OLR Bill Analysis

sSB 8

AN ACT CONCERNING DRUG AFFORDABILITY.

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SUMMARY

This bill takes various steps to address prescription drug affordability and access for Connecticut consumers, including:

1. requiring the Office of Health Strategy (OHS) to establish the Canadian Prescription Drug Importation Program to import from Canada safe and effective drugs with potential cost savings for Connecticut's Medicaid and Children's Health Insurance Program (CHIP) programs;

2. establishing the Prescription Drug Affordability Board (PDAB) and Prescription Drug Affordability Stakeholder Council to review and make recommendations on prescription drugs' costs and affordability;

3. allowing PDAB to review and set upper payment limits for drugs with high inflation or affordability challenges;

4. prohibiting state entities and health insurance plans from purchasing, and pharmacies from distributing to certain consumers, drugs purchased at a price higher than its upper payment limit;

5. requiring state entities and health insurance plans to use cost

savings attributable to an upper payment limit to reduce consumers' health care costs;

6. prohibiting manufacturers from withdrawing from distribution in Connecticut a drug with an established upper payment limit without first notifying the state and contracted purchasers;

7. requiring state entities and health insurance plans to cover, in a preferred tier and without copayment or out-of-pocket costs, insulin products at the lowest wholesale acquisition cost;

8. requiring Connecticut hospitals and drug purchasing agencies to have drug shortage prevention strategies that cover at least one-third of the expected use of at least 40 drugs; and

9. prohibiting drug manufacturers, wholesalers, and distributors from limiting, or requiring claims and utilization data as a condition of, a pharmacy or health care organization's access to drugs under the federal 340B drug program.

EFFECTIVE DATE: Various; see below.

§§ 1-9 — CANADIAN PRESCRIPTION DRUG IMPORTATION PROGRAM

Requires OHS to consult with DCP, DPH, and DSS to establish a program to import from Canada prescription drugs with potential cost savings for Medicaid; specifies program participation requirements for suppliers and wholesalers; requires OHS to report annually on the program

The bill requires the OHS executive director, in consultation with the Department of Consumer Protection (DCP), Department of Public Health (DPH), and Department of Social Services (DSS) commissioners, to establish the "Canadian Prescription Drug Importation Program" to import from Canada safe and effective prescription drugs with the highest potential cost savings to the state's medical assistance program (i.e., Medicaid and CHIP).

EFFECTIVE DATE: July 1, 2024

Application for Federal Approval (§ 2)

By January 1, 2025, the OHS executive director must submit a request

to the federal Food and Drug Administration (FDA) for approval of the importation program. (Under federal law, drug importation programs require federal approval.)

The request must, at least:

1. describe the state's plans for operating the program,

2. demonstrate that the prescription drugs imported under the program will (a) meet all applicable federal and state safety and effectiveness standards and (b) comply with all federal tracing procedures, and

3. disclose the program's cost.

If the FDA approves the request, the OHS executive director and DCP and DSS commissioners must:

1. notify the DPH commissioner and the Appropriations, General Law, Human Services, and Public Health committees that the request was approved and

2. with the DPH commissioner, begin operating the program within 180 days after the approval date.

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

Importation (§§ 3 & 4)

Under the bill, a participating wholesaler (i.e., a wholesaler designated by DCP to distribute prescription drugs imported from Canada through the program) may import and distribute drugs if they:

1. meet FDA safety, effectiveness, misbranding, and adulteration standards and

2. are not (a) controlled substances, (b) biologics, (c) infused, (d) intravenously injected, (e) inhaled during surgery, or (f) parenteral drugs that the federal Health and Human Services

secretary determines pose a public health threat.

Wholesalers are also prohibited from importing prescription drugs if doing so violates federal patent laws.

Wholesalers may import and distribute prescription drugs to a pharmacy or institutional pharmacy for the medical assistance program or to a DPH-registered laboratory for analytical testing.

