As Introduced

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H. B. No. 890

Representative Hall, D.

Cosponsors: Representatives Piccolantonio, Brennan, White, E., Upchurch, McNally

To enact sections 3901.85, 3901.851, 3901.852, 3901.853, 3901.854, 3901.855, 3901.856, 3901.857, and 3901.858 and to repeal section 125.95 of the Revised Code to establish the Prescription Drug Affordability Board and Prescription Drug Affordability Stakeholder Council, to authorize the establishment of upper payment limits on certain prescription drug products, to repeal the law establishing the Prescription Drug Transparency and Affordability Advisory Council, and to name this act the Prescription Relief and Inflation Cost Elimination or P.R.I.C.E. Act.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3901.85, 3901.851, 3901.852, 3901.853, 3901.854, 3901.855, 3901.856, 3901.857, and 3901.858 of the Revised Code be enacted to read as follows:

Sec. 3901.85. As used in sections 3901.85 to 3901.858 of the Revised Code:

(A) "340B covered entity" has the same meaning as in

section 5167.01 of the Revised Code.

(B) "Biological product" and "biosimilar" have the same meanings as in 42 U.S.C. 262.

(C) "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. 355(c). "Brand name drug" does not include an authorized generic as defined by 42 C.F.R. 447.502.

(D) "Consumer price index" means the United States consumer price index for all urban consumers as defined and reported by the United States department of labor, bureau of labor statistics.

(E) "Generic drug" means:

(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;

(3) A drug that entered the market before 1962 and was not originally marketed under a new drug application.

(F) "Health benefit plan" has the same meaning as in section 3922.01 of the Revised Code.

(G) "Manufacturer" means an entity that meets either of the following:

(1) Owns the patent to a prescription drug product or enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name and sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or has leased the

right to market;

(2) Is the labeled entity of a generic drug at the point of manufacture and sets or changes the wholesale acquisition cost of a generic drug that it manufactures.

(H) "Pharmacy" has the same meaning as in section 4729.01 of the Revised Code.

(I) "Pharmacy benefit manager" has the same meaning as in section 3959.01 of the Revised Code.

(J) "Prescription drug product" means a biological product, biosimilar, brand name drug, or generic drug.

(K) "Prescription drug product purchaser" means an entity that purchases and takes ownership of a prescription drug product for resale or providing to patients.

(L) "Third-party payer" means a health benefit plan, the department of medicaid, a person administering a self-funded plan, or a pharmacy benefit manager.

(M) "Wholesale acquisition cost" has the same meaning as in 42 U.S.C. 1395w-3a(c)(6)(B).

Sec. 3901.851. (A) The prescription drug affordability board is established in the department of insurance. The board consists of nine members, each appointed by the governor and confirmed by the senate. The members shall collectively have expertise in health care economics, health policy, health equity, and clinical medicine. At least one member of the board shall be an individual who advocates for patients. A member shall not be employed by, or serve as a board member of, consultant to, or lobbyist for, a drug manufacturer or trade association of drug manufacturers or have any personal or

financial interest related to drug manufacturing. Members shall be appointed not later than thirty days after the effective date of this section.

(B) Of the initial members, four shall be appointed for one-year terms and five shall be appointed for two-year terms. Thereafter, each membership term shall be for four years.

Members may be removed by the governor at any time for good cause, including incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance.

Members may be reappointed, and vacancies shall be filled in the manner provided for original appointments. Any member appointed to fill a vacancy occurring before the expiration date of the term for which the member's predecessor was appointed shall hold office as a member for the remainder of that term.

Each member shall be compensated for each day that the member is actually engaged in the performance of board duties. Members also shall be reimbursed for ordinary travel expenses, including meals and lodging incurred in the performance of their duties.

(C) The board's initial meeting shall take place at the call of the governor. At the initial meeting, the board shall select from among its members a chairperson and any other officers it considers necessary or appropriate.

After the initial meeting, the board shall meet at least four times a year. The board also may meet at other times specified by the call of the chairperson or a majority of board members.

A majority of board members constitutes a quorum and is required for the transaction of official board business, except

that when one or more members have recused themselves, two-thirds of the members present and serving are required for official board business.

