OLR Bill Analysis

sHB 7267 (as amended by House "A")*

AN ACT CONCERNING PUBLIC OPTIONS FOR HEALTH CARE IN CONNECTICUT.

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§ 10 — REINSURANCE PROGRAM

Requires OHS to apply for an innovation waiver from the federal government to establish a state reinsurance program and annually determine the funding needed for the program; requires the insurance commissioner to establish the program and the Health Reinsurance Association to administer it; requires certain health carriers to pay an annual reinsurance fee to fund the program; allows the insurance commissioner to adopt implementing regulations

§§ 11-19 — CANADIAN DRUG IMPORTATION PROGRAM

Requires the DCP and DPH commissioners to apply for federal approval and, if received, to establish and operate a program to import prescription drugs from Canada

§§ 20 & 21 — MAIL ORDER PRESCRIPTION DRUGS

Allows individual and group health insurance policies or contracts to require a person to obtain maintenance prescription drugs through a mail order pharmacy

SUMMARY

This bill expands the duties of the Office of Health Strategy (OHS) to include, among other things, setting an annual health care cost growth benchmark for the state starting by October 1, 2020. If the increase in total state health care spending exceeds the benchmark in 2022 or later, the bill:

1. requires OHS to identify health care entities or payers that exceeded the benchmark;

2. generally requires these entities and payers to file and implement performance improvement plans, subject to OHS's approval;

3. requires OHS to identify other entities (e.g., drug manufacturers) that significantly contributed to growth in health care costs; and

4. allows OHS to require these other entities to participate in a public hearing to discuss, among other topics, ways to reduce their contribution to future health costs.

Additionally, the bill requires the OHS executive director to appoint a quality council to develop a proposed standard quality measure set to submit to OHS.

The bill also:

1. requires OHS to apply for a federal innovation waiver to establish a state reinsurance program,

2. establishes a program to import certain prescription drugs from Canada, and

3. allows individual and group health insurance policies or contracts to require a person to obtain maintenance prescription drugs through a mail order pharmacy.

*House Amendment "A" replaces the underlying bill, which would have (1) established a "public option" health insurance program; (2) allowed the comptroller to offer nonstate public employers coverage under another group health insurance plan he creates, rather than through the state health insurance plan as required under current law; and (3) required the comptroller to establish a group health insurance and pharmacy plan for private employers with less than 50 employees or allow these small employers to join the state health insurance plan.

EFFECTIVE DATE: July 1, 2019

§ 1 — OFFICE OF HEALTH STRATEGY RESPONSIBILITIES

Expands the scope of OHS's duties

The bill expands OHS's responsibilities by requiring the office to:

1. set an annual health care cost growth benchmark for the state across all payers and populations (see below),

2. enhance the transparency of health care entities in the state,

3. monitor the (a) development of Connecticut's accountable care organizations (ACOs) and patient-centered medical homes and (b) adoption of alternative payment methodologies in the state.

OHS's existing duties include directing and overseeing the State Innovation Model (SIM) initiative and related successor initiatives. The bill expands this by requiring OHS to direct and oversee innovative health care delivery and payment models in the state that reduce cost growth and improve patient care, including the SIM Initiative and

related successors.

OHS was established by PA 17-2, June Special Session, and is within the Department of Public Health for administrative purposes only.

§§ 2 & 3 — HEALTH CARE COST GROWTH BENCHMARK

Requires OHS to set an annual health care cost growth benchmark for the state

Starting by October 1, 2020, the bill requires OHS to annually establish a health care cost growth benchmark for the following calendar year. The benchmark must address the average growth in health care expenditures across all payers and populations in the state.

The bill defines various terms for these and related purposes. For example, "payers" are those that, during a given year, pay providers for health care services on behalf of, or pharmacies for prescription drugs dispensed to, more than 10,000 in-state individuals.

All references to "years" in the benchmark provisions refer to calendar years, not fiscal years.

Establishment and Modification; Informational Hearings

In establishing this annual benchmark, OHS must consider (1) any change in the consumer price index for all urban consumers in the northeast region from the prior year and (2) the most recent publicly available information on the growth rate of the gross state product.

OHS must also hold informational public hearings on this annual benchmark, except it can waive the hearing requirement if a given year's benchmark (beginning in 2022) is the same as the prior year. The OHS executive director determines when and where the hearings occur, and notice of the hearings must appear prominently on the office's website.

The hearing must be based on (1) the most recent annual report OHS prepared on health status adjusted total medical expenses (see § 5 below) and (2) any other information that the executive director deems relevant. After any such hearing, OHS may modify the benchmark if the executive director determines that a modification is reasonably

warranted.

The bill requires OHS to post each annual cost growth benchmark on its website. It also allows OHS to enter into contracts as needed to carry out these provisions, including contracts with experts and consultants to help the office set the benchmark.

§§ 2 & 4 — COMPARISON OF TOTAL HEALTH CARE SPENDING TO THE BENCHMARK

Requires OHS, starting in 2022, to hold hearings to compare the growth in total health care spending to the benchmark

The bill requires OHS, starting by May 1, 2022, to annually hold a public hearing to compare the growth in total health care expenditures during the prior year to OHS's cost growth benchmark for that year.