Track-and-Trace (§ 5)

Under the bill, the OHS executive director must require Canadian suppliers and participating wholesalers to comply with all applicable track-and-trace requirements (e.g., document the manufacturer, supply, and distribution chain) and prohibits them from distributing, dispensing, or selling any imported drugs outside of Connecticut.

Under the bill, the suppliers and wholesalers must make track-and-trace records available to the executive director within 48 hours after her request.

Safety (§ 6)

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 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, test a statistically valid sample for authenticity and degradation.

Wholesalers must also:

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

2. maintain laboratory records, including data from all tests

necessary to ensure the drug complies with the bill's requirements; and

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

The bill requires wholesalers to maintain the records required under the bill for at least three years from the date they are submitted, as noted below.

Wholesaler Records (§ 6)

The bill requires each wholesaler to 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 OHS executive director requires for the protection of public health.

This information must be submitted to OHS upon the executive director's request.

Supplier Records (§ 6)

The bill requires each participating Canadian supplier to maintain the following information for each exported drug:

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

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

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

4. any other information and documentation the OHS executive director, in consultation with the DCP, DPH, and DSS commissioners, requires for the protection of public health.

This information must be submitted to the OHS executive director and the DCP commissioner upon request.

Enforcement (§ 7)

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

She must also issue a written order requiring the recall or seizure of any imported drug that has been misbranded or identified as adulterated.

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

If the executive director receives a timely request for a hearing, she must convene it as a contested case under the Uniform Administrative Procedure Act (UAPA) within 30 days of receiving the request, and must issue a final decision vacating, modifying, or affirming the order within 60 days after the request. Any supplier or wholesaler aggrieved by a final decision may appeal to Superior Court according to existing UAPA provisions.

Regulations (§ 8)

The bill authorizes the OHS executive director, in consultation with the DCP, DPH, and DSS commissioners, to adopt regulations to

implement the drug importation program.

Reporting (§ 9)

Starting no later than 180 days after the program begins, the bill requires the OHS executive director to annually submit a report to the Appropriations, General Law, Human Services, and Public Health committees describing the importation program's operations and recommendations for expanding the program to other state-funded and privately funded health care programs.

§ 10 — PRESCRIPTION DRUG AFFORDABILITY BOARD

Creates the Prescription Drug Affordability Board to advise OHS on prescription drug affordability; requires the board, beginning by December 31, 2025, to report annually to certain legislative committees on drug affordability

The bill establishes PDAB within OHS for administrative purposes to advise the OHS executive director on decisions regarding prescription drug affordability. Specifically, the board must:

1. explore strategies to reduce out-of-pocket drug costs for consumers while supporting biotechnology innovations and scientific discovery,

2. identify opportunities for consumer savings by studying the prescription drug supply chain and pharmaceutical pricing strategies,

3. monitor prescription drug prices in Connecticut,

4. promote innovative strategies for the use of more affordable drugs,

5. consider recommendations from the stakeholder council established by this bill (see § 11), and

6. recommend drug cost affordability tool options to the OHS executive director.

To carry out its duties, the bill authorizes PDAB to do the following:

1. collect and review (a) publicly available information and (b)

information available via private subscriptions about various health care organizations' prescription drug pricing and business practices, including the pharmacy benefit managers' annual report required by state law;

2. identify innovative strategies, including importing prescription drugs from Canada or other foreign jurisdictions, to lower prescription drug costs for consumers;

3. identify states with innovative programs to lower prescription drug costs, and, if approved by the board, enter into memoranda of understanding (MOU) with these states to collect data and information to establish similar programs in Connecticut; and

4. receive any aid or contributions from any source, as long as it is not a conflict of interest, to use to carry out its purposes.

EFFECTIVE DATE: July 1, 2024

Membership

Under the bill, PDAB is comprised of five gubernatorial appointees who must have an (1) advance degree and (2) experience or expertise in health care economics, health services research, pharmacoeconomics, pharmacology, or clinical medicine. At least one member must have experience in consumer advocacy and health equity.

