General Assembly

Raised Bill No. 1202

January Session, 2023

LCO No. **5059**

Referred to Committee on HUMAN SERVICES

Introduced by:
(HS)

AN ACT CONCERNING PRESCRIPTION DRUG AFFORDABILITY.

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

Section 1. (NEW) (*Effective January 1, 2024, and applicable to contracts entered into, amended or renewed on and after January 1, 2024*) (a) For the purposes of this section and sections 2 and 3 of this act:

(1) "Distributor" means any person or entity, including any wholesaler, who supplies drugs, devices or cosmetics prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, clinics, practitioners or pharmacies or federal, state and municipal agencies;

(2) "Manufacturer" means the following:

(A) Any entity described in 42 USC 1396r-8(k)(5) that is subject to the pricing limitations set forth in 42 USC 256b; and

(B) Any wholesaler described in 42 USC 1396r-8(k)(11) engaged in the distribution of covered drugs for any entity described in 42 USC1396r-8(k)(5) that is subject to the pricing limitations set forth in 42 USC 256b;

(3) "ERISA plan" means an employee welfare benefit plan subject to the Employee Retirement Income Security Act of 1974, as amended from time to time;

(4) (A) "Health benefit plan" means any insurance policy or contract offered, delivered, issued for delivery, renewed, amended or continued in the state by a health carrier to provide, deliver, pay for or reimburse any of the costs of health care services;

(B) "Health benefit plan" does not include:

(i) Coverage of the type specified in subdivisions (5), (6), (7), (8), (9), (14), (15) and (16) of section 38a-469 of the general statutes or any combination thereof;

(ii) Coverage issued as a supplement to liability insurance;

(iii) Liability insurance, including general liability insurance and automobile liability insurance;

(iv) Workers' compensation insurance;

(v) Automobile medical payment insurance;

(vi) Credit insurance;

(vii) Coverage for on-site medical clinics; or

(viii) Other similar insurance coverage specified in regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended from time to time, under which benefits for health care services are secondary or incidental to other insurance benefits; and

(C) "Health benefit plan" does not include the following benefits if such benefits are provided under a separate insurance policy, certificate or contract or are otherwise not an integral part of the plan:

(i) Limited scope dental or vision benefits;

(ii) Benefits for long-term care, nursing home care, home health care, community-based care or any combination thereof;

(iii) Other similar, limited benefits specified in regulations issued pursuant to the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended from time to time;

(iv) Other supplemental coverage, similar to coverage of the type specified in subdivisions (9) and (14) of section 38a-469 of the general statutes, provided under a group health plan; or

(v) Coverage of the type specified in subdivision (3) or (13) of section 38a-469 of the general statutes or other fixed indemnity insurance if (I) such coverage is provided under a separate insurance policy, certificate or contract, (II) there is no coordination between the provision of the benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor, and (III) the benefits are paid with respect to an event without regard to whether benefits were also provided under any group health plan maintained by the same plan sponsor;

(5) "Maximum fair price" means the maximum rate for a prescription drug published by the Secretary of the United States Department of Health and Human Services under Section 1191 of the Inflation Reduction Act of 2022, P.L. 117-169, as amended from time to time. "Maximum fair price" does not include any dispensing fee paid to a pharmacy for dispensing any referenced drug;

(6) "Participating ERISA plan" means any employee welfare benefit plan subject to the Employee Retirement Income Security Act of 1974, as amended from time to time, that elects to participate in the requirements pursuant to section 2 or 3 of this act;

(7) "Price applicability period" has the same meaning as provided in Section 1191 of the Inflation Reduction Act of 2022, P.L. 117-169, as amended from time to time;

(8) "Purchaser" means any state entity, health benefit plan or participating ERISA plan;

(9) "Referenced drug" means any prescription drug subject to the maximum fair price; and

(10) "State entity" means any agency of this state, including, any agent, vendor, fiscal agent, contractor or other person acting on behalf of this state, that purchases a prescription drug on behalf of this state for a person who maintains a health insurance policy that is paid for by this state, including health insurance coverage offered through local, state or federal agencies or through organizations licensed in this state. "State entity" does not include the medical assistance program administered under Title XIX of the Social Security Act, 42 USC 1396 et seq., as amended from time to time.

