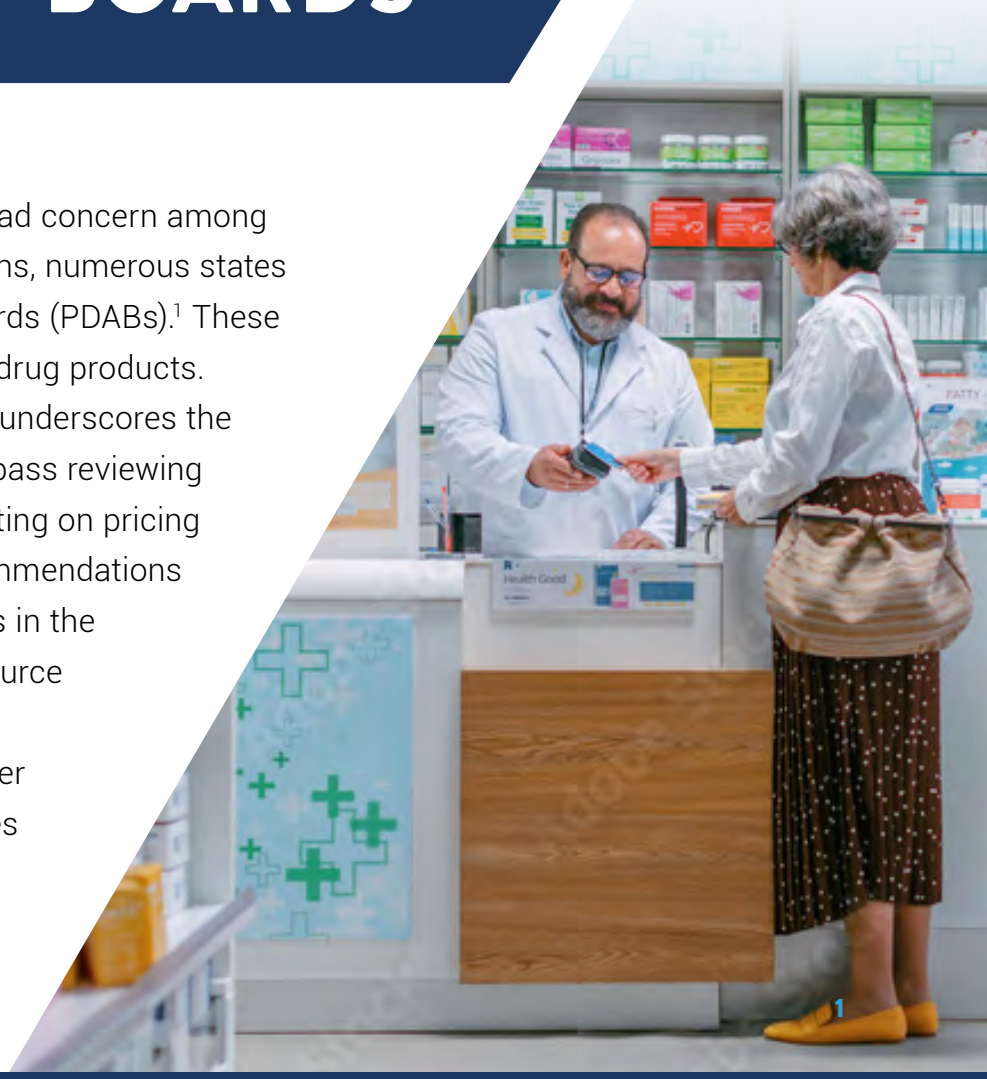
AIMEDALLIANCE

ENACTED PRESCRIPTION DRUG AFFORDABILITY BOARDS

2019–2023

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).[1] 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 enacted PDAB laws from 2019-2023, 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.[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.

COLORADO | SB21-175 (2021) HB23-1225 (2023)

MODEL	BOARD MEMBERSHIP	OPPORTUNITIES FOR ENGAGEMENT
UPL – Through 2024, the Board can establish UPLs for up to 12 drugs that the Board, after conducting an affordability review, has determined are unaffordable for Colorado consumers. No limit for how many UPLs can be set after 2024. RP – When conducting an affordability review, the Board may consider prescription drug pricing in foreign countries.	The Board consists of five members, who must each have an advanced degree and experience in healthcare economics or clinical medicine. The governor shall appoint each board member, subject to confirmation by the senate. **PROHIBITED:** Employees, board members, or consultants of a manufacturer, PBM, or manufacturer or PBM trade association of manufacturers.	**General Engagement:** The Colorado prescription drug affordability advisory council provides stakeholder input to the Board. The advisory council consists of 15 members, including: (1) The Executive Director of the Department of Healthcare Policy and Financing (or Executive Director's designee); The remaining 14 Members are appointed by the Board but must include: (2) Members who are healthcare consumers; (1) Member representing a statewide healthcare consumer advocacy organization; (1) Member representing healthcare consumers who are living with chronic diseases; (1) Member representing a labor union; (1) Member representing employers; (1) Member representing carriers; (1) Member representing PBMs; (1) Member representing healthcare professionals with prescribing authority; (1) Member representing individuals employed by an organization that performs research concerning prescription drugs, including research concerning pricing information; (1) Member representing manufacturers of brand-name drugs; (1) Member representing manufacturers of generic drugs; (1) Member representing pharmacists; (1) Member representing wholesalers. To the extent possible, the Board shall appoint council members who have experience serving underserved communities and reflect the diversity of the state with regard to race, ethnicity, immigration status, income, wealth, disability, age, gender identity, and geography. **Affordability Review:** In performing an affordability review, the Board must consider input from: - Patients and caregivers affected by the condition or disease that is treated by the prescription drug under review. - Individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review. **UPL Setting:** Stakeholder input can be submitted through the UPL rulemaking process. Input can include information relevant to any of the considerations that the Board may take into account in establishing a UPL. **Other opportunities for engagement:** The Board may establish ad hoc work groups to consider matters related to the work of the board. Ad hoc work groups may include members of the public. The Board's meetings and the meetings of ad hoc work groups of the Board are public meetings.

