General Assembly

Raised Bill No. 260

February Session, 2022

LCO No. **2224**

Referred to Committee on AGING

Introduced by:
(AGE)

AN ACT CONCERNING A PRESCRIPTION DRUG COST CONTROL BOARD.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2022*) (a) There is hereby established the Prescription Drug Cost Control Board, a body politic and corporate, constituting a public instrumentality and political subdivision of the state established and created for the performance of an essential public and governmental function. The board shall not be construed to be a department, institution or agency of the state.

(b) The purposes of the Prescription Drug Cost Control Board shall be to monitor prescription drug prices in the state and recommend upper price limits on prescription drugs to the Insurance Commissioner.

(c) The powers of the board shall be vested in and exercised by a board of directors, which shall consist of five voting members and three voting alternate members, with expertise in health care, economics and clinical medicine, appointed by the Governor and confirmed by the Senate to serve for five-year terms. The chairperson of the board shall

be appointed by the Governor, with the advice and consent of both houses of the General Assembly, and shall serve at the pleasure of the Governor. Alternate members shall, when seated as provided in this section, have all powers and duties of a member of the board. If a regular member of the board is absent or has a conflict of interest, the chairperson of the board shall designate an alternate to so act, choosing alternates in rotation so that they shall act as nearly equal a number of times as possible. If any alternate is not available in accordance with such rotation, such fact shall be recorded in the minutes of the meeting. A member or alternate member shall serve until a successor is appointed.

(d) Any vacancy occurring other than by expiration of term shall be filled in the same manner as the original appointment for the balance of the unexpired term. The Governor may remove a member for any one or more of the following: Wilful neglect of duty, misfeasance or malfeasance.

(e) Each member of the board shall be entitled to reimbursement for such member's actual and necessary expenses incurred during the performance of such member's official duties.

(f) Members of the board may engage in private employment, or in a profession or business, subject to any applicable laws, rules and regulations of the state regarding official ethics or conflict of interest. It shall not constitute a conflict of interest for a trustee, director, partner or officer of any person, firm or corporation, or any individual having a financial interest in a person, firm or corporation, to serve as a board member of the board, provided such trustee, director, partner, officer or individual shall abstain from deliberation, action or vote by the board in specific request to such person, firm or corporation.

(g) The board shall meet not less than four times annually to review prescription drug product information. A majority of the members of the board shall constitute a quorum for the transaction of any business or the exercise of any power of the board.

(h) In carrying out its purposes, the board may:

(1) Assess and collect fees from prescription drug manufacturers doing business in the state to be used exclusively to finance the work of the board, provided the board shall account for and audit funds of the board;

(2) Maintain an office at such place or places as it may designate and an Internet web site;

(3) (A) Employ such assistants, agents and other employees as may be necessary or desirable who shall not be employees, as defined in subsection (b) of section 5-270 of the general statutes; (B) establish all necessary or appropriate personnel practices and policies, including those relating to hiring, promotion, compensation, retirement and collective bargaining, which need not be in accordance with chapter 68 of the general statutes, and the board shall not be an employer as defined in subsection (a) of section 5-270 of the general statutes; and (C) engage consultants, attorneys and appraisers as may be necessary or desirable to carry out its purposes in accordance with this section and section 3 of this act;

(4) Receive and accept aid or contributions from any source of money, property, labor or other things of value, to be held, used and applied to carry out the purposes of the board, provided acceptance of such aid or contributions does not present a conflict of interest for any board member or staff hired pursuant to subdivision (3) of this subsection; and

(5) Make and enter into all contracts and agreements necessary or incidental to the performance of its duties and the execution of its powers, including contracts and agreements for such professional services as the board deems necessary, including, but not limited to, financial consultants, counsel, underwriters and technical specialists.

