OLR Bill Analysis
sSB 13

AN ACT REDUCING PRESCRIPTION DRUG PRICES.

SUMMARY

The bill prohibits pharmaceutical manufacturers from selling a prescription drug for a price higher than the drug's reference price (i.e., the drug's wholesale acquisition cost) adjusted for changes in the consumer price index for urban consumers, plus 2% of the reference price per year compounded annually on the anniversary of the date the drug was first commercially marketed. The price limits apply to drugs with a wholesale acquisition cost of $100 or more.

Under the bill, pharmaceutical manufacturers who violate the price limit are liable to the state for a civil penalty of 80% of the increased revenue the pharmaceutical manufacturer earned by selling the drug higher than allowed. It also establishes procedures and due process for reporting, collecting, and contesting the penalty.

The bill also subjects pharmaceutical manufacturers to a $500,000 civil penalty if they withdraw a drug from the Connecticut market (1) without giving advance written notice or (2) to avoid paying the civil penalty for selling a drug above the price limit.

It exempts (1) from the price limitations, drugs the U.S. Health and Human Services (HHS) secretary determines are in shortage in the United States and (2) from the civil penalty, pharmaceutical manufacturers making less than $250,000 in annual sales in Connecticut in the calendar year the penalty would be imposed.

Lastly, bill establishes a program to import certain legend drugs from Canada and distribute them to Connecticut pharmacies. The program is dependent upon federal approval and requires drug importers and wholesalers to adhere to safety, testing, and tracking standards.

EFFECTIVE DATE: July 1, 2022

§§ 1-4 — PHARMACEUTICAL MANUFACTURER PRICING LIMITS

Price Limit (§§ 2 & 3)

Beginning January 1, 2023, the bill prohibits pharmaceutical manufacturers from selling a prescription drug with a wholesale acquisition cost of $100 or more for more than:

1. the drug's reference price, adjusted for any change in the consumer price index for urban consumers, plus

2. 2% for each 12-month period since the date the reference price was determined, compounded annually on the anniversary of that date.

Under the bill, a "pharmaceutical manufacturer" is anyone manufacturing and selling a prescription drug, either directly or through another person, for distribution in Connecticut. A drug's "reference price" is the drug's wholesale acquisition cost as of January 1, 2022, or for new drugs, the date when it is first commercially marketed in the United States. A drug's "wholesale acquisition cost" is generally the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States, excluding discounts, rebates, or reductions, for the most recent month for which data is available.

Drugs that the HHS secretary determines are in shortage are exempt from the pricing limitations.

Civil Penalty (§§ 1 & 3)

Under the bill, a pharmaceutical manufacturer selling a prescription drug above the price limit is subject to a civil penalty, determined and collected on a calendar year basis. The penalty equals 80% of the increased revenue the pharmaceutical company made by selling the drug at the higher price compared to a price allowed under the bill.

Under the bill, all money collected from the civil penalty must be deposited into the Covered Connecticut account, which the bill establishes as a separate, nonlapsing General Fund account that must

contain any money required by law to be deposited into it. Money in the account must be used by (1) the Office of Health Strategy (OHS) to administer the Covered Connecticut program and (2) Department of Social Services to administer the state medical assistance program (e.g., Medicaid). (By law, the Covered Connecticut program provides eligible individuals health insurance at no out-of-pocket cost to them (CGS § 19a-754c).)

The penalties are deemed a civil fine or penalty under federal law (therefore excluding them from state tax revenue for certain federal benefit calculations) and cannot be waived by the Revenue Services Penalty Review Committee or under any other applicable law. Additionally, the bill prohibits tax credits from being applied towards the penalty.

Penalty Payment Provisions. Beginning March 1, 2024, the bill requires pharmaceutical manufacturers that violated the pricing provisions during the previous calendar year to annually pay the Department of Revenue Services (DRS) commissioner the civil penalty the bill imposes.

They must also file with the DRS commissioner a statement containing information in a form and manner he prescribes. The statement and civil penalty must be electronically filed and paid, regardless of how the manufacturer would have otherwise filed with, or paid money to, DRS. If no statement is filed by the due date, the bill authorizes the commissioner to make the statement at any time after the due date according to the best obtainable information and prescribed form.