PLANS IMPACTED	FUNDING
All state-regulated plans.	2021 - 2022 FY: $730,711 was appropriated for implementation of the PDAB. The 2023 - 2024 Long Bill provides additional funding for the Board.

COLORADO | SB21-175 (2021) HB23-1225 (2023)

IMPLEMENTATION TIMELINE	CURRENT STATUS
Apr. 2022 – Board may begin setting UPLs for 12 drugs. Jan. 2023 – Plans must comply with UPLs established by the Board. July 2023 – Board must submit annual report to the governor, the health and insurance committee of the house of representatives, and the health and human services committee of the senate, or to any successor committees, summarizing the work of the Board during the preceding calendar year (Not yet published as of Dec. 2023). Jan. 2025 – Updates in HB1225 take effect. Board must meet at least every six weeks thereafter to review prescription drugs. Meeting information	The first five drugs were selected for review in 2023: (1) Enbrel; (2) Genvoya; (3) Cosentyx; (4) Stelara; and (5) Trikafta. The Board adopted rules for affordability reviews of prescription drugs.

DRUG SELECTION PROCESS	TYPE OF DRUG ELIGIBLE FOR SELECTION
The Board shall determine whether to conduct an affordability review for an identified prescription drug by: (1) Evaluating the class of the prescription drug and whether any therapeutically equivalent prescription drugs are available; (2) Evaluating aggregated data; (3) Seeking and considering input from the advisory council about the prescription drug; and (4) Considering the average patient's out-of-pocket cost for the prescription drug.	Brand-name drug or biologic with (1) An initial WAC of $30,000+ for a 12-month supply or a course of treatment that is less than 12 months in duration; or (2) A WAC increase of 10%+ in the previous 12 months for a 12-month supply or course of treatment if > 12 months in duration. Biosimilar drug with an initial WAC that is not at least 15% lower than the corresponding biological product. Generic drug with a WAC that increased 200%+ in the previous 12 months and has a WAC of $100+ for: (1) A 30-day supply, based on FDA-approved recommended dosage labeling; or (2) A supply lasting > 30 days, based on FDA-approved recommended dosage labeling; or (3) A single dose if FDA labeling does not recommend a finite dosage. New Criteria Effective Jan. 2025: Any prescription drug that meets one of the following conditions is eligible for a UPL: (1) WAC of $3,000+; (2) An increase in WAC of $300+ in preceding 12 months; (3) An increase of 200%+ above WAC in preceding 12 months; or (4) A WAC of $30,000+ for an average course of treatment pp/year and any biosimilar with a WAC that is not at least 15% lower than the WAC that the corresponding biological product; and Any biosimilar drug with an initial WAC that is not at least 15% lower than the WAC of the corresponding biological product.

DEFINITION OF AFFORDABILITY
Does not define affordability.

AFFORDABILITY REVIEW

MUST Consider

(1) The WAC (current WAC and changes in the WAC over time);

(2) The cost and availability of therapeutic alternatives;

(3) The effect of the price on Colorado consumers' access to the prescription drug;

(4) The financial effects on health, medical, and social services, as the effects can be quantified, compared with therapeutic alternatives and/or no treatment;

(5) When the prescription drug is available through 340B, the Board will evaluate the utilization of the prescription drug by the safety net provider's patients, whether the safety net provider receives a 340B discount for the prescription drug, where the safety net provider does not receive a discount, whether access to the prescription drug is impeded, and any other topics identified by safety net provider stakeholders for discussion;

(6) Orphan drug status;

(7) Input from patients, caregivers, and experts on the disease or condition treated by the drug (i.e., information related to the impact of the disease, patient treatment preferences, patient perspective on the benefits and disadvantages of using the prescription drug, caregiver perspective on the benefits and disadvantages of using the prescription drug, and/or available patient assistance in purchasing the prescription drug);

(8) General information voluntarily submitted by manufacturers, PBMs, carriers and other entities, following the selection of the drug for review;

(9) To the extent practicable, the Board may consider estimated manufacturer net-sales or net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives and manufacturer financial assistance provided to pharmacies, providers, consumers, and other entities;

(10) Health equity impact;

(11) Information from the Department of Healthcare Policy and Financing; and

(12) Non-adherence and utilization management information, and information related to utilization management restrictions placed on the prescription drug.

The Board is also required to issue a report summarizing the data the Board considered in making the determination as to whether a prescription drug is unaffordable.

MAY Consider

Documents and information relating to the manufacturer's selection of the introductory price or price increase of the prescription drug, including information related to:

(1) Life-cycle management;

(2) The average cost of the prescription drug in the state;

(3) Market competition and context;

(4) Projected revenue;

(5) The estimated cost-effectiveness of the prescription drug; and

(6) Off-label usage of the prescription drug.

SETTING UPLS

The Board may establish up to 12 UPLs per year in 2022 – 2024. If the Board identifies a need for additional UPLs, in 2023 and 2024 it can establish an additional 6 per calendar year. Thus, the Board may establish up to 18 UPLs in 2023 and 2024.

The Board may establish a UPL for any prescription drug for which the Board has performed an affordability review and determined that the use of the prescription drug is unaffordable for Colorado consumers.

Once a drug is selected for negotiation, the UPL is based on:

(1) Prescription drug costs, including the cost of administering, dispensing, and distributing the drug (including, but not limited to the WAC, ASP, NADAC, out-of-pocket amounts, carrier paid amounts, retail discount amounts, public healthcare program fee schedules, estimates of manufacturer net-cost and net-sales amounts, Medicare's MFP, and cost information voluntarily provided by a wholesaler, pharmacist, or provider);

(2) The status of the drug on FDA's drug shortage list (including the availability and estimated shortage duration, shortage reason, and therapeutic classification);

(3) Impact of UPL to older adults and person with disabilities;

(4) Stakeholder input; and

(5) Other relevant costs related to the prescription drug.

PROHIBITED FROM USING: QALY, or similar measure, that discounts the value of life because of an individual's disability or age.