(D)(1) The following actions by the board shall be conducted in accordance with section 121.22 of the Revised Code:

(a) Any deliberation as to whether to conduct a cost review of a prescription drug;

(b) Any decision or deliberation toward a decision on any matter before the board except as provided in division (D)(2) of this section.

(2) The board may meet in executive session to discuss information relating to a trade secret.

(E) Any writing that is prepared, owned, used, in the possession of, or retained by the board in performing official business is a public record, except that the board shall keep strictly confidential any information it collects, uses, or relies upon if the information is confidential, proprietary, or a trade secret.

Sec. 3901.852. (A) The prescription drug affordability board may enter into a contract with a qualified, independent third party for any service necessary to carry out the powers and duties of the board. 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.

(B) The board shall adopt rules as necessary to implement this chapter. All rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Sec. 3901.853. (A)(1) The prescription drug affordability stakeholder council is established in the department of insurance. The purpose of the council is to provide stakeholder input to the prescription drug affordability board established under section 3901.851 of the Revised Code, in order to assist the board in making decisions as required by this chapter. The stakeholder council consists of the following twenty-three members:

(a) The superintendent of insurance or the superintendent's designee, but only if the designee is part of the department of insurance's executive leadership;

(b) The medicaid director or the director's designee, but only if the designee is part of the department of medicaid's executive leadership;

(c) A member of the board of pharmacy, appointed by resolution adopted by the board of pharmacy;

(d) An individual representing manufacturers of brand name drugs, appointed by the governor;

(e) Three individuals representing the general public, each appointed by the governor;

(f) An individual representing manufacturers of generic drugs, appointed by the governor;

(g) An individual representing employers and businesses from the prescription drug industry, appointed by the governor;

(h) An individual representing pharmacy benefit managers, appointed by the governor;

(i) An individual representing pharmacists, appointed by the governor;

(j) An individual representing physicians, appointed by the governor;

(k) An individual representing nurses, appointed by the governor;

(l) An individual representing hospitals, appointed by the governor;

(m) An individual representing a managed care organization, appointed by the governor, except that the managed care organization shall not be controlled or formerly controlled by, either directly or indirectly, a mutual insurance company;

(n) An individual representing clinical researchers, appointed by the governor;

(o) An individual representing a statewide organization that advocates for senior citizens, appointed by the governor;

(p) An individual representing a statewide organization that advocates for health care, appointed by the governor;

(q) An individual representing a statewide organization that advocates for diversity within communities, appointed by the governor;

(r) An individual representing a statewide organization that advocates for consumer rights, appointed by the governor;

(s) An individual from a labor union that represents prescription drug industry employees, appointed by the governor;

(t) An individual representing researchers who specialize in prescription drug products, appointed by the governor;

(u) An individual representing a mutual insurance company, appointed by the governor, except that the mutual insurance

company shall not be controlled or formerly controlled by, either directly or indirectly, a managed care organization.

The members described in division (A)(1) of this section shall be appointed as soon as practicable after the effective date of this section.

(2) For each of the following topics, at least one member from among the members appointed by the governor as described in division (A)(1) of this section shall have knowledge in that topic:

(a) The pharmaceutical business model;

(b) Supply chain business models;

(c) The practice of medicine or clinical training;

(d) Consumer or patient perspectives;

(e) Health care cost trends;

(f) Clinical and health services research.

(B) Of the initial members described in divisions (A)(1)(c) to (u) of this section, seven shall serve terms of one year, seven shall serve terms of two years, and seven shall serve terms of three years.

Thereafter, each membership term shall be for three years.

Members may be removed by the governor at any time for good cause, including incompetence, dereliction of duty, malfeasance, misfeasance, or nonfeasance.

Members may be reappointed, and vacancies shall be filled in the manner provided for original appointments. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall

hold office as a member for the remainder of that term.

(C) Members of the stakeholder council shall not be compensated for their service but shall be reimbursed for ordinary travel expenses, including meals and lodging incurred in the performance of their duties.

(D) The council's initial meeting shall take place at the call of the chairperson of the prescription drug affordability board established under section 3901.851 of the Revised Code. At the initial meeting, the council shall select from among its members a chairperson and any other officers it considers necessary or appropriate.