Tax Warrants and Liens. The bill allows the civil penalty to be collected according to existing law that authorizes DRS and other state collection agencies to (1) issue a tax warrant on the real property or tangible or intangible personal property (e.g., bank accounts, receivables, and securities) of a taxpayer who fails to pay state taxes and (2) serve the warrant on a third party (e.g., bank or payment settlement entity) who possesses the property or is obligated to it in some way

(CGS § 12-35). Under the bill, the warrant must be signed by the DRS commissioner or his authorized agent.

Additionally, the amount of the civil penalty becomes a lien on the pharmaceutical manufacturer's real property, beginning on the last day of the month before the penalty was due, until it is paid. The commissioner may record the lien in the records of the town in which the manufacturer is located, but the bill prohibits the lien from being enforced against a bona fide purchaser or qualified encumbrancer of the property. If the lien is satisfied, the commissioner must discharge it upon request from an interested party.

The bill allows the (1) attorney general to bring a foreclosure action against the lien in the Superior Court in the judicial district where the property is located and (2) court to make any order it deems equitable.

It also applies existing laws on collecting taxes and related penalties from taxpayers to the civil penalties imposed under the bill.

Examination Authority and Record Keeping. If a pharmaceutical manufacturer is subject to the civil penalty, the bill authorizes the DRS commissioner to examine its books and determine if it paid the full penalty amount. If the commissioner determines that it did not, he must bill the pharmaceutical manufacturer for the full amount. The commissioner, or any person he authorizes, may also examine the books, papers, records, and equipment of anyone subject to the bill's provisions, and investigate the character of their business to verify the accuracy of the filed statement (or if no statement is filed, to ascertain and determine the civil penalty amount).

The bill authorizes the commissioner to require all pharmaceutical manufacturers subject to a civil penalty to keep any records he prescribes and produce books, papers, documents, and other data he needs to determine the penalty amount and collect it.

The bill grants the commissioner and his agents the power to administer oaths and take testimony under oath in matters related to an inquiry or investigation.

Requests for a Hearing and Reduction. Under the bill, an aggrieved pharmaceutical manufacturer may apply in writing to the DRS commissioner for a hearing, laying out why a hearing should be granted and how much the civil penalty should be reduced. The pharmaceutical manufacturer must apply within 60 days after receiving the penalty notice or after it is delivered or mailed to the manufacturer. The commissioner may also order a hearing on his own initiative.

The commissioner must promptly consider and either grant or deny each application. If he denies it, he must immediately notify the applicant; if he approves it, he must provide the hearing date, time, and place. Following the hearing, he must provide the applicant a copy of any order he makes.

Additionally, the bill allows the commissioner to require a pharmaceutical manufacturer or any other person he believes has relevant information to appear, along with any specified documents for examination under oath.

In any hearing, the bill allows the commissioner or his authorized agents to subpoena witnesses and require the production of books, papers, and documents related to the investigation. A witness may not be excused from testifying or from producing documents if doing so would incriminate him or her. However, the bill prevents such evidence from being used in a criminal proceeding against the witness.

The bill allows the commissioner to apply to the Superior Court that has jurisdiction over the pharmaceutical manufacturer being investigated, or another court of competent jurisdiction, to compel any person to obey a subpoena. The bill requires the court to commit an individual still disobeying a subpoena or summons to a community correctional center until they do so, for up to 60 days.

The bill requires that officers serving subpoenas and witnesses attending hearings receive fees and compensation at the same rate as they would for appearing in court.

Appeals. Any pharmaceutical manufacturer aggrieved by the

commissioner's orders, decisions, determinations, or disallowances may appeal, within 30 days after receiving notice of the commissioner's action, to the Superior Court for the New Britain judicial district. The appeal must be accompanied by a citation to the commissioner to appear. It must be signed, served, and returned in the same way existing law requires for a civil summons in a civil action.

The authority issuing the citation must take from the person appealing the case, a bond or recognizance, with surety, to prosecute the appeal to effect and to comply with the court orders and decrees. These appeals must be preferred cases, to be heard at the first session of the court or an appointed committee, unless cause appears to the contrary.