(i) (1) The chairperson of the board shall provide to the Insurance Commissioner the name of any prescription drug manufacturer that fails to pay any assessment or fee under subdivision (1) of subsection (h)

of this section to the board. The Insurance Commissioner shall see that all laws respecting the board's authority pursuant to said subdivision are faithfully executed. The commissioner has all the powers that are reasonable and necessary to enforce the provisions of said subdivision.

(2) Any prescription drug manufacturer aggrieved by an administrative action taken by the commissioner under subdivision (1) of this subsection may appeal therefrom in accordance with the provisions of section 4-183, except venue for such appeal shall be in the judicial district of New Britain.

(j) The members of the Prescription Drug Cost Control Board shall adopt written procedures, in accordance with the provisions of section 1-121 of the general statutes, for: (1) Adopting an annual budget and plan of operations, including a requirement of board approval before the budget or plan may take effect; (2) hiring, dismissing, promoting and compensating employees of the board, including an affirmative action policy and a requirement of board approval before a position may be created or a vacancy filled; (3) acquiring personal property and personal services, including a requirement of board approval for any nonbudgeted expenditure in excess of an amount to be determined by the board; (4) contracting for financial, legal and other professional services, including a requirement that the board solicit proposals at least once every three years for each such service which it uses; and (5) the use of surplus funds.

Sec. 2. (NEW) (*Effective October 1, 2022*) As used in this section and sections 3 and 4 of this act:

(1) "Biologic" means a drug licensed under 42 USC 262;

(2) "Biosimilar" means a drug that is highly similar to a biologic and is produced or distributed in accordance with a biologics license application approved under 42 USC 262, as amended from time to time;

(3) "Board" means the Prescription Drug Cost Control Board established pursuant to section 1 of this act;

(4) "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 USC 355, as amended from time to time, but does not include a generic drug as defined in 42 CFR 447.502, as amended from time to time;

(5) "Generic drug" means (A) a prescription drug product that is marketed or distributed in accordance with an abbreviated new drug application approved under 21 USC 355, as amended from time to time, (B) a generic drug as defined in 42 CFR 447.502, as amended from time to time, or (C) a drug that entered the market before calendar year 1962 that was not originally marketed under a new prescription drug product application;

(6) "Manufacturer" means an entity that (A) engages in the manufacture of a drug product, or (B) 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 markets;

(7) "Prescription drug product" means a brand name drug, a generic drug, a biologic or biosimilar; and

(8) "Stakeholder council" means the Prescription Drug Affordability Stakeholder Council established pursuant to section 4 of this act.

Sec. 3. (NEW) (*Effective October 1, 2022*) (a) To the extent practicable, the Prescription Drug Cost Control Board shall access pricing information for prescription drug products by: (1) Entering into a memorandum of understanding with another state to which a manufacturer already reports pricing information, (2) assessing spending for the drug in the state, and (3) accessing other available pricing information.

(b) The board shall identify prescription drug products that, as adjusted annually for inflation in accordance with the consumer price index for all urban consumers, as published by the United States

Department of Labor, Bureau of Labor Statistics, are:

(1) Brand name drugs that have a launch wholesale acquisition cost of thirty thousand dollars or more per year or course of treatment;

(2) Brand name drugs that have a wholesale acquisition cost increase of three thousand dollars or more in any twelve–month period;

(3) Biosimilars that have a launch wholesale acquisition cost that is not at least fifteen per cent lower than the referenced brand biologic at the time the biosimilars are launched; and

(4) Generic drugs that have:

(A) A wholesale acquisition cost of one hundred dollars or more for (i) a thirty-day supply lasting 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, (ii) a supply lasting a patient for fewer than thirty days based on the recommended dosage approved for labeling by the United States Food and Drug Administration, or (iii) one unit of the drug if the labeling approved by the United States Food and Drug Administration does not recommend a finite dosage; and

(B) A wholesale acquisition cost that increased by two hundred per cent or more during the immediately preceding twelve-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 twelve months.