After the initial meeting, the council shall meet at least four times a year. The council also may meet at other times at the call of the chairperson or by request of at least seven council members.

A majority of council members constitutes a quorum, and a majority of the members present and serving are required for the transaction of official council business. The council shall transact official council business in accordance with section 121.22 of the Revised Code.

Any writing that is prepared, owned, used, in the possession of, or retained by the council in transacting official business is a public record, except that the council shall keep strictly confidential any information it collects, uses, or relies upon if the information is proprietary, a trade secret, or otherwise confidential under law.

Sec. 3901.854. (A) Beginning eighteen months after the effective date of this section, the prescription drug affordability board, in consultation with the prescription drug

affordability stakeholder council, shall select one or more prescription drug products based on the following criteria:

(1) The prescription drug product is a brand name drug or biological product that, as adjusted annually for inflation in accordance with the consumer price index, has a wholesale acquisition cost of sixty thousand dollars or more per year or course of treatment or a wholesale acquisition cost increase of three thousand dollars or more in any twelve-month period.

(2) The prescription drug product is a biosimilar that has a wholesale acquisition cost that is not at least fifteen per cent lower than the referenced brand biologic.

(3) The prescription drug product is a generic drug that, as adjusted annually for inflation in accordance with the consumer price index, has a wholesale acquisition cost of at least one hundred dollars for a thirty-day supply that lasts a patient for a period of thirty consecutive days based on the recommended dosage approved for labeling by the United States food and drug administration, for a supply that lasts a patient for fewer than thirty days based on the recommended dosage approved for labeling by the United States food and drug administration, or for one unit of the drug if the labeling approved by the United States food and drug administration does not recommend a finite dosage, and that increased by two hundred per cent or more during the preceding twelve-month period, as determined by the difference between the resulting wholesale acquisition cost and the average of the wholesale acquisition reported over the preceding twelve months.

(4) The prescription drug product may create affordability challenges for this state's hospitals and health care systems or patients, including a drug to address a public health emergency.

(B) The board is not required to select every prescription drug that meets the criteria of division (A) of this section.

(C) The board shall determine whether to conduct a cost and affordability review for each prescription drug product selected under division (A) of this section. In making a determination under this division, the board shall consider input from the prescription drug affordability stakeholder council and the average patient cost share for each prescription drug product.

(D) If the board conducts a review of the cost and affordability of a prescription drug product, the board may consider any document or 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 this state, market competition, projected revenue, and the estimated cost-effectiveness of the prescription drug product. In its review, the board shall determine whether use of the prescription drug product in a manner 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 this state's hospitals and health care systems or high out-of-pocket costs for patients.

(E) In making its determination under this section, the board shall consider any information that a manufacturer chooses to provide to the board and, to the extent practicable, all of the following factors:

(1) The wholesale acquisition cost for the prescription drug product sold in this state;

(2) The average monetary price concession, discount, or rebate that the manufacturer provides to health benefit plans and pharmacy benefit managers in this state or is expected to provide to health benefit plans and pharmacy benefit managers in this state, expressed as a per cent of the wholesale acquisition cost for the prescription drug product under review;

(3) The price at which therapeutic alternatives for the prescription drug product have been sold in this state;

(4) The average monetary concession, discount, or rebate that another manufacturer provides or is expected to provide to health benefit plans and pharmacy benefit managers in this state for therapeutic alternatives;

(5) The cost to health benefit plans based on patient access consistent with United States food and drug administration labeled indications or recognized standard medical practice;

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

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

(8) The relative financial impact to health, medical, or social service costs as can be quantified and compared to baseline effects of existing therapeutic alternatives;

(9) The average patient copay or other cost sharing for the prescription drug product in this state;

(10) The impact on hospital access to the prescription drug product, prescription drug product shortage concerns, and

the impact on the cost to hospitals purchasing the prescription drug product;

(11) Any other factor established by the board by rule.