Sec. 2. (NEW) (*Effective January 1, 2024, and applicable to contracts entered into, amended or renewed on and after January 1, 2024*) (a) No purchaser shall purchase a referenced drug or seek reimbursement for a referenced drug to be dispensed, delivered or administered to an insured in this state, by hand delivery, mail or by other means, directly or through a distributor, for a cost that exceeds the maximum fair price for such drug during the price applicability period published pursuant to Section 1191 of the Inflation Reduction Act of 2022, P.L. 117-169, as amended from time to time.

(b) Each purchaser shall calculate such purchaser's savings generated pursuant to subsection (a) of this section and shall apply such savings to reduce prescription drug costs for the purchaser's insureds. Not later than January fifteenth of each calendar year, a purchaser shall submit a report to the Insurance Department that (1) provides an assessment of such purchaser's savings for each referenced drug for the previous calendar year, and (2) identifies how each purchaser applied such savings to (A) reduce prescription drug costs for such purchaser's insureds, and (B) decrease cost disparities.

(c) An ERISA plan may elect to participate in the requirements of this

section by notifying the Insurance Department, in writing, not later than January first of each calendar year.

(d) Any violation by a purchaser of subsection (a) of this section shall be subject to a civil penalty of one thousand dollars for each such violation.

(e) The Insurance Commissioner shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section and section 3 of this act.

Sec. 3. (NEW) (*Effective January 1, 2024, and applicable to contracts entered into, amended or renewed on and after January 1, 2024*) (a) No manufacturer or distributor of a referenced drug shall withdraw such referenced drug from sale or distribution in this state to attempt to avoid any loss of revenue resulting from the maximum fair price requirement established in section 2 of this act.

(b) Each manufacturer or distributor shall provide not less than one hundred eighty days' written notice to the Insurance Commissioner and Attorney General prior to withdrawing a referenced drug from sale or distribution in this state.

(c) If any manufacturer or distributor violates the provisions of subsection (a) or (b) of this section, such manufacturer or distributor shall be subject to a civil penalty of (1) five hundred thousand dollars, or (2) such purchaser's amount of annual savings generated pursuant to subsection (a) of section 2 of this act, as determined by the Insurance Commissioner, whichever is greater.

(d) It shall be a violation of this section for any manufacturer or distributor of a referenced drug to negotiate with a purchaser or seller of a referenced drug at a price that exceeds the maximum fair price.

(e) The Attorney General shall have exclusive authority to enforce violations of this section and section 2 of this act.

Sec. 4. (NEW) (*Effective July 1, 2023*) (a) As used in this section, (1)

"federal 340B Drug Pricing Program" means the plan described in Section 340B of the Public Health Service Act, 42 USC 256b, as amended from time to time, (2) "340B covered entity" means a provider participating in the federal 340B Drug Pricing Program, and (3) "prescription drug" has the same meaning as provided in section 19a-754b of the general statutes. There is established a Prescription Drug Payment Evaluation Committee to recommend to the executive director of the Office of Health Strategy upper payment limits on not fewer than eight prescription drugs based on evaluation of upper payment limits on such drugs set by other states or foreign jurisdictions.

(b) Members of the committee shall be as follows:

(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) an academic who has conducted research on prescription drug costs, 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 Senate, who shall be representatives of associations or organizations representing health care providers;

(4) Two appointed by the majority leader of the House of Representatives, who shall be representatives of 340B covered entities participating in the federal 340B Drug Pricing Program;

(5) 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 a pharmaceutical company doing business in the state;

(6) Two appointed by the minority leader of the Senate, who shall be (A) a representative of a pharmaceutical company doing business in the state, and (B) a representative of an academic institution with expertise in health care costs;

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

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

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

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

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

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

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

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

(c) All initial appointments to the committee 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 committee from among the members of the committee. Such chairpersons shall schedule the first meeting of the committee, 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 committee.

(f) Not later than December 1, 2023, and annually thereafter, the committee shall submit a report, in accordance with the provisions of section 11-4a of the general statutes, to the executive director of the Office of Health Strategy and the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies, human services, insurance and public health with its recommendations concerning upper payment limits for not fewer than eight prescription drugs.