MAINE | LD 1499 / SB 461 (2019)

MODEL	BOARD MEMBERSHIP	OPPORTUNITIES FOR ENGAGEMENT
No specific approach adopted. Board required to establish spending targets for specific prescription drugs that may cause affordability challenges for plan enrollees and determine methods to reduce costs to individual purchasers.	The Board has 5 members with expertise in healthcare economics or clinical medicine, who may not be affiliated with or represent the interests of a public payor. Board appointment: (2) Members are appointed by President of the Senate (one 4-year term and one 3-year term); (2) Members are appointed by the Speaker of the House (one 4-year term and one 3-year term); and (1) Member is appointed by the Governor (5-year term). **PROHIBITED:** Individuals affiliated with, or represent, the interest of a public payor.	**Comments:** Each public meeting must provide an opportunity for comment from the public in attendance at the meeting. The Board is also required to provide the opportunity for the public to submit written comments on pending decisions. **General Engagement:** A 12-member advisory council is established to advise the Board on establishing annual spending targets. Members include: - Representatives from the Maine State Employees Association; - Representatives from the University of Maine System; - Representatives from the Maine Community College System; and - Representatives from consumer interests; and The Board may also include designees made by: - The Governor; - The Attorney General; - The Executive Director of Employee Health and Benefits, and - The Commissioners of the Administrative and Financial Services, Corrections, and Health and Human Services.

PLANS IMPACTED	FUNDING
Plans administered by public payors (i.e., state, county, or municipal governments, and state employees, etc.).	The Board may apply for and receive funds, grants or contracts from public and private sources. The Board may also recommend that a public payor pays an annual assessment to support the administrative costs of the Board. Funds appropriated to the Office of Affordable Healthcare, which will provide staffing assistance to the Board.

IMPLEMENTATION TIMELINE	CURRENT STATUS
Mar. 2020 – Board required to meet in a public session at least every 12 weeks. Meeting and Minutes Jan. 1 2021 – Board required to submit recommendations, including spending targets (and on Jan. 30 annually thereafter). Board may begin setting spending targets.	2021 Annual Report 2022 Annual Report The Board's 2023 Report recommended that it would be most expedient to set UPLs based on reference rates available from Canada and/or Medicare price negotiations.

MAINE | LD 1499 / SB 461 (2019)

DRUG SELECTION PROCESS	TYPE OF DRUG ELIGIBLE FOR SELECTION
While there is no specific process for drug selection, in determining which drugs will be subject to spending targets the Board may consider: (1) A public payor's prescription drug spending data, which the 3rd-party administrator or insurer for the public payor's health plan shall provide upon request notwithstanding any provision of law to the contrary (including expenditures and utilization data for prescription drugs; the formulary for each plan and prescription drugs common to each formulary; PBM services and other administrative expenses of; and enrollee cost); and (2) Data compiled by the Maine Health Data Organization.	All prescription drugs purchased by public payors.

DEFINITION OF AFFORDABILITY

Does not define affordability or affordability challenges.

SPENDING TARGETS

MUST Consider	MAY Consider
N/A	(1) A public payor's prescription drug spending data, which the 3rd-party administrator or insurer for the public payor's health plan shall provide upon request notwithstanding any provision of law to the contrary (including expenditures and utilization data for prescription drugs; the formulary for each plan and prescription drugs common to each formulary; PBM services and other administrative expenses of; and enrollee cost); and (2) Data compiled by the Maine Health Data Organization.

SETTING UPLS

The Board's 2023 Report recommended that it would be most expedient to set UPLs based on reference rates available from Canada and/or Medicare price negotiations.

MARYLAND | HB768 (2019) HB1100 (2020) HB1034 (2021) HB279 (2023)

MODEL	BOARD MEMBERSHIP	OPPORTUNITIES FOR ENGAGEMENT
UPL – The Board may set UPLs for certain prescription drug products that have led or will lead to an affordability challenge. RP – If the Board is unable to determine whether a prescription drug product will produce or has produced an affordability challenge, the Board may consider pricing data from other countries for the prescription drug product. MFP – In selecting drugs for cost review, the Board may consider whether the prescription drug product is currently subject to or has been subject to the Medicare Drug Price Negotiation Program.	The Board consists of the following members, who must have expertise in healthcare economics or clinical medicine: Board Appointment: (1) Member appointed by the Governor; (1) Member appointed by the President of the Senate; (1) Member appointed by the Speaker of the House of Delegates; (1) Member appointed by the Attorney General; and (1) Member jointly appointed by the President of the Senate and the Speaker of the House of Delegates. One alternate member will be appointed by the Governor, the President of the Senate, and the Speaker of the House of Delegates. At least one member of the Board shall have expertise in: the 340B Program under the federal Public Health Service Act, the State's all–payer model contract, how the program and contract interact, and how decisions made by the Board will affect the model and contract. **PROHIBITED:** Employees, board members, or consultant of a manufacturer, PBM, or manufacturer or PBM trade association of manufacturers.	**Affordability Engagement:** Individual members of the public may report their personal experience with a drug or drugs that have caused or are causing an affordability issue for the individual by completing the form available on the Board's website electronically or by mailing it to the Board. Rules for reporting of affordability issues. **Comments:** Board must provide an opportunity for public comment at each open meeting of the Board and an opportunity to provide written comments on pending decisions of the Board. Rules for public comment process. **General Engagement:** The Stakeholder Council, provides input to the Board in making decisions. Membership consists of 26 members including: (8) Members appointed by the Speaker of the House of Delegates: (1) Member representing a generic drug corporation; (1) Member representing a nonprofit insurance carrier; (1) Member representing a statewide healthcare advocacy coalition; (1) Member representing a statewide advocacy organization for seniors; (1) Member representing a statewide organization for diverse communities; (1) Member representing a labor union; (1) Member representing a health services researcher specializing in prescription drugs; (1) Member of the public appointed at discretion of the Speaker of the House of Delegates. (8) Members appointed by the President of the Senate: (1) Member representing a brand name drug corporation; (1) Member representing a physician; (1) Member representing a nurse; (1) Member representing a dentist; (1) Member representing a managed care organization; (1) Member representing a Department of Budget and Management; (1) Member representing a clinical researcher; (1) Member appointed at discretion of the President of the Senate. (8) Members appointed by the Governor: (1) Member representing a brand name drug corporation; (1) Member representing a generic drug corporation; (1) Member representing a biotechnology company; (1) Member representing a for–profit health insurance carriers employer; (1) Member representing a PBM; (1) Member representing a pharmacist; (1) Member representing a pharmacologist; (1) Member representing a and member at the discretion of the Governor. Collectively, the members of the Stakeholder Council shall have knowledge of the pharmaceutical business model, supply chain business models, the practice of medicine or clinical training, consumer or patient perspectives, healthcare costs trends and drivers, clinical and health services research, or the State's healthcare marketplace. To the extent practicable and consistent with federal and State laws, the membership of the Board and the Stakeholder Council shall reflect the racial, ethnic, and gender diversity of the State.

