> <li>(3) The price at which therapeutic alternates have been/shall be sold in the state;</li> <li>(4) The average monetary price concession/discount/rebate the manufacturer provides to health plan payors in the state or is expected to provide to payors in the state for therapeutic</li> <li>(5) The relative clinical merits of the product under review compared to therapeutic alternates;</li> <li>(6) The cost to payors based on patient access consistent with FDA-labeled indication(s);</li> <li>(7) The impact on patient access resulting from the cost of the product relative to insurance benefit design;</li> <li>(8) The current or expected value of manufacturer-supported, drug-specific, patient access programs;</li> <li>(9) The relative financial impacts to health, medical and other social services costs, as can be quantified and compared to baseline effects of existing therapeutic alternatives; and</li> <li>(10) Other such factors as may be specified in regulation by the commission.</li> </ol>
<b>PRICING CONSIDERATIONS</b>	Does not specify.
<b>DRUGS COVERED</b>	Brand-name drugs with a WAC that increased by 10%+ or \$10,000 during any 12-month period, or that will have a WAC of \$30,000+ per year or per course of treatment; Brand-name drugs, biologics or biosimilars that impose costs on the state health care system that create significant challenges to affordability (lower than above threshold); and Generic or off-patent sole source branded product drug with a WAC that increased by more than \$300 or more than 25% during any 12-20 month; a generic drug that has a WAC that will increased by \$3,000+ annually; or a generic or off-patent sole source branded product drug with a WAC that will impose costs on the state health care system that create significant challenges to affordability (lower than above threshold).
<b>STATUS</b>	Failed.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>South Carolina</b> <a href="#">H4984</a> (2024)
<b>MODEL</b>	UPL – The Board shall establish UPLs for prescription drugs that pose affordability challenges for the health care system in the state or high out-of-pocket costs for citizens of the state.
<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 to conduct an affordability review, the Board shall consider preliminary information about the cost of the product, patient cost-sharing for the product, health plan spending on the product, stakeholder input, and other information as determined by the Board.
<b>PRICING CONSIDERATIONS</b>	In establishing a UPL, the Board shall consider the cost of administering the prescription drug product, the cost of delivering the prescription drug product to customers, and other relevant administrative costs related to the prescription drug product.
<b>DRUGS COVERED</b>	<p>The following drugs would be eligible for review:</p> <p>Brand-name drugs or biologics with a launch WAC of \$60,000+ per year or course of treatment or a WAC increase of \$3,000+ in any 12-month period;</p> <p>Biosimilars with a launch 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;</p> <p>Generic drugs with a WAC of \$100+ for:</p> <ul style="list-style-type: none"> <li>(1) a 30-day supply lasting 30 consecutive days based on FDA-approved recommended dosage labeling;</li> <li>(2) a supply lasting &lt; 30 consecutive 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;</li> </ul> <p>Generic drugs with a WAC that increased by 200%+ during the preceding 12-month period and is \$100+ for a 30-day supply or a course of treatment less than 30 days; and</p> <p>Other prescription drugs that may create affordability challenges for the health care system in the state and high out-of-pocket costs for patients, including drugs used to address public health emergencies.</p>
<b>STATUS</b>	Failed.



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>Vermont</b> <a href="#">H776</a> (2023)
<b>MODEL</b>	UPL – Would establish entity within the Green Mountain Care Board that would develop a plan for addressing the high cost of prescription drugs, which shall include having the Board conduct an affordability review on certain high-cost prescription drugs and set appropriate UPLs.
<b>PLANS AFFECTED</b>	Contingent on Board plan development.
<b>DEFINITION OF AFFORDABILITY</b>	Does not define affordability or affordability challenges.
<b>DRUG SELECTION PROCESS</b>	Contingent on Board's plan development.
<b>PRICING CONSIDERATIONS</b>	Contingent on Board's plan development.
<b>DRUGS COVERED</b>	Contingent on Board's plan development.
<b>STATUS</b>	Failed (but <a href="#">S98</a> (2024) bill enacted).



