**Section 1. Definitions**

* 1. The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:
		1. “Biologic.” A drug that is produced or distributed in accordance with a biologics license application approved under 42 C.F.R. § 447.502.
		2. “Biosimilar.” A drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(K)(3).
		3. “Board.” The Prescription Drug Affordability Board.
		4. “Brand name drug.” A drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355(C). This definition does not include an authorized generic as defined by 42 C.F.R. § 447.502.
		5. “Drug Product” or “Prescription Drug Product.” A brand name drug, a generic drug, a biologic or biosimilar.
		6. “Generic drug.”
			1. A retail drug that is marketed or distributed in accordance with an abbreviated new drug application, approved under 21 U.S.C. § 355(J);
			2. An authorized generic as defined by 42 C.F.R. § 447.502; or
			3. A drug that entered the market before 1962 that was not originally marketed under a new drug application.
		7. “Manufacturer.” An entity that:
			1. Owns the patent to a prescription drug product; or
			2. Enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity’s own name; and
			3. Sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.
		8. “Stakeholder council.” The Prescription Drug Affordability Stakeholder Council.

**Section 2. Prescription Drug Affordability Board.**

1. Establishment—There is established a Prescription Drug Affordability Board. The purpose of the board is to protect state residents, state and local governments, commercial health plans, healthcare providers, pharmacies licensed in the state, and other stakeholders within the healthcare system from the high costs of prescription drug products. The board is a body politic and an instrumentality of the state. The board is an independent unit of state government. The exercise by the board of its authority under this act is an essential function.
2. The 5 members of the board and 3 alternates shall be appointed by the governor and confirmed by the Senate.
3. The board membership must include individuals with demonstrated expertise in healthcare economics, pharmaceutical market, and clinical medicine. A member or an alternate member may not be an employee of, a board member of, or a consultant to a manufacturer or trade association for manufacturers.
4. Any conflict of interest, including whether the individual has an association, including a financial or personal association, which has the potential to bias or has the appearance of biasing an individual’s decision in matters related to the board or the conduct of the board’s activities, shall be considered and disclosed when appointing members and alternate members to the board.

e) Term of office.

* + 1. The term of a member or an alternate member is 5 years.
		2. The terms of the members and alternate members are staggered as required by the terms provided for members in Section 11.

f) Board staff.

* + 1. The chair shall hire an executive director, general counsel, and staff for the board.
			1. Staff of the board shall receive a salary as provided in the budget of the board.
		2. Compensation. A member of the board:
			1. May receive compensation as a member of the board in accordance with the state budget; and
			2. Is entitled to reimbursement for expenses under the standard state travel regulations, as provided in the state budget.

 (g) Quorum. A majority of the members of the board shall constitute a quorum for the purposes of conducting the business of the board.

 (h) Meetings. Subject to subparagraph (ii) of this paragraph, the board shall meet in open session at least 4 times per year to review prescription drug product information.

i) The chair may cancel or postpone a meeting if there is no business to transact.

ii) The following actions by the board shall be made in open session:

* + - 1. Deliberations on whether to subject a prescription drug product to a cost review under section 5(g) of this act;
			2. Any vote on whether to impose an upper payment limit on purchases and payor reimbursements of prescription drug products in the state;
			3. The board shall provide public notice of each board meeting at least 3 weeks in advance of the meeting.
		1. The board may meet in closed session to discuss proprietary data and information.
		2. Materials for each board meeting shall be made available to the public at least 3 weeks in advance of the meeting.

iv) The board shall provide an opportunity for public comment at each open meeting of the board.

v) The board shall provide the public with the opportunity to provide written comments on pending decisions of the board.

(viii) The board may allow expert testimony at board meetings, including when the board meets in closed session.

(g) Conflict of interest. —

i) Members of the board shall recuse themselves from decisions related to a prescription drug product if the member, or an immediate family member of the member, has received or could receive any of the following:

(1) A direct financial benefit of any amount deriving from the result or finding of a study or determination by or for the board; or

(2) A financial benefit from any person that owns, manufactures, or provides prescription drug products, services, or items to be studied by the board that taken together exceeds $5,000 per year.

ii) For the purposes of subparagraph (i) of this paragraph, a financial benefit includes honoraria, fees, stock, the value of the member’s or immediate family member’s stock holdings, and any direct financial benefit deriving from the finding of a review conducted under this act.

 iii) A conflict of interest shall be disclosed:

(1) By the board when hiring board staff;

(2) By the appointing authority when appointing members and alternate members to the board and members to the stakeholder council; and

(3) By the board, when a member of the board is recused in any final decision resulting from a review of a prescription drug product.

 iv) A conflict of interest shall be disclosed:

(1) In advance of the first open meeting after the conflict is identified; or

(2) Within 5 days after the conflict is identified.

 v) A conflict of interest disclosed under this section shall be posted on the website of the board unless the chair of the board recuses the member from any final decision resulting from a review of a prescription drug product.

 vi) A posting under paragraph (i) of this subsection shall include the type, nature, and magnitude of the interests of the member involved.

 vii) Members and alternate members of the board, board staff, and third–party contractors may not accept any gift or donation of services or property that indicates a potential conflict of interest or has the appearance of biasing the work of the board.

