

Prescription Drug Affordability Board State Model Act

October 2019

1) Section 1. Definitions

- a) 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:
 - i) “Biologic.” A drug that is produced or distributed in accordance with a biologics license application approved under 42 C.F.R. § 447.502.
 - ii) “Biosimilar.” A drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(K)(3).
 - iii) “Board.” The Prescription Drug Affordability Board.
 - iv) “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.
 - v) “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.
- b) “Manufacturer” An entity that:
 - i) Engages in the manufacture of a prescription drug product; or
 - ii) Enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity’s own name; and
 - iii) Sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.
- c) “Prescription drug product.” A brand name drug, a generic drug, a biologic, or a biosimilar.
- d) “Stakeholder council.” The Prescription Drug Affordability Stakeholder Council.

2) Section 2. Prescription Drug Affordability Board.

- a) 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, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system from the high costs of prescription drug products. The board is a body politic and corporate and is 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.
- b) The 5 members of the board and 3 alternates shall be appointed by the governor and confirmed by the Senate.
- c) The board members and alternates must collectively have expertise in health care economics 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.
- d) Any conflict of interest, including whether the individual has an association, including a financial or personal association, that 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.

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(e) Term of office.

- i) The term of a member or an alternate member is 5 years.
- ii) The terms of the members and alternate members are staggered as required by the terms provided for members in Section 10.

(f) Board staff.

- i) 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.
- ii) 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 subparagraphs (ii) and (iv) of this paragraph, the board shall meet in open session at least once every 6 weeks to review prescription drug product information.

(i) The chair may cancel or postpone a meeting if there are no prescription drug products to review.

(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(d) 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; and
- (3) Any decision by the board.

(iii) The board may meet in closed session to discuss proprietary data and information.

(iv) The board shall provide public notice of each board meeting at least 2 weeks in advance of the meeting.

(v) Materials for each board meeting shall be made available to the public at least 1 week in advance of the meeting.

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

(vii) 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. —

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(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:

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

(B) A financial benefit from any person that owns, manufactures, or provides prescription drug products, services, or items to be studied by the board that in the aggregate 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:

(A) By the board when hiring board staff;

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

(C) 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:

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

(B) 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.

(A) 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.

- a) To the extent practicable, the board shall access pricing information for prescription drug products by:
 - i) Entering into a memorandum of understanding with another state to which manufacturers already report pricing information; and
 - ii) Accessing other available pricing information.
- b) In addition to the powers set forth elsewhere in this act, the board may:
 - i) Promulgate regulations for the implementation of this act; and

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- ii) Enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board.
 - A) 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.

1) Section 4. Prescription Drug Affordability Stakeholder Council.

- a) 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 21 members appointed in accordance with this subsection.
 - i) The Speaker of the House of Representatives shall appoint:
 - (a) One representative of a statewide health care advocacy coalition;
 - (b) One representative of a statewide advocacy organization for seniors;
 - (c) One representative of a statewide organization for diverse communities;
 - (d) One representative of a labor union;
 - (e) Two health services researchers specializing in prescription drugs; and
 - (f) One public member at the discretion of the speaker of the House of Representatives.
 - ii) The President pro tempore of the Senate shall appoint:
 - (a) One representative of doctors;
 - (b) One representative of nurses;
 - (c) One representative of hospitals;
 - (d) One representative of health insurers;
 - (e) One representative of the department of budget and management;
 - (f) One clinical researcher; and
 - (g) One public member at the discretion of the President pro tempore of the Senate.
 - iii) The governor shall appoint:
 - (a) One representative of brand name drug corporations;
 - (b) One representative of generic drug corporations;
 - (c) One representative of employers;
 - (d) One representative of pharmacy benefits managers;
 - (e) One representative of pharmacists;
 - (f) One pharmacologist; and
 - (g) One public member at the discretion of the governor.
- b) The members of the stakeholder council shall have knowledge in one or more of the following:
 - i) The pharmaceutical business model;
 - ii) Supply chain business models;
 - iii) The practice of medicine or clinical training;
 - iv) Consumer or patient perspectives;
 - v) Health care costs trends and drivers;
 - vi) Clinical and health services research; or
 - vii) The state's health care marketplace.
- c) From among the membership of the stakeholder council, the board chair shall appoint two members to be cochairs of the stakeholder council.
- d) The term of a member is 3 years.

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- i) The initial members of the stakeholder council shall serve staggered terms as required by the terms provided for members in Section 10.
- e) A member of the stakeholder council:
 - i) May not receive compensation as a member of the stakeholder council; but
 - ii) Is entitled to reimbursement for expenses under the standard state travel regulations, as provided in the state budget.