The governor, with approval from either legislative chamber, must make initial board appointments by January 1, 2025. The governor must also select the board's chairperson from among its members. Generally, board members will serve three-year terms, except initial appointees' terms will expire as follows:

1. two members will serve three-year terms,

2. two members will serve two-year terms, and

3. one member will serve a one-year term.

The bill allows the governor to assign these term limits among initial

board members. Under the bill, the governor may also, without review, remove any board member for malfeasance, failure to regularly attend meetings, or any reason that makes the member incapable of fulfilling PDAB duties. The governor must fill any vacancies, and appointments occurring other than by term expiration are for the unexpired term balance.

The bill allows members to be privately employed, subject to any applicable state ethics rules, but if a member discovers a conflict of interest (i.e., a financial or personal association that may cause bias or a financial benefit related to the board's work), he or she must report it at the next board meeting.

Meetings

The bill requires the chairperson to schedule and hold the board's first meeting by February 1, 2025, and the board must meet at least four times annually. A majority of members constitutes a quorum for conducting business, and any determination the board makes must have majority support.

Reporting Requirement

The bill requires PDAB, beginning by December 31, 2025, to annually report to the Aging, General Law, Human Services, Insurance and Real Estate, and Public Health committees on the following:

1. strategies to identify and eliminate pricing or business practices that do not support drug development innovation;

2. price trends and affordability strategies for specific drugs identified to have recent high-cost increases (see § 13);

3. recommendations for legislation to make prescription drugs more affordable while enhancing drug development innovation;

4. purchasing strategies, cost effectiveness evaluations, and new technology or drug developments that increase affordability; and

5. a summary and evaluation of the board's activities and

recommendations.

§ 11 — PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER COUNCIL

Establishes the Prescription Drug Affordability Stakeholder Council to advise PDAB; requires the council to report on prescription drug prices to the board annually beginning by September 1, 2025

The bill establishes the 21-member Prescription Drug Affordability Stakeholder Council to advise PDAB on decisions about prescription drug affordability. Beginning by September 1, 2025, the council must annually report its recommendations on prescription drug prices to PDAB. Additionally, the council must give recommendations to the board at its request.

The bill designates the Insurance and Real Estate Committee's administrative staff as the council's administrative staff. The council must hold its first meeting by August 30, 2024 (i.e., within 60 days after this section's effective date).

EFFECTIVE DATE: July 1, 2024

Membership and Appointments

Under the bill, the council has seven ex officio members and the following 14 appointed members:

1. three members appointed by the House speaker, including a representative from a statewide advocacy organization for (a) a health care coalition, (b) elderly people, and (c) diverse communities;

2. three members appointed by the Senate president pro tempore, including a (a) labor union representative, (b) health services researcher, and (c) consumer who has experienced barriers to getting prescription drugs due to their cost;

3. two members appointed by the House majority leader, including a representative of (a) physicians and (b) nurses;

4. two members appointed by the House minority leader, including

a representative of (a) private insurers and (b) brand-name drug corporations;

5. two members appointed by the Senate minority leader, including a representative of (a) generic drug corporations and (b) an academic institution with expertise in health care costs; and

6. two members appointed by the governor, including a representative of (a) pharmacists and (b) pharmacy benefit managers.

The council's ex officio members are the Office of Policy and Management secretary; DCP, DPH, DSS, and insurance commissioners; OHS executive director; and Healthcare Advocate, or their designees.

Under the bill, initial appointments must be made by November 1, 2024 (though the bill requires the council to hold its first meeting prior to this date), and council members serve three-year terms. The bill requires the House and Senate leaders to select the council's chairpersons from among its members.

