STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
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The Honorable John Carney
Governor

John McNeal
SCPD Director

MEMORANDUM

DATE: March 10, 2021

TO: All Members of the Delaware State Senate
and House of Representatives

FROM: Terri Hancharick – Chairperson TH
State Council for Persons with Disabilities

RE: H.B. 62 (Prescription Drug Pricing)

The State Council for Persons with Disabilities (SCPD) has reviewed H.B. 62, which amends Title 6 chapter 25. Chapter 25 contains all the prohibited trade practices. This bill adds subchapter XI, Prevention of Excessive and Unconscionable Prices for Prescription Drugs.[1] SCPD endorses the proposed legislation and has the following observations.

This bill[2] is a comprehensive effort to control the prices of generic and off-patent drugs[3] sold, dispensed, or delivered to any individual in the state and provides stiff penalties for a violation. The bill is very technical in nature and very specific in

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[1] Chapter XI was previously titled Cumulative Remedies and Enhanced Penalties. Section 2598 was previously titled violation of order or injunction; penalty. Section 2598 was repealed 77 Del. Laws, c. 282, § 4, effective June 10, 2010.

[2] This bill is adopted from the Model Act to Prevent Excessive and Unconscionable Prices for Prescription Drugs developed by the National Academy for State Health Policy (NASHP). According to their website, the NASHP is a "nonpartisan forum of policymakers throughout state government, learning, leading and implementing innovative solutions to health policy challenges."

[3] A generic or off-patent drug is any prescription drug to which any exclusive marketing rights held by the manufacturer under the federal Food, Drug, and Cosmetic Act, the federal Public Health Service Act, and patent law have expired. A generic or off-patent drug includes any "drug-device combination product for the delivery of a generic drug." 6 *Del. C.* §2598(1)d.

the prices of drugs it seeks to regulate. If the bill is enacted, it will take effect on January 1, 2022.

The bill requires Pharmacy Benefits Managers[4] and State agencies to monitor the prices of generic and off-patented drugs and notify the manufacturers and the Attorney General of any excessive price increases. The bill gives power to the Attorney General to gather information and records from the manufacturer to determine whether a violation of the statute has occurred. 6 Del. C. §2599(3). The bill allows the Attorney General to utilize the courts to enforce the provisions of the statute when a violation occurs. 6 Del. C. §2599(4).

The bill defines excessive price increase as an increase, after adjustment for inflation by the consumer price index, that exceeds fifteen percent (15%) of the wholesale acquisition cost[5] during the last calendar year or forty percent (40%) of the wholesale acquisition cost during the last three (3) calendar years. 6 *Del. C.* §2598(2)b.1. An excessive price increase also occurs when the increase, after adjustment for inflation by the consumer price index, exceeds $30.00 for a thirty (30) day supply of the generic or off-patent drug or for a supply for a course of treatment lasting less than thirty (30) days. 6 *Del. C.* §2598(2)b.2. However, a wholesale distributor or pharmacy can increase the price of a generic or off-patent drug if the increase if "directly attributable to additional costs for the drug imposed on the wholesale distributor or pharmacy by the manufacturer of the drug." 6 *Del. C.* §2598(2)c.

If a manufacturer of generic and off-patent drugs is found by the Attorney General to have imposed an excessive price increase, in violation of the above-mentioned definitions, the Attorney General can utilize the courts for a number of remedies. A court can enjoin or stop the violation and order the prices to be lowered to levels that comply with the statute. 6 *Del. C.* § 2599(3)b. The court can require the manufacture to provide the Attorney General with an accounting that shows the revenues received by the manufacturer as a result of the excess price increase. 6 *Del. C.* §2599(3)c. The court can order restitution of the excess price increase revenues to consumers and third party payers (6 *Del. C.* §2599(3)d.) or to the State

[4] A pharmacy benefits manager (PBM) is someone who contracts with pharmacists or pharmacies on behalf of an insurer or third-party administrator to: process claims for prescription drugs or medical supplies; pay pharmacies or pharmacists for prescription drugs or medical supplies; or negotiate rebates with manufacturers for drugs. 18 *Del. C.* §3302A.

[5] Whole sale acquisition cost is the estimate of the manufacturer's list price for a drug to a wholesaler or direct purchaser without taking into consideration discounts or rebates. 6 *Del. C.* §2598(1)b.

if the manufacturer cannot identify the individual transactions entitled to a refund. 6 *Del. C.* §2599(3)e. The court can impose a fine of up to $10,000 per day for each violation (6 *Del. C.* §2599(3)f.), and every transaction that results in an excess price is considered a separate violation. 6 *Del. C.* §2599(5). The court can also award attorney's fees and costs to the Attorney General in prosecuting the action. 6 *Del. C.* §2599(3)g.

A manufacturer or distributor of a generic or off-patent drug cannot withdraw the drug from sale or distribution in Delaware to avoid the provisions in the statute. 6 *Del. C.* §2599(6). Any manufacturer who intends to withdraw a generic or off-patent drug from the sale or distribution in Delaware must give at least 180 day notice to the Board of Pharmacy and the Attorney General of its intent to do so. 6 *Del. C.* §2599(7). If the Attorney General determines that the manufacturer withdrew a generic or off-patent drug from distribution or sale, the Attorney General shall impose a penalty of $500,000 on the manufacturer or distributor. 6 *Del. C.* §2599(8).

This bill reflects the sponsor's concern about the cost of drugs in general and specifically the cost of generic drugs and drugs where the patent protection has expired. Delaware is among the states that are taking action to control the rising cost of prescription drugs. According to the NASHP, as of the end of October of 2018, state legislators introduced 174 bills addressing the cost of prescription drugs and 45 were enacted into law.

Based on the model act, this is a laudable effort by the legislature to help control the cost of drugs in Delaware and will directly benefit individuals with health conditions, especially low income individuals and those with plans that require the use of generics.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our position and observations on the proposed legislation.

cc: Ms. Laura Waterland, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disabilities Council

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