Sec. 5. Subsection (d) of section 19a-754b of the general statutes is repealed and the following is substituted in lieu thereof (*Effective July 1, 2023*):

(d) (1) On or before March 1, 2020, and annually thereafter, the executive director of the Office of Health Strategy, in consultation with the Comptroller, Commissioner of Social Services and Commissioner of Public Health, shall prepare and make public a list of not more than ten outpatient prescription drugs that the executive director, in the executive director's discretion, determines are (A) provided at substantial cost to the state, considering the net cost of such drugs, or (B) critical to public health. The list shall include outpatient prescription drugs from different therapeutic classes of outpatient prescription drugs and at least one generic outpatient prescription drug.

(2) **[**The executive director shall not list any outpatient prescription drug under subdivision (1) of this subsection unless the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, (A) increased by at least (i) twenty per cent during the immediately preceding calendar year, or (ii) fifty per cent during the immediately preceding three calendar years, and (B) was not less than sixty dollars for (i) a thirty-day supply of such drug, or (ii) a course of treatment of such drug lasting less than thirty days.**]** Prior to publishing the annual list of outpatient

prescription drugs pursuant to subdivision (1) of this subsection, the executive director shall prepare a preliminary list of those outpatient prescription drugs that the executive director plans to include on the list. The executive director shall make the preliminary list available for public comment for not less than thirty days, during which time any manufacturer of an outpatient prescription drug named on the preliminary list may produce documentation to establish that the wholesale acquisition cost of the drug, less all rebates paid to the state for such drug during the immediately preceding calendar year, does not exceed the limits established in subdivision (3) of this subsection. If such documentation establishes, to the satisfaction of the executive director, that the wholesale acquisition cost, less all rebates paid to the state for such drug during the immediately preceding calendar year, does not exceed the limits established in subdivision (3) of this subsection, the executive director shall remove such drug from the list before publishing the final list. The executive director shall publish a final list pursuant to subdivision (1) of this subsection not later than fifteen days after the closing of the public comment period.

(3) The executive director shall not list any outpatient prescription drug under subdivision (1) or (2) of this subsection unless the wholesale acquisition cost of the drug (A) increased by at least sixteen per cent cumulatively during the immediately preceding two calendar years, and (B) was not less than forty dollars for a course of therapy.

[(3)**]** (4) (A) The pharmaceutical manufacturer of an outpatient prescription drug included on a list prepared by the executive director pursuant to subdivision (1) of this subsection shall provide to the office, in a form and manner specified by the executive director, (i) a written, narrative description, suitable for public release, of all factors that caused the increase in the wholesale acquisition cost of the listed outpatient prescription drug, and (ii) aggregate, company-level research and development costs and such other capital expenditures that the executive director, in the executive director's discretion, deems relevant for the most recent year for which final audited data are available.

(B) The quality and types of information and data that a pharmaceutical manufacturer submits to the office under this subdivision shall be consistent with the quality and types of information and data that the pharmaceutical manufacturer includes in (i) such pharmaceutical manufacturer's annual consolidated report on Securities and Exchange Commission Form 10-K, or (ii) any other public disclosure.

[(4)**]** (5) The office shall establish a standardized form for reporting information and data pursuant to this subsection after consulting with pharmaceutical manufacturers. The form shall be designed to minimize the administrative burden and cost of reporting on the office and pharmaceutical manufacturers.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*January 1, 2024, and applicable to contracts entered into, amended or renewed on and after January 1, 2024*	New section
Sec. 2	*January 1, 2024, and applicable to contracts entered into, amended or renewed on and after January 1, 2024*	New section
Sec. 3	*January 1, 2024, and applicable to contracts entered into, amended or renewed on and after January 1, 2024*	New section
Sec. 4	*July 1, 2023*	New section
Sec. 5	*July 1, 2023*	19a-754b(d)

Statement of Purpose:

To (1) require that certain prescription drugs purchased in the state not exceed upper payment limits set by Medicare pursuant to the federal Inflation Reduction Act, (2) establish a Prescription Drug Payment Evaluation Committee to recommend upper payment limits on not less

than eight drugs based on such limits in other states or countries, and (3) require the Office of Health Strategy to monitor and make public the costliest prescription drugs.

[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.]