MARYLAND | HB768 (2019) HB1100 (2020) HB1034 (2021) HB279 (2023)

PLANS IMPACTED	FUNDING
State-administered plans (i.e., health benefit plans administered on behalf of the state/local government).	The Board shall assess and collect an annual fee in accordance with criteria established in regulations adopted by the Board, from manufacturers, PBMs, carriers, and wholesale distributors that operate in the State. The Board must use general funds allocated within the state budget. 2023 – $1, 441,034 2024 - $1,426,736

IMPLEMENTATION TIMELINE	CURRENT STATUS
Dec. 2021 – Conduct a study and produce a report on the pharmaceutical distribution and payment system in the state, and review policy options being used in other states and countries to lower the list of pharmaceuticals, including UPLs, reverse auction marketplaces, and a bulk purchasing process. Based on the findings, the Board was required to report its recommendation on how to determine whether a prescription drug product has led or will lead to affordability challenges for the state healthcare system or result in high out-of-pocket costs for patients. June 1, 2022 – Conduct a study of the operation of the generic drug market in the United States. Study of the Operation of the Generics Drug Market Dec. 2026 – Report on the legality, obstacles, and benefits of setting UPLs on all purchases and payor reimbursements of prescription drug products in the state; and issue recommendations regarding whether the General Assembly should pass legislation to expand the authority of the Board to set UPLs to all purchases and payor reimbursements of prescription drug products in the state. The Board must meet in open session at least once every six weeks and shall provide an opportunity for public comment at each open meeting. Meeting recordings	2022 Annual Cost Review Report (no cost reviews completed in 2022) 2023 Annual Cost Review Report (no cost reviews completed in 2023) On July 24, 2023, the Board formally adopted regulations for the cost review study process. Drugs may be selected for review in early 2024. Upper Payment Limit regulations currently being drafted (see November 2023 Agenda).

MARYLAND | HB768 (2019) HB1100 (2020) HB1034 (2021) HB279 (2023)

DRUG SELECTION PROCESS	TYPE OF DRUG ELIGIBLE FOR SELECTION
In selecting a prescription drug product for cost review, the Board **must** consider: (a) The prescription drug products referred to the Stakeholder Council; (b) The average cost share of the prescription drug product, the average patient total out-of-pocket cost, the average total payor cost, and publicly available data on direct-to-consumer advertising spending for the prescription drug product; (c) Input from the Stakeholder Council; and (d) Input from the public. Board staff may create a dashboard to include all relevant data and information about selected products. Full list of considerations that may be included in the dashboard is available here. To identify drugs eligible for a cost review study, the Board **may** apply the following metrics: (1) Aggregated spending and pricing data; (a) The 100 prescription drug products with the highest total gross spending in the most recent year; (b) The 100 prescription drug products with the highest total gross spending per patient in the most recent year; (c) The 100 prescription drug products with the highest percent change increase in WAC over the most recent year; (d) The 100 prescription drug products with the highest percent change increase in WAC over the most recent 5-year period; (e) The 100 prescription drug products with the highest dollar increase in WAC per year or course of treatment over the most recent year; (f) The 100 prescription drug products with the highest dollar increase in WAC over the most recent 5-year period; and (g) The 100 prescription drug products with the highest percent change increase in total gross spending; (2) Patient out-of-pocket costs: (a) The 100 prescription drug products with the highest total patient total out-of-pocket costs in the most recent available calendar year; (b) The 100 prescription drug products with the highest average patient total out-of-pocket costs in the most recent year; (c) The 100 prescription drug products ranked at the 50th percentile for patient total out-of-pocket costs in the most recent year; and (d) The 100 prescription drug products ranked at the 90th percentile for patient total out-of-pocket costs; and (3) Any prescription drug product added by the Board to the list of prescription drug products eligible for cost review.	The Board shall identify drugs for a cost review that are: Brand-name drugs or biologics with a launch WAC of $30,000+/year or course of treatment or a WAC increase >$30,000 in any 12-month period or course of treatment if < 12 months; Biosimilar drugs with a launch WAC that is not at least 15% lower than the referenced brand biologic; Generic drugs with a WAC that increased 200%+ in the previous 12 months and has a WAC of $100+ for: (1) a 30-day supply based on based on FDA-approved recommended dosage labeling; or (2) a supply lasting < 30 days based on FDA-approved recommended dosage labeling; or (3) one unit of the drug if labeling FDA-approved labeling does not recommend a finite dosage; and Other prescription drug products that may create affordability challenges for the state healthcare system and patients.

DEFINITION OF AFFORDABILITY
Does not define affordability, affordability challenges, or “high costs”.

COST REVIEW

MUST Consider

(1) The wholesale acquisition cost and any other relevant prescription drug cost index for the prescription drug product sold in the State;

(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 wholesale acquisition cost for the prescription drug product under review;

(3) The total amount of the price concession, discount, or rebate the manufacturer provides to each pharmacy benefits manager 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 wholesale acquisition costs;

(4) The price at which therapeutic alternatives have been sold in the State;

(5) The average monetary concession, discount, or rebate the manufacturer provides or is expected to provide to health plan payors and pharmacy benefits managers in the State for therapeutic alternatives;

(6) The costs to health plans based on patient access consistent with United States Food and Drug Administration labeled indications;

(7) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;

(8) The current or expected dollar value of drug–specific patient access programs that are supported by the manufacturer;

(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;

(10) The average patient copay or other cost–sharing for the prescription drug product in the State; and

(11) Any other factors as determined by the Board in regulations adopted by the Board.