Under the bill, the court may grant equitable relief, and if the civil penalty has already been paid, may order the treasurer to refund it. If the appeal has been taken without probable cause, the court may tax double or triple costs, as the case demands. After an appeal is denied, the court may, at its discretion, tax the manufacturer the costs of the appeal, but no costs must be taxed against the state.

Officer or Employee Penalties (§ 3)

Under the bill, a pharmaceutical manufacturer officer or employee who owes a duty to pay a civil penalty, file statements, or keep or produce records under the bill's provisions and willfully fails to do so is subject to a fine up to $1,000, up to a year in prison, or both. Regardless of other state law, the bill establishes a three-year statute of limitations for officers or employees to be prosecuted after each violation.

Additionally, any officer or employee who willfully delivers or discloses any fraudulent or false list, statement, return, account statement, or other document to the commissioner is guilty of a class D felony, punishable by a fine up to $5,000, up to 5 years in prison, or both.

The bill prohibits an officer or employee from being charged with an offense under both the provisions described above in connection with the same civil penalty. However, it allows the officer or employee to be charged for both offenses upon the same information.

List of Offenders (§ 3)

Beginning by July 1, 2024, the bill requires the DRS commissioner to annually prepare, and make publicly available, a list of each pharmaceutical manufacturer that violated the bill's provisions during the preceding year.

Implementing Regulations (§ 3)

The bill authorizes the DRS commissioner to adopt implementing regulations.

Pharmaceutical Manufacturer's Withdrawing Prescription Drugs (§ 4)

Additionally, the bill prohibits a pharmaceutical manufacturer from withdrawing a prescription drug in Connecticut after it has been identified as being sold above the bill's price limits to avoid the civil penalty. Pharmaceutical manufacturers must notify OHS in writing at least 180 days before withdrawing one of these drugs from the Connecticut market. Under the bill, a pharmaceutical manufacturer that violates either of these provisions is subject to a $500,000 civil penalty.

§§ 5-10 — CANADIAN LEGEND DRUG IMPORTATION PROGRAM

The bill requires the Department of Consumer Protection (DCP) commissioner to establish the "Canadian legend drug importation program" to:

1. import from Canada safe and effective legend drugs with the highest potential cost savings to Connecticut patients,

2. develop and implement an application and approval process for participating wholesalers, and

3. designate one or more participating wholesalers to distribute imported legend drugs in Connecticut.

Participating wholesalers must distribute legend drugs in the manufacturer's original container; from a participating Canadian supplier; and to a pharmacy, institutional pharmacy, or qualified laboratory.

Under the bill, a "legend drug" is a drug that (1) any federal or state law requires a prescription for or allows to be used by a prescribing practitioner or (2) federal law requires to bear "RX ONLY" IN ACCORDANCE WITH GUIDELINES ESTABLISHED IN THE FEDERAL FOOD, DRUG AND COSMETIC ACT (i.e., the legend).

Application for Federal Approval (§ 6)

By July 1, 2023, the DCP commissioner must submit a request to the HHS secretary for approval of the importation program. (Under federal law, drug importation programs require federal approval.)

The request must, at least:

1. describe the commissioners' plans for operating the program;

2. demonstrate that the prescription drugs imported and distributed through the program will (a) meet all applicable federal and state safety and effectiveness standards and (b) comply with all federal tracing procedures (e.g., a documented supply chain); and

3. disclose the program's cost.

If the HHS secretary approves the request, the DCP commissioner must:

1. notify the public health commissioner and the Appropriations, General Law, Human Services, and Public Health committees of the approval and

2. begin operating the program within 180 days after the approval date.

The bill prohibits the DCP commissioner from operating the importation program without federal approval.

Importation (§ 7)

Under the bill, a participating wholesaler (i.e., a registered wholesaler designated by DCP to distribute legend drugs imported from Canada

through the program) may import and distribute legend drugs from a participating Canadian supplier and distribute them to a licensed pharmacy, institutional pharmacy, or qualified laboratory (i.e., a laboratory accredited by the International Organization for Standardization and staffed and equipped to properly test legend drugs) in accordance with the bill's provisions.

The imported legend drugs:

1. may be imported in accordance with applicable federal patent laws;

2. must meet U.S. Food and Drug Administration (FDA) standards for safety, effectiveness, misbranding, and adulteration; and

3. cannot be (a) controlled substances, (b) biologics, (c) infused, (d) intravenously, intradermally, intrathecally, intramuscularly, or subcutaneously injected, (e) inhaled during surgery, (f) parenteral drugs that HHS determines pose a public health threat, or (g) compounded drugs that are not commercially available.