(c) The board shall identify other prescription drug products that may create affordability challenges for the health care system in the state or patients, including, but not limited to, drugs needed to address public health emergencies.

(d) After identifying prescription drug products as required by subsections (b) and (c) of this section, the board shall determine whether to conduct an affordability review for each identified prescription drug

product by seeking (1) input from the stakeholder council, and (2) considering the average patient cost share of the prescription drug product.

(e) In conducting an affordability review of prescription drugs, the board may examine any document and research related to the manufacturer's selection of the introductory price or price increase of the prescription drug product, including, but not limited to, (1) net average price in the state, (2) market competition and context, (3) projected revenue to the manufacturer, and (4) the estimated value or cost effectiveness of the prescription drug product.

(f) The board shall determine whether use of the prescription drug product, 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 health care system in the state or high out–of–pocket costs for patients. In determining whether a prescription drug product has led or will lead to an affordability challenge, the board shall consider the following factors:

(1) The wholesale acquisition cost 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 per cent 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 per cent 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 and recognized standard medical practice;

(7) The impact on patient access resulting from the cost of the prescription drug product relative to health plan 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 copayment or other cost sharing for the prescription drug product in the state;

(11) Any information a manufacturer chooses to provide; and

(12) Any other factors as determined 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 recommend an upper payment limit to the Insurance Commissioner after considering: (1) The cost of administering the drug, (2) the cost of delivering the drug to patients, and (3) other relevant administrative costs related to the drug.

(h) Any conflict of interest involving a member of the board shall be disclosed at the next board meeting after the conflict is identified and on the board's Internet web site.

(i) The board's recommendations shall not apply to Medicare Part D

prescription drug plans.

(j) On or before December 31, 2023, and annually thereafter, the board shall submit a report, in accordance with the provisions of section 11-4a of the general statutes, to the joint standing committees of the General Assembly having cognizance of matters relating to aging, human services, insurance and public health. The report shall include, but not be limited to: (1) Price trends for prescription drug products, (2) the number of such products subject to board review, (3) the results of the reviews, and (4) any recommendations the board may have on further legislation needed to make prescription drug products more affordable in the state.

Sec. 4. (NEW) (*Effective October 1, 2022*) (a) There is established a Prescription Drug Affordability Stakeholder Council to advise the board on decisions regarding the affordability of prescription drugs.

(b) Members of the council shall serve for three years and shall consist of:

(1) Three appointed by the speaker of the House of Representatives, who shall be (A) a representative of a state-wide health care advocacy coalition, (B) a representative of a state-wide advocacy organization for elderly persons, and (C) a representative of a state-wide organization for diverse communities;

(2) Three appointed by the president pro tempore of the Senate, who shall be (A) a representative of a labor union, (B) a health services researcher, and (C) a consumer who has experienced barriers to obtaining prescription drugs due to the cost of such drugs;

(3) Two appointed by the majority leader of the House of Representatives, who shall be (A) a representative of doctors, and (B) a representative of nurses;

(4) Two appointed by the minority leader of the House of Representatives, who shall be (A) a representative of private insurers,

and (B) a representative of brand name drug corporations;

(5) Two appointed by the minority leader of the Senate, who shall be (A) a representative of generic drug corporations, and (B) a representative of an academic institution with expertise in health care costs;

(6) Two appointed by the Governor, who shall be (A) a representative of pharmacists, and (B) a representative of pharmacy benefit managers;

(7) The Secretary of the Office of Policy and Management, or the secretary's designee;

(8) The Commissioner of Social Services, or the commissioner's designee;

(9) The Commissioner of Public Health, or the commissioner's designee;

(10) The Insurance Commissioner, or the commissioner's designee;

(11) The Commissioner of Consumer Protection, or the commissioner's designee;

(12) The executive director of the Office of Health Strategy, or the executive director's designee; and

(13) The Healthcare Advocate, or the Healthcare Advocate's designee.

(c) All initial appointments to the council shall be made not later than thirty days after the effective date of this section. Any vacancy shall be filled by the appointing authority.