MAY Consider

(1) The manufacturer's research and development costs, as indicated on the manufacturer's federal tax filing or information filed with the Federal SEC for the most recent tax year in proportion to the manufacturer's sales in the State;

(2) The portion of direct–to–consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that are specific to the prescription drug product under review and that are multiplied by the ratio of total manufacturer in–State sales to total manufacturer sales in the United States for the product under review;

(3) Gross and net manufacturer, PBM, and wholesale distributor revenues for the prescription drug product under review for the most recent tax year;

(4) Any additional factors proposed by the manufacturer and appropriate health insurance carriers, health maintenance organizations, managed care organizations, wholesale distributors, and pharmacy benefits managers that the Board considers relevant; and

(5) Any additional factors as established by the Board in regulations.

SETTING UPLS

The Board may set UPLs for prescription drugs:

(1) Purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including state or county correctional facilities; state hospitals; and health clinics at State institutions of higher education;

(2) Paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan; or

(3) Purchased for or paid for by the Maryland State Medicaid.

UPLs shall be set for prescription drug products that have led or will lead to an affordability challenge.

Criteria for setting UPLs will be established by the Board and approved by the Legislative Policy Committee of the General Assembly. Criteria for setting UPLs must include:

(1) The cost of administering the prescription drug;

(2) The cost of delivering the prescription drug product to consumers; and

(3) Other relevant administrative costs related to the prescription drug products.

MINNESOTA | SF 2744 (2023)

MODEL	BOARD MEMBERSHIP	OPPORTUNITIES FOR ENGAGEMENT
UPL – Board is authorized to establish UPLs after conducting a cost review of certain prescription drug products that have led or will lead to affordability challenges for the state healthcare system or for patients. RP – In establishing a UPL, the Board is required consider the range of prices at which the drug is sold in the U.S. and the range at which pharmacies are reimbursed in Canada. MFP – When setting a UPL for a drug subject to the Medicare MFP, the Board is required to set the UPL at the Medicare MFP.	Board consists of nine members, which have knowledge and demonstrated expertise in pharmaceutical economics and finance or healthcare economics and finance. Board Appointment (7) Voting Members appointed by the governor, (1) Non-voting Member appointed by the Majority Leader of the Senate; (1) Non-voting Member appointed by the Speaker of the House. **PROHIBITED:** Employees, board members, or consultant of a manufacturer, PBM, or manufacturer or PBM trade association of manufacturers.	**Comment:** At each public meeting, the Board must provide an opportunity for comments from the public. Written comments can also be submitted to the Board prior to a decision. Prior to the Board establishing the standards for the information related to a drug cost review to be considered proprietary, the public shall be provided notice and the opportunity to submit comments. **Drug Specific:** The Board must consider requests by the public for the Board to proceed with a cost review of any prescription drug product. **General Engagement:** 18-member stakeholder advisory council provides advice to the Board on drug cost issues and to represent stakeholders' views. Governor appoints all members based on the members' knowledge and demonstrated expertise in one or more of the following areas: the pharmaceutical business, practice of medicine, patient perspectives, healthcare cost trends and drivers, clinical and health services research, and the healthcare marketplace. The council's membership shall consist of the following: (2) Members representing patients and healthcare consumers; (2) Members representing healthcare providers; (2) Members representing employers, with one member representing large employers and one member representing small employers; (1) Member representing government employee benefit plans; (1) Member representing pharmaceutical manufacturers; (1) Member representing health services clinical researcher; (1) Member representing a pharmacologist; (1) Member representing the commissioner of health with expertise in health economics; (1) Member representing pharmaceutical wholesalers; (1) Member representing PBMs; (1) Member representing the Rare Disease Advisory Council; (1) Member representing generic drug manufacturers; (1) Member representing pharmaceutical distributors; and (1) Member representing an oncologist who is not employed by, under contract with, or otherwise affiliated with a hospital. The advisory council shall meet publicly at least every three months to advise the Board on drug cost issues related to the prescription drug product information submitted to the Board.

MINNESOTA | SF 2744 (2023)

PLANS IMPACTED	FUNDING
All state-regulated plans.	Legislature has allocated funds for 2024-2026: 2024 – $568,000 2025 – $537,000 2026 – $500,000

IMPLEMENTATION TIMELINE	CURRENT STATUS
Jan. 2024 – Initial appointments of Board members must be made. Mar. 2024 – Board must submit an annual report on general price trends for prescription drug products and the number of prescription drug products that were subject to the Board's cost review and analysis, including the result of any analysis as well as the number and disposition of appeals and judicial reviews. Annually – Health plan companies and PBMs must report annually to the Board on how cost savings resulting from the establishment of UPLs have been used by the health plan company or PBM to benefit enrollees, including but not limited to reducing enrollee cost-sharing. The Board shall meet publicly at least every three months to review prescription drug product information submitted to the Board (may cancel if no submissions).	Awaiting 2024 implementation.

DRUG SELECTION PROCESS	TYPE OF DRUG ELIGIBLE FOR SELECTION
While there is no specific process for drug selection, the Board shall consider requests by the public for the Board to proceed with a cost review of any prescription drug product. If there is no consensus among the members of the Board on whether to initiate a cost review of a prescription drug product, any member of the Board may request a vote to determine whether to review the cost of the prescription drug product.	The Board may initiate a cost review of any of the following prescription drug products: Brand name drugs or biologics with a WAC increases by > 15%+ or by > $3,000 during any 12-month period or course of treatment if <12 months; Brand name drugs or biologics with a WAC of $60,000+/year or course of treatment; Biosimilar drugs with a WAC that is not at least 20% lower than the referenced brand name biologic at the time the biosimilar is introduced; Generic drugs with a WAC that increased by 200%+ during the preceding 12-month period and is $100+ for: (1) A 30-day supply; (2) A course of treatment lasting <30 days; or (3) One unit of the drug, if FDA does not recommend a finite dosage; and Any prescription drug products that may impose costs that create significant affordability challenges for the state healthcare system or for patients.

DEFINITION OF AFFORDABILITY

Does not define affordability or affordability challenges.