Track-and-Trace (§ 7)

Importing wholesalers must be registered with HHS and hold a valid FDA labeler code. Additionally, the bill (1) requires them to comply with all applicable track-and-trace requirements (e.g., document the manufacture, supply, and distribution chain) and (2) prohibits them from distributing, dispensing, or selling any imported drugs outside of Connecticut or in any way other than the bill specifies.

Under the bill, wholesalers must make track-and-trace records available to the DCP commissioner within 48 hours of her request.

Safety Testing and Wholesaler Record Keeping (§ 7)

Under the bill, participating wholesalers must ensure the safety and quality of all imported drugs. This includes:

1. for each initial shipment of imported drugs, having a qualified

laboratory test a statistically valid sample size for each batch of each drug in the shipment for authenticity and degradation consistent with federal requirements and

2. for subsequent shipments, having a qualified laboratory test a statistically valid sample of each shipment for authenticity and degradation.

The bill additionally requires importers to quarantine subsequent shipments until the laboratory test confirms the drug is consistent with its labeling.

Wholesalers must also:

1. certify to the DCP commissioner that each imported drug is approved for marketing in the United States, is not adulterated or misbranded, and meets all federal labeling requirements;

2. maintain laboratory records, including complete data from all authenticity and degradation tests necessary to ensure the drug is safe;

3. maintain documentation that the testing required by the bill was performed at a laboratory in compliance with all federal and state laws and regulations; and

4. ensure that any drugs failing laboratory testing are appropriately quarantined and destroyed.

The bill requires each wholesaler to also maintain for each imported drug:

1. the name and quantity of the drug's active ingredient;

2. a description of the drug's dosage form;

3. the quantity of and date on which the wholesaler received the drug, and the price it paid;

4. the drug's origin point and destination;

5. a report for any drug that failed laboratory testing; and

6. any other information and documentation the DCP commissioner requires to protect public health.

A wholesaler must submit this information to the DCP commissioner upon her request. It must maintain any information submitted to the commissioner for at least three years.

Supplier Record Keeping (§ 8)

Under the bill, Canadian legend drug suppliers must meet all applicable track-and-trace requirements and may not distribute, dispense, or sell outside of Connecticut any legend drugs that are imported under the program. Additionally, the bill requires each participating Canadian supplier to maintain the following information for each exported drug and submit it to the DCP commissioner upon her request:

1. the drug's original source, including the manufacturer's name and the drug's manufactured date and location, shipment date, and quantity shipped;

2. the quantity of each lot of drug the supplier originally received and its source;

3. the manufacturer-assigned lot or control number and batch number; and

4. any other information and documentation the DCP commissioner requires to protect public health.

Commissioner Enforcement (§ 9)

The bill requires the DCP commissioner to issue a written order suspending a drug's import and distribution, or suspending all importation and distribution of drugs by a wholesaler or Canadian supplier, if she discovers the importation or distribution or the wholesaler or supplier violates the bill's provisions or any other applicable state or federal law or regulation.

The commissioner must also issue a written order requiring (1) the quarantine, recall, or seizure of any imported drug that has been misbranded or identified as adulterated or (2) retesting of a drug, if she deems it necessary, at the wholesaler's expense and by a laboratory the commissioner approves.

If the commissioner issues such an order against a wholesaler or supplier, she must notify the wholesaler or supplier that (1) the order has been issued, along with its legal and factual basis, and (2) they may make a written request for a hearing within 30 days after the notice's date.

If the commissioner receives a request for a hearing, she must convene it as a contested case hearing under the Uniform Administrative Procedure Act (UAPA) within 30 days after receiving the request. She must issue a final decision vacating, modifying, or affirming the order within 60 days after receiving the hearing request. Any supplier or wholesaler aggrieved by a final decision may appeal it to Superior Court in accordance with the UAPA.

Regulations (§ 10)

The bill authorizes the DCP commissioner, in consultation with the public health commissioner, to adopt implementing regulations.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Substitute
Yea 17 Nay 0 (03/10/2022)