(d) The speaker of the House of Representatives and the president pro tempore of the Senate shall select the chairpersons of the council from among the members of the council. Such chairpersons shall schedule the first meeting of the council, which shall be held not later than sixty days after the effective date of this section.

(e) The administrative staff of the joint standing committee of the General Assembly having cognizance of matters relating to insurance shall serve as administrative staff of the council.

(f) Not later than September 1, 2023, and annually thereafter, the council shall submit a report to the board, in accordance with the provisions of section 11-4a of the general statutes, on its recommendations concerning prescription drug prices. The council shall also provide recommendations to the board at any time the board requests such recommendations.

Sec. 5. Subdivision (12) of section 1-79 of the 2022 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2022*):

(12) "Quasi-public agency" means Connecticut Innovations, Incorporated, the Connecticut Health and Education Facilities Authority, the Connecticut Higher Education Supplemental Loan Authority, the Connecticut Student Loan Foundation, the Connecticut Housing Finance Authority, the State Housing Authority, the Materials Innovation and Recycling Authority, the Capital Region Development Authority, the Connecticut Lottery Corporation, the Connecticut Airport Authority, the Connecticut Health Insurance Exchange, the Connecticut Green Bank, the Connecticut Retirement Security Authority, the Connecticut Port Authority, the Connecticut Municipal Redevelopment Authority, the State Education Resource Center, **[**and**]** the Paid Family and Medical Leave Insurance Authority and the Prescription Drug Cost Control Board.

Sec. 6. Section 1-120 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2022*):

As used in sections 1-120 to 1-123, inclusive:

(1) "Quasi-public agency" means Connecticut Innovations, Incorporated, the Connecticut Health and Educational Facilities Authority, the Connecticut Higher Education Supplemental Loan

Authority, the Connecticut Student Loan Foundation, the Connecticut Housing Finance Authority, the Connecticut Housing Authority, the Materials Innovation and Recycling Authority, the Capital Region Development Authority, the Connecticut Lottery Corporation, the Connecticut Airport Authority, the Connecticut Health Insurance Exchange, the Connecticut Green Bank, the Connecticut Retirement Security Authority, the Connecticut Port Authority, the Connecticut Municipal Redevelopment Authority, the State Education Resource Center, **[**and**]** the Paid Family and Medical Leave Insurance Authority and the Prescription Drug Cost Control Board.

(2) "Procedure" means each statement, by a quasi-public agency, of general applicability, without regard to its designation, that implements, interprets or prescribes law or policy, or describes the organization or procedure of any such agency. The term includes the amendment or repeal of a prior regulation, but does not include, unless otherwise provided by any provision of the general statutes, (A) statements concerning only the internal management of any agency and not affecting procedures available to the public, and (B) intra-agency memoranda.

(3) "Proposed procedure" means a proposal by a quasi-public agency under the provisions of section 1-121 for a new procedure or for a change in, addition to or repeal of an existing procedure.

Sec. 7. Section 38a-8 of the general statutes is amended by adding subsection (h) as follows (*Effective October 1, 2022*):

(NEW) (h) The commissioner shall have all the powers that are reasonable and necessary to enforce the provisions of section 1 of this act concerning assessment of fees on prescription drug manufacturers. The commissioner may also set upper payment limits on prescription drugs in the state after receiving recommendations on such limits from the Prescription Drug Cost Control Board pursuant to section 3 of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2022*	New section
Sec. 2	*October 1, 2022*	New section
Sec. 3	*October 1, 2022*	New section
Sec. 4	*October 1, 2022*	New section
Sec. 5	*October 1, 2022*	1-79(12)
Sec. 6	*October 1, 2022*	1-120
Sec. 7	*October 1, 2022*	38a-8

Statement of Purpose:

To establish a board with authority to monitor prescription drug costs and recommend price caps on such drugs sold in the state.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]