AFFORDABILITY REVIEW

MUST Consider

N/A

MAY Consider

(1) The price the prescription drug product in the state;

(2) Manufacturer concessions, discounts, rebates, and drug-specific patient assistance;

(3) The price of therapeutic alternatives;

(4) The cost to group purchasers based on patient access consistent with the FDA-labeled indications and standard medical practice;

(5) Measures of patient access, including cost-sharing;

(6) The extent to which the AG or a court has determined that a price increase for a generic or off-patent was excessive;

(7) Any information a manufacturer chooses to provide;

(8) Any other factors determined by the Board.

SETTING UPLS

If a prescription drug product creates an affordability challenge, the Board shall establish a UPL after considering:

(1) Extraordinary supply costs;

(2) The range of prices at which the drug is sold in the U.S. and the range at which pharmacies are reimbursed in Canada; and

(3) Any other relevant pricing and administrative cost information for the drug.

NEW HAMPSHIRE | HB 1280 (2020)[14]

MODEL	BOARD MEMBERSHIP	OPPORTUNITIES FOR ENGAGEMENT
No specific approach adopted. Board is required to: (1) Determine spending targets for *specific* prescription drugs that may cause affordability challenges to enrollees in a public payor health plan; (2) Determine annual spending targets for prescription drugs purchased by public payors based upon a 10-year rolling average of the medical care services component of the U.S DOL, Bureau of Labor Statistics CPI, medical care services index, plus a reasonable percentage for inflation and minus a spending target for pharmacy savings as determined by the Board; (3) Identify strategies that optimize spending by public payors for pharmaceutical products while reasonably ensuring subscriber access to needed pharmaceutical products.	The Board shall consist of five members with expertise in healthcare economics or clinical medicine. Board Appointment: (2) Members by the President of the Senate; (2) Members by the Speaker of the House of Representatives; and (1) Member by the Governor. The President of the Senate, Speaker of the House, and Governor shall each also appoint one alternate Board member. **PROHIBITED:** Employees, board members, or consultant of a manufacturer, PBM, or manufacturer or PBM trade association of manufacturers; or public payors, or health insurance providers.	**Comment:** Each public meeting must provide an opportunity for comment from the public in attendance at the meeting. Board must also provide the public with an opportunity to submit written comments on pending decisions. **Experts:** The Board may allow expert testimony at public meetings and any meeting conducted in Executive Session. **General Engagement:** A 12-member advisory council advises the Board on establishing annual spending targets. Board must include: - Member representing consumer interests; - Member representing the Commissioner of the Department of Administrative Services; - Member representing the Commissioner of the Department of Corrections; - Member representing the Commissioner of Department of Health and Human Services; - Member representing the Attorney General; - Member representing the Director of the Division of Risk and Benefits; - Member representing Department of Administrative Services; - Member representing the President of the New Hampshire State Employees Association; - Member representing the President of the New Hampshire Education Association; - Member representing the Executive Director of the New Hampshire Municipal Association; - Member representing the Chancellor of the University system of New Hampshire; and - Member representing the Chancellor of the New Hampshire community college system.

PLANS IMPACTED	FUNDING
State-administered plans (i.e., health benefit plans administered on behalf of the state/local government).	The expenses and cost of operating the Board shall be funded by reasonable user fees and assessments.

NEW HAMPSHIRE | HB 1280 (2020)[14]

IMPLEMENTATION TIMELINE	CURRENT STATUS
Nov. 2020 – The Board must annually report its recommendations, including prescription drug spending targets, their strategies for optimization of the affordability of prescription drugs for the state and all of its residents, the progress of implementing those recommendations, as well as the annual net spending by public payors on prescription pharmaceutical products as a measure of the efficacy of implementation of those recommendations to date, to the standing committees of the general court with jurisdiction over health coverage and insurance matters and to the governor. Mar. 2021 – The Board shall meet in a public session at least every 12 weeks to review prescription drug information and to make recommendations for its report to the governor. Nov. 2021 – The Board shall produce and post on its publicly accessible website an annual report, the major components of prescription drug pricing, and the impacts on insurance premiums and cost sharing; and any other information the Board determines is relevant to providing greater consumer awareness.	2021 Annual Report 2022 Annual Report 2023 Annual Report Meeting recordings and minutes NH PDAB Website

DRUG SELECTION PROCESS	TYPE OF DRUG ELIGIBLE FOR SELECTION
Legislation does not provide specific process for drug selection.	Prescription drugs purchased by public payors are eligible for consideration.

DEFINITION OF AFFORDABILITY
Does not define affordability or affordability challenges. Does not define spending targets.

SPENDING TARGETS	
MUST Consider Any medical cost offsets achieved by utilization of the drug. **PROHIBITED FROM CONSIDERING:** 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.	**MAY Consider** (1) A public payor's prescription drug spending data, including: (a) Expenditures and utilization data for prescription drugs for each plan offered by a public payor; (b) The formulary for each plan offered by a public payor and prescription drugs common to each formulary; (c) PBM services and other administrative expenses of the prescription drug benefit for each plan offered by a public payor; (d) Enrollee cost sharing for each plan offered by a public payor; (e) Aggregate net spending on the prescription drug benefit; and (f) Data compiled by the department of health and human services.

OREGON | SB844 (2021) SB192 (2023)

MODEL	BOARD MEMBERSHIP	OPPORTUNITIES FOR ENGAGEMENT
UPLs – Board must conduct affordability reviews for nine prescription drugs (and at least one insulin product) that may create affordability challenges for healthcare systems or high out-of-pocket costs for patients in this state and develop a plan for establishing UPLs on drugs sold in this state that are subject to such reviews.	The Board consists of five members and three alternates appointed by the Governor and subject to confirmation by the Senate. Board Membership: The members of the Board must be residents of this state with expertise in healthcare economics and clinical medicine. **PROHIBITED:** Employees, board members, or consultant of a manufacturer, PBM, or manufacturer or PBM trade association of manufacturers.	**Comment:** The Board must provide an opportunity for public comment at each open meeting of the Board. Board must also provide an opportunity to submit written comments on any pending decisions. Submit public comments here. **Experts:** The Board may allow expert testimony at Board meetings, including when the Board meets in Executive Session. **Drug Specific:** The Board must accept testimony from patients and caregivers affected by a condition or disease that is treated by a prescription drug under review by the Board. Board must also consider testimony from individuals with scientific or medical training with respect to the disease or condition. View deadlines and submit comments here. **Other Engagement:** The Board may consider input from: (1) Healthcare providers that care for uninsured patients and patients with low income and receive discounted prices on prescription drugs through section 340B; and (2) Payers on the total cost of care for disease(s), cost of the prescription drug to the payer, the availability of therapeutic alternatives on the formulary, coverage mandates and impacts to per member per month or premiums, affordability concerns of the prescription drug from employer groups and other plan sponsors, and other costs to consider.