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

STATE	<p><b>Virginia</b>  <b>SB274/H570</b> (2024)</p>
MODEL	<p>UPL – The Board would establish UPLs for prescription drug products that have led or will lead to affordability challenges for the health care system in the state or high out-of-pocket costs for citizens of the state, particularly patients experiencing physical and mental illnesses, communities affected by the opioid crisis, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system.</p> <p>MFP – Board may use MFP for UPL.</p>
PLANS AFFECTED	<p>All state-regulated health plans.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability or affordability challenges.</p> <p>To determine whether a prescription drug product has led or will lead to an affordability challenge, the Board shall consider the following factors:</p> <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 in the state as reported by manufacturers and health plans, expressed as a percentage of the WAC;</li> <li>(3) The total price concession, discount, or rebate the manufacturer provides to each PBM operating in the state for the prescription drug product, as reported by manufacturers and PBMs, 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 to health plan payers and PBMs for therapeutic alternatives;</li> <li>(6) The cost to health plans based on patient access consistent with FDA-labeled indications and recognized standard medical practice;</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 for the prescription drug product in the state;</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> <p><b>PROHIBITED FROM USING:</b> Board prohibited from using QALY, or similar measure, that discounts the value of life because of an individual's disability or age.</p>
DRUG SELECTION PROCESS	<p>To determine whether to conduct a cost review, the Board should consider public input, preliminary information about the cost of the product, patient cost sharing, stakeholder input, and other information as determined by the Board.</p>
PRICING CONSIDERATIONS	<p>The Board shall establish a UPL after considering the exceptional costs of administering the prescription drug product, the cost of delivering the prescription drug product to customers, and other relevant administrative costs related to the prescription drug product. The Board shall not use QALY, or similar measure, that discounts the value of life because of an individual's disability or age.</p>
DRUGS COVERED	<p>The following drugs would be eligible for review:</p> <p>Brand-name drugs or biologics that have a launch WAC of \$60,000+ per year or course of treatment or a WAC increase of \$3,000+ in any 12-month period;</p> <p>Biosimilars with a launch WAC that is not at least 20% lower than the referenced brand biologic that has been suggested for review by members of the public, medical professionals, or other stakeholders;</p> <p>Generics, that increased by 200%+ during the preceding 12-month period:</p> <ol style="list-style-type: none"> <li>(1) a 30-day supply lasting 30 consecutive days based on FDA-approved recommended dosage labeling;</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</li> </ol> <p>Other prescription drug products that may create affordability challenges for the health care system in the state and high out-of-pocket costs for patients, including drugs used to address public health emergencies.</p>
STATUS	<p>Passed by state legislature, but vetoed by Governor Youngkin.</p>

# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

STATE	<p><b>West Virginia</b>  <a href="#">HB5682</a> (2024)</p>
MODEL	<p>UPL – The Board would submit plan to establish a process for setting UPLs for prescription drug products that may create affordability challenges for the state health care system and patients.</p>
PLANS AFFECTED	<p>State employee plans and Medicaid.</p>
DEFINITION OF AFFORDABILITY	<p>Does not define affordability or affordability challenges.</p> <p>In determining whether a prescription drug product has led or will lead to an affordability challenge, the Board shall consider the following factors:</p> <ol style="list-style-type: none"> <li>(1) The WAC and any other relevant prescription drug costs;</li> <li>(2) The average monetary price concession, discount, or rebate the manufacturer provides to health plans in the state or is expected to provide to health plans in the state as reported by manufacturers and health plans, expressed as a percent of the WAC for the prescription drug product under review;</li> <li>(3) The total amount of the price concession, discount, or rebate the manufacturer provides to each PBM operating in the state for the prescription drug product under review, as reported by manufacturers and pharmacy benefits managers, expressed as a percent of the WAC;</li> <li>(4) The price at which therapeutic alternatives have been sold in the state;</li> <li>(5) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and PBMs for therapeutic alternatives;</li> <li>(6) The costs to health plans based on patient access consistent with FDA-labeled indications;</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 for the prescription drug product in the state; and</li> <li>(11) Any other factors as determined by the Board in regulations adopted by the Board.</li> </ol>
DRUG SELECTION PROCESS	<p>In determining whether to conduct a cost review, the Board shall consider stakeholder council input and the average cost share of the prescription drug product.</p>
PRICING CONSIDERATIONS	<p>In establishing UPLs, the Board shall draft a plan of action, which should include consideration of:</p> <ol style="list-style-type: none"> <li>(1) The cost of administering the prescription drug product;</li> <li>(2) The cost of delivering the prescription drug product to consumers; and</li> <li>(3) Other relevant administrative costs related to the prescription drug product.</li> </ol>
DRUGS COVERED	<p>The following drugs would be eligible for review:</p> <p>Brand name drugs or biologics with a launch WAC of \$30,000+ per year or course of treatment or a WAC increase of \$3,000+ in any 12-month period, or course of treatment if less than 12 months;</p> <p>Biosimilar drugs that have a launch WAC that is not at least 15% lower than the referenced brand biologic;</p> <p>Generics with a WAC that increased by 200%+ during the preceding 12-month period and that is \$100+ for:</p> <ol style="list-style-type: none"> <li>(1) a 30-day supply lasting 30 consecutive days based on FDA-approved recommended dosage labeling;</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</li> </ol> <p>Prescription drug products that may create affordability challenges for the state health care system and patients, in consultation with the stakeholder council.</p>
STATUS	<p>Failed.</p>