§§ 12 & 13 — PRESCRIPTION DRUG PRICING ASSESSMENT

Requires PDAB to (1) identify drugs with high inflation or affordability challenges and (2) recommend upper payment limits for drugs with affordability challenges to OHS; allows PDAB to review drug prices and pricing practices

The bill allows PDAB to assess prescription drug pricing information by doing the following:

1. entering into an MOU with another state to which a drug manufacturer reports pricing information;

2. assessing spending for a drug in Connecticut;

3. using data and findings, including consumer affordability strategies, developed by (a) similar boards in other states or (b) other state or federal entities;

4. using the federally established prescription drug maximum fair price for Medicare members; and

5. assessing any other available pricing information.

EFFECTIVE DATE: July 1, 2024

Annual Inflation-Adjusted Costs

The bill requires PDAB, beginning July 1, 2025, to identify prescription drugs that, when adjusted annually for inflation, are:

1. brand-name drugs with a launch wholesale acquisition cost of at least $30,000 or more per year or treatment course,

2. brand-name drugs with a wholesale acquisition cost increase of at least $3,000 in a 12-month period, or

3. biosimilars (i.e., drugs similar to other licensed drugs) with a launch wholesale acquisition cost not at least 15% lower than the referenced brand biologic.

The board must also identify generic drugs that have:

1. a wholesale acquisition cost of at least $100 for (a) a 30-day dosage supply, (b) a supply lasting a patient fewer than 30 days based on the recommended dosage, or (c) one unit of drug if the FDA does not recommend a finite dosage; or

2. a wholesale acquisition cost that increased by at least 200% in the previous 12-month period.

Affordability Challenges

Beginning July 1, 2025, the bill requires the board to identify other drugs or pricing practices that have created, or may create, affordability challenges for Connecticut's health care system or patients, including drugs to address significant public health priorities. To do so, the bill allows the board to consider the following:

1. the drug's wholesale acquisition cost;

2. the price of therapeutic alternatives;

3. the price concession, discount, or rebate the manufacturer

provides or is expected to provide to health plans and pharmacy benefits managers for (a) the drug under review and (b) therapeutic alternatives;

4. the cost to health plans for patient access based on standard dosage;

5. how the drug's cost relative to health plan benefit design impacts patient access;

6. the current or expected cost for manufacturer-supported patient access programs;

7. the drug's financial impacts on health, medical, or social services costs relative to those for therapeutic alternatives;

8. a Connecticut patient's average copayment or other cost sharing for the drug; and

9. any other factors it deems necessary or any other information the manufacturer provides.

Prescription Drug Review

The bill allows PDAB to review, within available appropriations, any drug or pricing practice that has a high cost when adjusted for inflation or creates an affordability challenge if, after (1) seeking stakeholder input and (2) considering the average patient cost share of the drug, it determines a review is in the interest of consumers.

Under the bill, when doing a review, the board must examine any information related to the drug's pricing, including:

1. net average price in the state;

2. market competition and context;

3. the manufacturer's projected revenue;

4. estimated value or cost effectiveness;

5. if and how the drug is an innovative therapy or likely to improve health for target consumers; and

6. cost mitigation strategies relevant to the drug, such as rebates, discounts, and patient access programs.

The bill also allows the board to examine costs or potential costs of FDA breakthrough and orphan drugs (i.e., drugs to treat rare conditions).

Upper Payment Limits

The bill requires the board to recommend to the OHS executive director and insurance commissioner an upper payment limit for any drug it determines has led or will lead to an affordability challenge. The board must consider (1) the cost of administering the drug, (2) the cost of delivering the drug to patients, and (3) relevant administrative costs when determining its recommended upper payment limit.

To makes its recommendation, the bill allows the board to use:

1. upper payments set by (a) boards in other states and (b) other state or federal entities, as long as their price justification process is as rigorous as that outlined in this bill; and

2. a prescription drug's Medicare maximum fair price.