Section 5. Drug Cost Affordability Review

- a) 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.
- b) The board shall identify prescription drug products that are:
 - i) Brand name drugs or biologics that, as adjusted annually for inflation in accordance with the consumer price index, have:
 - (1) A launch wholesale acquisition cost of \$30,000 or more per year or course of treatment; or
 - (2) A wholesale acquisition cost increase of \$3,000 or more in any 12-month period, or course of treatment if less than 12 months;
 - ii) Biosimilar drugs that have a launch wholesale acquisition cost that is not at least 15% lower than the referenced brand biologic at the time the biosimilars are launched;
 - iii) Generic drugs that, as adjusted annually for inflation in accordance with the consumer price index, have a wholesale acquisition cost:
 - (1) Of \$100 or more for:
 - (a) A 30-day supply lasting a patient for a period of 30 consecutive days based on the recommended dosage approved for labeling by the United States Food and Drug Administration;
 - (b) A supply lasting a patient for fewer than 30 days based on the recommended dosage approved for labeling by the United States Food and Drug Administration; or
 - (c) One unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage; and
 - (2) That 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
 - iv) Other prescription drug products that may create affordability challenges for the state health care system and patients, in consultation with the stakeholder council.
- c) After identifying prescription drug products as required by subsection (b) of this section, the board shall determine whether to conduct an affordability review for each identified prescription drug product by:
 - i) Seeking stakeholder council input about the prescription drug product; and
 - ii) Considering the average patient cost share of the prescription drug product.
- d) The information to conduct an affordability review may include any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including life cycle management, net average price in the state,

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market competition and context, projected revenue, and the estimated value or cost–effectiveness of the prescription drug product.

- e) 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.
- f) 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 health care system or high out-of-pocket costs for patients.
 - i) To the extent practicable, in determining whether a prescription drug product has led or will lead to an affordability challenge, the board shall consider the following factors:
 - (a) The wholesale acquisition cost for the prescription drug product sold in the state;
 - (b) 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;
 - (c) 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;
 - (d) The price at which therapeutic alternatives have been sold in the state;
 - (e) 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;
 - (f) The costs to health plans based on patient access consistent with United States Food and Drug Administration labeled indications and recognized standard medical practice;
 - (g) The impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design;
 - (h) The current or expected dollar value of drug–specific patient access programs that are supported by the manufacturer;
 - (i) The relative financial impacts to health, medical, or social services costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;
 - (j) The average patient copay or other cost–sharing for the prescription drug product in the state;
 - (k) Any information a manufacturer chooses to provide; and
 - (l) Any other factors as determined by the board in regulations adopted by the board.
- g) 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 under paragraph after considering:
 - i) The cost of administering the drug;
 - ii) The cost of delivering the drug to consumers;
 - iii) Other relevant administrative costs related to the drug; and

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- h) The Upper Payment Limit applies to all purchases and payor reimbursements of the prescription drug product dispensed or administered to individuals in the state in person, by mail, or by other means;
- i) 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. Remedies

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

Section 7. Appeals

- a) 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.
- b) The board shall hear the appeal and make a final decision within 60 days after the appeal is requested.
- c) Any person aggrieved by a final decision of the board may petition for judicial review as provided by the administrative procedure act.

Section 8. Prescription Drug Affordability Fund.

- a) In this section, “fund” means the prescription drug affordability fund.
- b) There is a prescription drug affordability fund.
- c) The board shall be funded by an assessment on all manufacturers.
- d) The board shall assess and collect fees from manufacturers as provided for in this section.
 - i) The board shall assess each manufacturer on the manufacturer’s relative share of gross revenue from drug sales in the state.
- e) Each year, a manufacturer assessed under this section shall pay a fee to the board.
- f) The board shall pay all funds collected from the assessment into the fund.
- g) The state treasurer shall hold the fund separately, and the comptroller shall account for the fund.
- h) 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.
- i) The fund shall be invested and reinvested in the same manner as other state funds.
- j) Any investment earnings shall be retained to the credit of the fund.
- k) This subsection may not be construed to prohibit the fund from receiving funds from any other source.
- l) The board shall be established using general funds, which shall be repaid to the state with the assessments required under this section.

Section 9. 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;

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(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 June 1, 2021, the Prescription Drug Affordability Board shall:

(1) Conduct a study of the operation of the generic drug market in the United States that includes a review of physician-administered drugs and considers:

(i) The prices of generic drugs on a year-over-year basis;

(ii) The degree to which generic drug prices affect yearly insurance premium changes;

(iii) Annual changes in insurance cost-sharing for generic drugs;

(iv) The potential for and history of drug shortages;

(v) The degree to which generic drug prices affect yearly State Medicaid spending; and

(vi) Any other relevant study questions; and

(2) Report its findings to the General Assembly

Section 10. Terms of Office for Initial Board and Council Members

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

(1) One member and one alternate member in 2023;

(2) Two members and one alternate member in 2024; and

(3) Two members, including the chair of the Board, and one alternate member in 2025.

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

(1) Seven members in 2023;

(2) Seven members in 2024; and

(3) Seven members in 2025.

Section 12. ERISA Plans and Medicare Drug Plans

This act obligates state-sponsored and state regulated health plans and health programs to limit drug reimbursements and drug payment to no more than the board-established upper payment limit. ERISA plans and Part D plans are not bound by decisions of the board and can choose to reimburse more than the upper payment limit. Providers who dispense and administer drugs in the state to individuals in the state are bound to bill all payers no more than the upper payment limit to the patient without regard to

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whether or not an ERISA plan or Medicare Part D plan chooses to reimburse the provider above the upper payment limit.

Section 13. 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 14. Effective Date

This act shall take effect in 180 days.