(F) If the board determines that spending on a prescription drug product reviewed under this section has led or will lead to affordability challenges to hospitals and health care systems in this state or high out-of-pocket costs for patients in this state, the board shall establish by rule an upper payment limit on that drug. In establishing an upper payment limit under this division, the board shall consider both of the following:

(1) Relevant administrative costs related to supplying or stocking the prescription drug product;

(2) The impact of an upper payment limit for the prescription drug product on 340B covered entities.

(G) An upper payment limit established under this section shall not include professional dispensing fees. An upper payment limit shall not be established for any prescription drug product that is listed as currently in shortage in the drug shortage database maintained by the United States food and drug administration.

(H) If the board considers the estimated cost-effectiveness of a prescription drug product under this section, the board shall comply with both of the following:

(1) The board shall not use a cost-per-quality adjusted life year, or a similar measure, to identify a subpopulation for which a prescription drug product would be less cost-effective due to severity of illness, age, or preexisting disability.

(2) If the board uses a cost-effectiveness analysis for a prescription drug product that extends an individual's life, the board shall use a cost-effectiveness analysis that weighs the value of all additional lifetime gained equally for any individual, no matter the severity of illness, age, or preexisting disability.

(I) An upper payment limit established under this section takes effect on the date prescribed by the board by rule but not earlier than six months after the date the upper payment limit is established.

Sec. 3901.855. (A) Except as provided in division (B) of this section, if the prescription drug affordability board establishes an upper payment limit under section 3901.854 of the Revised Code for a prescription drug product, then beginning on the effective date of the upper payment limit, a prescription drug product purchaser or third-party payer shall not purchase, bill, or reimburse for the prescription drug product in an amount that exceeds the upper payment limit, regardless of whether the prescription drug product is dispensed or distributed in person, by mail, or by other means.

(B) A prescription drug product purchaser or third-party payer shall not reimburse any of the following prescription drug product purchasers for a prescription drug product in an amount less than an upper payment limit established under section 3901.854 of the Revised Code for the prescription drug product:

(1) An independent pharmacy;

(2) A hospital pharmacy;

(3) A hospital, including one that provides behavioral health care;

(4) A 340B covered entity.

Sec. 3901.856. (A) The attorney general may investigate a violation of section 3901.855 of the Revised Code and may commence a civil action against a person for appropriate relief, including injunctive relief, for a violation of that section.

(B) A person aggrieved by a decision of the board may appeal the decision in accordance with Chapter 119. of the Revised Code.

Sec. 3901.857. The prescription drug affordability fund is created in the state treasury. All money appropriated for purposes of administering sections 3901.85 to 3901.858 of the Revised Code or collected from any other source for such purposes shall be deposited into the state treasury to the credit of the fund. All investment earnings of the fund shall be credited to the fund. The department of insurance shall use the money in the fund to support the prescription drug affordability board and prescription drug affordability stakeholder council in the performance of their duties under sections 3901.85 to 3901.858 of the Revised Code.

Sec. 3901.858. (A) Not later than the thirty-first day of December of each year, the prescription drug affordability board shall prepare and submit to the general assembly a report that includes all of the following information:

(1) Price trends for prescription drug products;

(2) The number of prescription drug products reviewed by the board, including the results of the reviews and the number and disposition of appeals and judicial reviews of board decisions;

(3) Recommendations, if any, for legislative changes to

address prescription drug affordability in this state.

(B) The report shall be submitted to the general assembly in accordance with section 101.68 of the Revised Code.

Section 2. That section 125.95 of the Revised Code is hereby repealed.

Section 3. (A) The Prescription Drug Affordability Board shall review the operation of the United States market for generic drugs. The review shall address all of the following topics:

(1) The prices of generic drugs on a year-to-year basis;

(2) The degree to which generic drug prices affect yearly insurance premium charges;

(3) Annual changes in cost sharing for generic drugs;

(4) The potential for and history of generic drug shortages;

(5) The degree to which the prices of generic drugs affect annual Medicaid spending in this state;

(6) The impact of an upper payment limit on 340B covered entities;

(7) Any other topic the board considers relevant to generic drug prices.

(B) Not later than one year after the effective date of this section, the Board shall submit a report of its findings to the General Assembly in accordance with section 101.68 of the Revised Code.

Section 4. This act shall be known as the Prescription Relief and Inflation Cost Elimination or P.R.I.C.E. Act.