PLANS IMPACTED	FUNDING
Applies to all state-regulated plans.	The Department of Consumer Business Services shall adopt by rule, in consultation with the Board, annual fees to be paid by manufacturers that sell prescription drugs in this state. The Division of Financial Regulation, in consultation with the Board, is entering into the rulemaking process to establish annual fees to be paid by drug manufacturers that sell prescription drugs in this state.

IMPLEMENTATION TIMELINE	CURRENT STATUS
June 1 – Annually report to the Legislative Assembly findings on price of generic drugs on a year-to-year basis; degree to which generics impact insurance premiums; annual changes in cost-sharing for generics; potential for and history of generic drug shortages; and the degree to which generic drug prices impact annual spending in state medical assistance program. Dec. 31 – Annually report to the Healthcare Cost Growth Target program on price trends for list of certain prescription drugs provided to the Board; and recommendations, if any, for legislative changes necessary to make prescription drug products more affordable. Sept. 2024 – Report plan to interim committees of the Legislative Assembly for establishing UPLs and analysis of potential savings including a methodology for establishing UPLs; analysis of the resources needed by the Board to implement the plan; analysis of how UPLs would be enforced; and an analysis of how UPLs could be implemented with respect to pubic employee and state-administered benefits, and other health benefit plans. Report must also include an analysis of potential savings from, or costs of, implementing the plan with respect to the state, insurers, hospitals, pharmacies, and consumers.	2022 Generic Drug Report 2023 Generic Drug Report Healthcare Cost Growth Target Program Report – December 2022 Report The Board shall meet at least once every six weeks. Any deliberation on whether to conduct an affordability review of a prescription drug or any decision on any matter before the Board except to discuss trade secret information shall be open to the public. Public Hearings On July 29, 2023, the Board adopted rules governing the affordability review process.

OREGON | SB844 (2021) SB192 (2023)

DRUG SELECTION PROCESS	TYPE OF DRUG ELIGIBLE FOR SELECTION
There is no specific process for drug selection.	Eligible drugs include: (1) Prescription drugs where the price was $100+ for a one-month supply or for a course of treatment lasting less than 1 month; and there was a net increase of 10%+ in the price of the prescription drug over the calendar year; (2) The 25 most frequently prescribed drugs; (3) The 25 most costly drugs as a portion of total annual spending; (4) The 25 drugs that have caused the greatest increase in total plan spending from one year to the next; (5) New prescription drugs for sale in the U.S. at a price that exceeds the threshold established by the CMS for specialty drugs in the Medicare Part D program; and (6) Insulin drugs marketed in the state during the previous calendar year.

DEFINITION OF AFFORDABILITY

Does not define affordability or affordability challenges.

AFFORDABILITY REVIEW

MUST Consider

(1) Whether the prescription drug has led to health inequalities in communities of color;

(2) The number of residents prescribed the drug in the state (including the off-label use of prescription drugs used to treat other conditions);

(3) The price the prescription drug is sold in the state;

(4) The estimated average money price concession discount, or rebate the manufacturer provides or is expected to provide to health insurance plans or PBMs, expressed as a percent of the WAC;

(5) The estimated price for therapeutic alternatives to the drug that are sold in the state (including the estimated net price; and the cost and availability of therapeutic alternatives to the prescription drug in the state, including any relevant data regarding costs, expenditures, availability, and utilization related to the prescription drug and its therapeutic alternatives);

(6) The estimated average price concession, discount, or rebate the manufacturer provides or is expected to provide to health insurance plans and PBMs for therapeutic alternatives;

(7) The costs to health insurance plans based on patient use of the drug consistent with FDA labeling and standard practice;

(8) The impact on patient access to the drug considering standard prescription drug benefit designers in health insurance plans offered in the state;

(9) The relative financial impacts to health, medical or social services as can be quantified and compared to the costs of existing therapeutic alternatives (including, to the extent such information can be quantified, the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment, and the total cost of the disease and the drug price offset);

MAY Consider

The information used to conduct an affordability review may include any document and research related to the introductory price or price increase of a prescription drug, including life cycle management, net average price in this state, market competition and context, projected revenue and the estimated value or cost-effectiveness of the prescription drug.

AFFORDABILITY REVIEW *(CONTINUED)*

(10) The average patient copayment or other cost-sharing for prescription drugs in the state (including patient copayment or other cost sharing data) across different health benefit plan designs, including:

(A) Copayment and coinsurance impact from patient assistance programs and copay coupons;

(B) Deductibles;

(C) Patient out-of-pocket costs;

(D) Any other cost sharing data;

(11) Any info a manufacturer chooses to provide;

(12) Any other factors determined by the Board in rules adopted by the Board;

(13) Whether the pricing of the prescription drug results in or has contributed to health inequities in under-resourced communities or regions with limited pharmacy access;

(14) Information submitted by manufacturers related to patient assistant programs and coupons;

(15) Current WAC of the prescription drug and changes in the prescription drug's net cost over time;

(16) Analysis to consider acquisition cost for pharmacies;

(17) Effect of price on consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time;

(18) Potential market for prescription drug for labeled and off-label indications and budget impact on various payors in the state;

(19) Input from patients and caregivers affected by a condition or disease that is treated by the prescription drug under review by gathering information related to the impact of the disease; patient treatment preferences; patient perspectives on the benefits and disadvantages of using the prescription drug; caregiver perspective on the benefits and disadvantages of using the prescription drug; and available patient assistance in purchasing the prescription drug.