# PROPOSED PRESCRIPTION DRUG AFFORDABILITY BOARD UPDATES

<b>STATE</b>	<b>Wisconsin</b> <a href="#">AB747/SB718</a> (2023)
<b>MODEL</b>	UPL – The Board shall establish UPLs for prescription drugs that will lead to affordability challenges for the health care system in Wisconsin.
<b>PLANS AFFECTED</b>	State-sponsored and state-administered plans.
<b>DEFINITION OF AFFORDABILITY</b>	<p>Does not define affordability or affordability challenges.</p> <p>In determining whether a prescription drug product has led or will lead to an affordability challenge, the Board shall consider:</p> <ol style="list-style-type: none"> <li>(1) The WAC;</li> <li>(2) The average monetary price concession, discount, or rebate the manufacturer provides, or is expected to provide, to health plans in this state as reported by manufacturers and health plans, expressed as a percent of the WAC for the prescription drug product under review;</li> <li>(3) The total amount of the price concessions, discounts, and rebates the manufacturer provides to each PBM for the prescription drug product under review, as reported by the manufacturer and pharmacy benefit manager and expressed as a percent of the WAC;</li> <li>(4) The price at which therapeutic alternatives are sold;</li> <li>(5) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and PBMs in this state for therapeutic alternatives to the prescription drug product;</li> <li>(6) The costs to health plans based on patient access consistent with labeled indications by the FDA and recognized standard medical practice;</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 that can be quantified and compared to baseline effects of existing therapeutic alternatives to the prescription drug product;</li> <li>(10) The average patient copay or other cost-sharing for the prescription drug product in this state.</li> </ol>
<b>DRUG SELECTION PROCESS</b>	The Board shall determine whether to conduct an affordability review after seeking stakeholder input and considering the average patient cost share of the prescription drug product.
<b>PRICING CONSIDERATIONS</b>	In establishing a UPL, the Board must consider the cost of administering the drug, the cost of delivering it to consumers, and other relevant administrative costs.
<b>DRUGS COVERED</b>	<p>The following drugs would be eligible for review:</p> <p>A brand name drug or biologic with a launch WAC of \$30,000+ per year or course of treatment.</p> <p>A brand name drug or biologic with a WAC that increased by \$3,000+ during a 12-month period.</p> <p>A biosimilar that has a launch WAC that is not at least 15% lower than the referenced brand biologic at the time the biosimilar is launched.</p> <p>A generic drug with a WAC that increased by 200%+ during the preceding 12-month period and is \$100+:</p> <ol style="list-style-type: none"> <li>(1) a 30-day supply lasting 30 consecutive days based on FDA-approved recommended dosage labeling;</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;</li> </ol> <p>Prescription drug products, including drugs to address public health emergencies, that may create affordability challenges for the health care system and patients in this state.</p>
<b>STATUS</b>	Failed.

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1455 Pennsylvania Avenue NW, Suite 400  
Washington, DC 20004

202-349-4089

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