§ 14 — PAYMENT LIMIT VIOLATIONS

Prohibits state entities, health benefit plans, and participating ERISA plans from purchasing drugs at a price higher than its upper payment limit; prohibits pharmacies from distributing to certain consumers drugs purchased at a price higher than its upper payment limit

The bill makes it a violation for a state entity, health benefit plan (e.g., a commercial health insurance policy), or participating Employee Retirement Income Security Act (ERISA) plan (e.g., a health plan subject to federal minimum standards that chooses to participate in the bill's requirements) to purchase drugs for consumers at a price higher than the PDAB-established upper payment limit. The bill requires any contract between a state entity, health benefit plan, or participating ERISA plan and a third party to include that rates paid for drugs may

not exceed the upper payment limit.

Similarly, under the bill a Connecticut-licensed retail pharmacy may not purchase drugs meant for people whose health care is provided by a state entity, health benefit plan, or ERISA plan at a price higher than the PDAB's upper payment limit.

The bill is silent on how these violations will be assessed and what penalties may be imposed.

EFFECTIVE DATE: July 1, 2025

§ 15 — COST SAVINGS

Requires state entities, health benefit plans, and participating ERISA plans to (1) use any savings generated by an upper payment limit to lower consumers' costs and (2) annually report to PDAB and OHS on savings achieved; requires OHS to annually report on the savings to certain legislative committees

Under the bill, any savings a state entity, health benefit plan, or participating ERISA plan generates that are attributable to an implemented upper payment limit must be used to reduce consumers' health care costs, prioritizing reducing out-of-pocket prescription drug costs.

Beginning by April 1, 2026, the bill requires the state entities and plans to annually report to PDAB and OHS on savings achieved and how savings were used to reduce consumers' costs.

The bill requires the OHS executive director, beginning by July 1, 2026, to annually report on savings achieved and recommendations to increase savings to the Appropriations, General Law, Human Services, Insurance and Real Estate, and Public Health committees.

EFFECTIVE DATE: July 1, 2025

§ 16 — DRUG WITHDRAWAL

Requires manufacturers to (1) provide six-months' notice before withdrawing from sale a drug with an established upper payment limit and (2) notify PDAB within 30 days if it expects a drug shortage; requires PDAB to fine a manufacturer up to $500,000 for failure to give notice before withdrawing a drug

The bill requires a manufacturer to give at least six-months' written

notice before it discontinues distributing a drug for which the board has established an upper payment limit to (1) PDAB, (2) the insurance commissioner, (3) the attorney general, and (4) any entity with which it is contracted with for the drug's sale. The bill also requires a manufacturer that expects a shortage of its drug to notify PDAB within 30 days after making this determination.

Under the bill, PDAB must fine a manufacturer up to $500,000 if it fails to give the required notice before withdrawing a drug.

EFFECTIVE DATE: July 1, 2025

§§ 17-19 — INSULIN

Requires state entities and health benefit plans to cover certain insulin products at the lowest wholesale acquisition cost in a preferred tier with no copayment or out-of-pocket cost; allows plans to cover and offer more than one insulin product

The bill requires state entities and health benefit plans (other than as required in collectively bargained agreements that affect the state employee plan) to make available to beneficiaries an eligible insulin product at the lowest wholesale acquisition cost in a preferred tier with no copayment or out-of-pocket cost. An "eligible insulin product" is an insulin product, including pens or vials, for which at least two licenses have been issued and that continues to be marketed.

Under current law, health benefit plans generally must cap the cost of insulin at $25 per 30-day supply (CGS §§ 38a-492d & -518d).

The bill also allows state entities and health benefit plans to (1) cover more than one eligible insulin product in a preferred tier and (2) offer, without out-of-pocket costs, another eligible insulin product if the product has a net cost lower than the lowest wholesale acquisition cost.