(18) Input from individuals who possess scientific or medical training with respect to a condition or disease treated by the prescription drug that is under review, including: the impact of the disease; perspectives on benefits and disadvantages of the prescription drug, including comparisons with therapeutic alternatives if any exist; and input regarding the prescription drug utilization in standard medical practice, as well as input regarding off label usage;

(19) Input from healthcare providers that care for uninsured patients and patients with low income and receive discounted prices on prescription drugs through section 340B;

(20) Input from payers on the total cost of care for the disease(s), cost of the prescription drug to the payer, availability of therapeutic alternatives on the formulary, coverage mandates and impacts to per member per month or premiums, affordability concerns of the prescription drug from employer groups and other plan sponsors, and other costs to consider.

(21) Rebates, discounts, and price concessions. To the extent practicable, estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives and financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities.

(22) Information from the Oregon Health Authority, Health Evidence Review Commission, and Pharmacy and Therapeutics Committee that is relevant to the prescription drug or therapeutic alternative under review.

SETTING UPLS

Board charged with developing a methodology for establishing UPLs to submit to Legislative Assembly for approval.

PROHIBITED FROM USING: 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.

WASHINGTON | SB5532 (2022)

MODEL	BOARD MEMBERSHIP	OPPORTUNITIES FOR ENGAGEMENT
UPL – Board may establish UPL for up to 12 prescription drugs each year that the Board has determined have led or will lead to "excess costs" based on its affordability review.	The Board shall include five members who have expertise in healthcare economics or clinical medicine appointed by the governor. **PROHIBITED:** Employees, board members, or consultant of a manufacturer, PBM, or manufacturer or PBM trade association of manufacturers.	**Comments:** All coordination and collaboration by the Board with other entities (i.e., other boards, work groups, and commissions) must provide an opportunity for comment either at or before every regular meeting during at which final action is taken. The public comment may be taken orally at a public meeting, or by providing an opportunity for written testimony to be submitted before or at the meeting. **Drug Specific:** When conducting an affordability review, the Board is required to consider input from patients affected by the condition or disease treated by the drug. The Board must also consider individuals with medical or scientific expertise related to the condition or disease treated by the drug. All meetings of the Board must be open and public, except that the Board may hold Executive Sessions. **Advisory Groups:** Shall consist of relevant stakeholders, including but not limited to, patients and patient advocates for the condition treated by the drug and one member who is a representative of the prescription drug industry, for each drug affordability review conducted.

PLANS IMPACTED	FUNDING
Applies to all state-regulated plans.	$1,460,000 appropriated from the general fund for FY 2023 and $31,000 from the insurance commissioner's regulatory account.

IMPLEMENTATION TIMELINE	CURRENT STATUS
Dec. 15, 2022 – Board shall begin providing annual report on action taken in previous year (i.e., rules adopted, methodology for UPL, list of drugs identified etc.). June 30, 2023 – The Board must identify drugs for review (as of Dec. 2023, no drugs have been selected). Jan. 1, 2024 – The Board must establish a formula for calculating savings that are attributable to the UPLs established by the Board and how savings were used to reduce costs to consumers. Jan. 1, 2027 – Board may begin setting UPLs. All meetings of the Board must be open and public, except that the Board may hold executive sessions to the extent permitted. Meeting information	2022 Annual Report 2023 Annual Report As of Dec. 2023, no drugs have been selected for an affordability review.

WASHINGTON | SB5532 (2022)

DRUG SELECTION PROCESS	TYPE OF DRUG ELIGIBLE FOR SELECTION
The Board *may* choose to conduct an affordability review of up to 24 prescription drugs annually. When deciding whether to conduct a review, the Board shall consider: (a) The class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale; (b) Input from relevant advisory groups and (c) The average patient's out-of-pocket cost for the drug.	The following drugs are eligible for review: Prescription drugs that have been on the market for at least seven years; are dispensed at a retail, specialty, or mail-order pharmacy; and are a: Brand name prescription drug and biologic product with a WAC of $60,000+/year or course of treatment lasting < 1 year, or have a price increase of 15%+ in any 12-month period or for a course of treatment lasting <12 months, or a 50% increase over 3 years; Biosimilar product with an initial WAC that is not at least 15 percent lower than the reference biological product; Generic drug with a WAC of $100+ for a 30-day supply or less or that has increased in price by 200%+ in the preceding 12 months. **PROHIBITED FROM SELECTION:** Prescription drugs that are solely FDA-designated for the treatment of a rare disease or condition.

DEFINITION OF EXCESS COSTS
Defined as "costs of appropriate utilization of a prescription drug that exceed the therapeutic benefit relative to other alternative treatments" or "costs of appropriate utilization of a prescription drug that are not sustainable to public and private healthcare systems over a 10-year time frame."

AFFORDABILITY REVIEW	
MUST Consider	**MAY Consider**
(1) Factors contributing to price paid for the prescription, including WAC, discounts, rebates, or other price concessions; (2) The average copay or other cost-sharing for the drug; (3) The effect of the price on consumers' access to the drug in the state; (4) Orphan drug status; (5) The dollar value and accessibility of patient assistance programs offered by the drug manufacturer; (6) The price and availability of therapeutic alternatives; (7) Input from patients affected by the condition or disease treated by the drug or individuals with medical or scientific expertise related to the condition or disease treated by the drug; (8) Any info the drug manufacturer or relevant entity chooses to provide; (9) The impact of PBM policies on the price consumers pay for the drug; (10) Any other relevant factors as determined by the Board.	(1) Life-cycle management; (2) The average cost of the drug in the state; (3) Market competition and context; (4) Projected revenue; (5) Off-label usage of the drug; and (6) Any additional factors identified by the Board.

SETTING UPLS
Board may only set up to 12 UPLs per year, even though it may conduct up to 24 affordability reviews. The Board must adopt rules setting forth a methodology setting UPLs, which must take into consideration: (1) The cost of administering the drug; (2) The cost of delivering the drug to patients; (3) The status of the drug on the drug shortage list published by the FDA; and (4) Other relevant administrative costs related to the production and delivery of the drug. **PROHIBITED FROM USING:** 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.

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