**Section 3. Powers and duties of the Board.**

* 1. In addition to the powers set forth elsewhere in this act, the board may:
		1. Promulgate regulations for the implementation of this act; and
		2. Enter into a contract with a qualified, independent third party for any service necessary to conduct the powers and duties of the board.
			1. Unless permission is granted by the board, a third party hired by the board may not release, publish, or otherwise use any information to which the third party has access under its contract.

**Section 4. Prescription Drug Affordability Stakeholder Council.**

* 1. The purpose of the stakeholder council is to provide stakeholder input to assist the board in making decisions as required under this act. The stakeholder council consists of 15 members appointed within four months after enactment as follows:
		1. 5 members appointed by the Speaker of the House;
		2. 5 members appointed by the Senate President; and
		3. 5 members appointed by the governor.
	2. The members of the stakeholder council shall have knowledge in one or more of the following:
		1. The pharmaceutical business model;
		2. Supply chain business models;
		3. The practice of medicine or clinical training;
		4. Consumer or patient perspectives;
		5. Clinical and health services research; or
		6. The state’s healthcare marketplace.
	3. From among the membership of the stakeholder council, the board chair shall appoint 1 member to be council Chair.
	4. The term of a member is 3 years.
		1. The initial members of the stakeholder council shall serve staggered terms as required by the terms provided for members in Section 11.
	5. A member of the stakeholder council:
		1. May not receive compensation as a member of the stakeholder council; but
		2. Is entitled to reimbursement for expenses under the standard state travel regulations, as provided in the state budget.

**Section 5. Drug Cost Affordability Review**

* 1. This section may not be construed to prevent a manufacturer from marketing a prescription drug product approved by the United States Food and Drug Administration while the product is under review by the board.
	2. The board shall limit its review of prescription drug products to those that are:
		1. Brand name drugs or biologics that, as adjusted annually for inflation, have:
			1. A launch wholesale acquisition cost of $60,000 or more per year or course of treatment if less than a year; or
			2. A wholesale acquisition cost increase of $3,000 or more in any 12–month period; and
		2. Biosimilar drugs that have a launch wholesale acquisition cost that is not at least 20% lower than the referenced brand biologic at the time the biosimilars are launched; and that have been suggested for review by the members of public, medical professionals, and other stakeholders;
		3. Generic drugs that, as adjusted annually for inflation, that have a wholesale acquisition cost of at least $100 for a 30-day supply or course of treatment if less than 30 days and which increased by 200% or more during the immediately preceding 12–month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition cost reported over the immediately preceding 12 months; and
		4. Other prescription drug products that may create affordability challenges for the state healthcare system or patients, including but not limited to drugs to address public health emergencies.
	3. The board shall solicit public input on prescription drugs thought to be creating affordability challenges that meet the parameters of subsection (b)(i)-(iv) of this section. The board shall determine whether to conduct a full affordability review for the proposed prescription drugs after compiling preliminary information about the cost of the product, patient cost sharing for the product, health plan spending on the product and stakeholder input.
	4. If the board conducts a review of the cost and affordability of a prescription drug product, the review shall determine whether use of the prescription drug product that is fully consistent with the labeling approved by the United States Food and Drug Administration or standard medical practice has led or will lead to affordability challenges for the state healthcare system or high out–of–pocket costs for patients.
	5. The information to conduct an affordability review may include, but is not limited to, any document and research related to the manufacturer’s selection of the introductory price or price increase of the prescription drug product, patient assistance program or programs specific to the product, estimated or actual manufacturer product price concessions in the market, net product cost to State payers, and other information as determined by the board.
	6. Failure of a manufacturer to provide the board with the information for an affordability review does not affect the authority of the board to conduct such a review.
	7. If the board finds that the spending on a prescription drug product reviewed under this section has led or will lead to an affordability challenge, the board shall establish an upper payment limit (UPL) considering:
		1. The cost of administering the drug.
		2. The cost of delivering the drug to consumers.
		3. Other relevant administrative costs related to the drug.
	8. The Upper Payment Limit applies to all purchases and payor reimbursements of the prescription drug product intended for use by individuals in the state, in person, by mail, or by other means;[[1]](#endnote-1)
	9. Any information submitted to the board in accordance with this section shall be subject to public inspection only to the extent allowed under the public information act.