EFFECTIVE DATE: January 1, 2025

§ 20 — DRUG SHORTAGE PREVENTION

Requires hospitals and drug purchasing agencies to (1) have drug shortage prevention strategies covering at least one-third of expected use for at least 40 drugs and (2) include in any long-term drug purchasing contract certain drug shortage mitigation strategies

The bill requires hospitals and drug purchasing agencies (i.e., the

departments of correction, mental health and addiction services, and social services) to have a drug shortage prevention strategy that covers at least one-third of the hospital's or agency's expected use of at least 40 eligible drugs. Under the bill, "eligible drugs" are federally approved injectables on the FDA's drug shortage list, on the list within the past five years, or at risk of shortage.

EFFECTIVE DATE: July 1, 2024

Contract Requirements

In any long-term prescription drug purchase contract, a hospital or agency must require the contracting entity to:

1. hold physical reserve inventory equal to two quarters of the contract volume to buffer supply disruption or demand, unless the drug is in shortage or subject to a supply disruption;

2. have a competent quality control unit and processes to evaluate supplier quality;

3. have a process to ensure drug quality and complete documentation of good manufacturing practices; and

4. participate, following federal law, in the 340B Drug Pricing Program.

Reporting Requirements

The bill outlines the following drug shortage prevention compliance reporting requirements:

1. beginning by January 1, 2025, hospitals must annually report to the DPH commissioner documentation of their compliance;

2. beginning by February 1, 2025, the correction, mental health and addiction services, DPH, and DSS commissioners must annually report to OHS on hospitals', drug purchasing agencies', and contractors' compliance; and

3. beginning by April 1, 2025, the OHS executive director must

report this information to the General Law, Human Services, Judiciary, and Public Health committees.

§§ 21 & 22 — 340B DRUGS

Prohibits drug manufacturers, wholesalers, and distributors from (1) limiting a pharmacy's access to 340B drugs and (2) requiring health care organizations or pharmacies to submit claims or utilization data as a condition for receiving 340B drugs; establishes a hearing process and penalties for violators

Under federal law, the 340B Drug Pricing Program requires drug manufacturers participating in Medicaid to provide outpatient drugs to eligible healthcare organizations that treat low-income and uninsured patients (i.e., "covered entities") at reduced prices. Pharmacies may contract with 340B-participating healthcare organizations (e.g., hospitals or outpatient clinics) to also purchase reduced-price outpatient drugs.

The bill prohibits manufacturers, third-party logistics providers, wholesalers, or distributors, or their agents or affiliates, from directly or indirectly taking any of the following actions:

1. limiting a 340B-authorized pharmacy's access to 340B drugs, unless the pharmacy's receipt of a drug is federally prohibited; or

2. requiring a covered entity or pharmacy contracted with a covered entity to submit claims or utilization data as a condition for acquiring a 340B drug, unless the claims or data sharing is federally required.

EFFECTIVE DATE: Upon passage

Violations

Beginning July 1, 2024, the bill subjects entities to a civil penalty of up to $50,000 if the OHS executive director receives information or has reasonable belief that the entity has violated these restrictions.

The bill allows the executive director to issue notice of the violation and civil penalty by mail or personal service. The notice must include:

1. reference to the Connecticut law or regulation that has been violated;

2. a short and plain language statement of the violation;

3. a description of the activity to cease;

4. the amount of the imposed civil penalty; and

5. explanation of the right to request, in writing to OHS, a hearing within 10 business days of receiving the notice.

Under the bill, OHS must hold requested hearings following the UAPA. If after a hearing OHS find that a violation has occurred or that the entity has violated any OHS order, the office must issue a final cease and desist order in addition to any civil penalty imposed.

If a timely hearing request is not made, OHS must issue a cease and desist order or impose a civil penalty.

The bill specifies that its 340B drug provisions must not be applied in a way that conflicts with, or is less restrictive than, applicable state and federal laws.

COMMITTEE ACTION

Human Services Committee

Joint Favorable Substitute
Yea 15 Nay 7 (03/19/2024)