**Section 6. Protections** **and Other Board Considerations**[[2]](#endnote-2)

1. The board shall examine how a UPL would affect 340B providers
2. In determining whether a drug creates an affordability challenge or determining a UPL amount, the board may not use **cost-effectiveness analyses which includes the cost-per-quality adjusted life year 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. In addition, for any treatment that extends life, if board uses cost-effectiveness results, they must use results that weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability.**
3. **A UPL is effective no sooner than six months after it has been announced.**
4. **State regulated health plans**[[3]](#endnote-3) **shall inform the board of how any UPL-related cost savings are directed to the benefit of enrollees, with a priority on enrollee cost sharing.**
5. **The UPL shall not be inclusive of the pharmacy dispensing fee.**
6. **State licensed *independent* pharmacies may not be reimbursed less than the UPL.**[[4]](#endnote-4)

**Section 7. Remedies**

a) The office of the attorney general may pursue any available remedy under state law when enforcing this act.

**Section 8. Appeals[[5]](#endnote-5)**

* 1. A person aggrieved by a decision of the board may request an appeal of the decision within 30 days after the finding of the board.
	2. The board shall hear the appeal and make a final decision within 60 days after the appeal is requested.
	3. Any person aggrieved by a final decision of the board may petition for judicial review as provided by the administrative procedures act.

**Section 9. Prescription Drug Affordability Fund.**

* 1. In this section, “fund” means the prescription drug affordability fund.
	2. There is a prescription drug affordability fund.
	3. The board shall be funded by an annual assessment on all manufacturers whose products are sold in the State.
	4. The board shall pay all funds collected from the assessment into the fund.
	5. The state treasurer shall hold the fund separately, and the comptroller shall account for the fund.
	6. The fund shall be used only to provide funding for the board and for the purposes authorized under this act including any costs expended by any state agency to implement this act.
	7. The fund shall be invested and reinvested in the same manner as other state funds.
	8. Any investment earnings shall be retained to the credit of the fund.
	9. This subsection may not be construed to prohibit the fund from receiving funds from any other source that does not create the appearance of a conflict of interest.
	10. The board shall be established using general funds, which shall be repaid to the state with the assessments required under this section.

**Section 10. Reports to the Legislature**

a) On or before December 31 each year, the board shall submit to the Finance Committee of the Senate and the Health Committee of the House of Representatives a report that includes:

* + 1. Price trends for prescription drug products;
		2. The number of prescription drug products that were subject to board review, including the results of the review and the number and disposition of appeals and judicial reviews of board decisions; and
		3. Any recommendations the board may have on further legislation needed to make prescription drug products more affordable in the state.

b) On or before [one-time date], the Prescription Drug Affordability Board shall:

* + 1. Report to the legislature about the operation of the generic drug market in the United States that includes generic physician–administered drugs and considers:[[6]](#endnote-6)
			1. The price trend of generic drugs on a year–over–year basis;
			2. The degree to which generic drug prices affect insurance premiums as reported by health insurers in this State or other states that collect this information;
			3. Recent and current trends in patient cost–sharing for generic drugs;
			4. The causes and prevalence of generic drug shortages; and
			5. Any other relevant study questions,

**Section 11. Terms of Office for Initial Board and Council Members[[7]](#endnote-7)**

a) The terms of the initial members and alternate members of the Prescription Drug Affordability Board shall expire as follows:

i) One member and one alternate member in 2025;
ii) Two members and one alternate member in 2026; and
iii) Two members, including the chair of the board, and one alternate member in 2027.

b) The terms of the initial members of the Prescription Drug Affordability Stakeholder Council shall expire as follows:

* + 1. Seven members in 2025;
		2. Seven members in 2026; and
		3. Seven members in 2027.

**Section 12. Severability**

 If any provision of this act or the application thereof to any person or circumstance is held invalid for any reason in a court of competent jurisdiction, the invalidity does not affect other provisions or any other application of this act that can be given effect without the invalid provision or application, and for this purpose the provisions of this act are declared severable.

**Section 13. Effective Date**

This act shall take effect in 180 days.

1. It is important to structure the language to apply to all drugs intended for use in the state, even when the financial transaction for that drug intended for use in the state occurs out of state, as this language does. [↑](#endnote-ref-1)
2. This section includes important amendments added to the PDAB law in Colorado in 2021. [↑](#endnote-ref-2)
3. This provision cannot be applied to Medicare Part D plans. [↑](#endnote-ref-3)
4. Chain pharmacies may have drug acquisition costs below the UPL. Chain pharmacies will continue to negotiate with health plans/PBMs on formulas for drug product reimbursement so long as the reimbursement does not exceed the UPL. [↑](#endnote-ref-4)
5. A state can look to their appeals process for public utilities regulations as well or other state appeals processes. [↑](#endnote-ref-5)
6. This is not a project to generate new data on generic drug market but more of a review existing literature. [↑](#endnote-ref-6)
7. This section should be written with an eye to the effective date of the law and the effective date by which board and Council members are to be selected (if any). [↑](#endnote-ref-7)