Under the bill, "total health care expenditures" means the per capita sum of all health care expenditures in the state from public and private sources for a given year, including:

1. all categories of medical expenses and all non-claims-related payments to health care providers, as included in OHS's annual report on health status adjusted total medical expenses (see § 5);

2. all patient cost-sharing amounts (e.g., deductibles and copayments);

3. the net cost of nongovernment health insurance;

4. prescription drug expenditures net of rebates and discounts;

5. medical "device manufacturer" expenditures net of rebates and discounts, for manufacturers with annual sales of over $10 million to state residents; and

6. any other expenditures specified by the OHS executive director.

Hearing Components

Under the bill, the annual hearing comparing the growth in total health care expenditures to the benchmark must examine:

1. OHS's most recent annual report on the health status adjusted total medical expenses (see § 5 below);

2. the expenditures of health care entities (see below), including health care cost trends and the factors contributing to these costs;

3. whether one spending category may be offset by savings in another category; and

4. any other matters that the executive director deems relevant.

For these purposes, a "health care entity" is an ACO, ambulatory surgical center, clinic, hospital, or physician organization in the state. But the term does not include a physician contracting unit that, for a given year, (1) has a patient panel of 10,000 or fewer patients or (2) represents providers who collectively receive less than $20 million in net patient service revenue from health carriers.

Under the bill, the OHS executive director may require any health care entity to participate in the hearing if it was found to be a significant contributor to health care cost growth in the state during the prior year. If so, such an entity must provide (1) testimony on issues the executive director identifies and (2) additional information on actions taken to reduce its contribution to future statewide health care costs.

Annual Report to Legislature

The bill requires OHS, annually starting by October 1, 2022, to report to the Insurance and Public Health committees. The report must:

1. describe health care spending trends in the state and the factors underlying these trends;

2. be based on the office's analysis of the information submitted during the most recent such hearing and any other information that the executive director deems relevant; and

3. disclose the office's recommendations, if any, on strategies to

increase the efficiency of the state's health care system, including any recommended legislative changes.

§§ 2 & 5 — DATA REPORTING AND HEALTH STATUS ADJUSTED TOTAL MEDICAL EXPENSES

Requires institutional providers, non-institutional providers, and provider organizations to report specified data to OHS starting in 2021, which in turn must report on statewide medical expenses

Reporting to OHS

Under the bill, starting by March 1, 2021, the following entities must annually submit certain data to OHS: each in-state (1) institutional provider, on behalf of the provider and its parent organization and affiliated entities; (2) non-institutional provider; and (3) provider organization.

Specifically, they must submit the prior year's data on:

1. the utilization of the provider's or organization's health care services;

2. the charges, prices imposed, and payments received for these services;

3. the provider's or organization's costs incurred and revenues earned; and

4. any other matter that the executive director deems relevant.

Under the bill, hospitals must submit the above data as well as additional information the OHS executive director designates, including charge masters, cost data, audited financial statements, and merged billing and discharge data. The bill specifies that hospitals do not have to submit any data contained in reports filed pursuant to specified existing state public health law and available to the executive director.

Data Reporting Standards

The bill requires the OHS executive director to establish uniform data submission standards. These standards must enable the executive

director to identify, on a patient-centered and provider-specific basis, statewide and regional trends in the availability, cost, price, and utilization of medical, surgical, diagnostic, and ancillary services provided by acute care hospitals, chronic disease hospitals, rehabilitation hospitals, and other specialty hospitals, clinics (including psychiatric clinics), and facilities providing ambulatory care.

The standards may require hospitals to submit the required information electronically if the standards provide for an electronic submission waiver when the executive director determines it to be reasonable.

OHS Reporting

Starting by December 1, 2021, OHS must annually prepare and post on its website a report on health status adjusted total medical expenses for the prior year.

Under the bill, "health status adjusted total medical expenses" is:

1. the total cost of care for the patient population of a group of providers with at least 36,000 member months for a given year and

2. the total aggregate medical expenses for all physicians and physician groups with fewer than 36,000 member months for a given year.

For the first category (groups with 36,000+ member months), the cost must:

1. be calculated based on the allowed claims for all categories of medical expenses and all nonclaims payments, including cost-sharing payments, adjusted by health status and expressed on a per member, per month basis for all in-state members who are required to select a primary care physician for that year;

2. be reported separately for Medicaid, Medicare, and nongovernment health plans; and

3. disclose the health adjustment risk score and the version of the tool used to calculate that score for such group.

OHS's required annual reports must include a breakdown of these expenses by major service category, payment methodology, relative price, and direct and indirect hospital inpatient and outpatient cost.

The bill allows OHS to disclose provider-specific data only if the executive director provides at least 10 days' advance written notice to each affected provider.

Data Request to CMS

The bill requires the OHS executive director to annually submit a request to the federal Centers for Medicare and Medicaid Services (CMS) for the health status adjusted total medical expenses of provider groups that served Medicare patients during the prior year.

Contracted Assistance

The bill allows OHS enter into contracts as needed to carry out these provisions, such as contracts with experts and consultants.

§ 6 — ACTIONS IF HEALTH CARE ENTITIES OR PAYERS EXCEED BENCHMARK

Requires OHS, if the increase in total state health care spending exceeds the benchmark in 2022 or later, to identify health care entities or payers that exceeded the benchmark, and generally requires them to file and implement performance improvement plans

Under the bill, beginning in 2022, if the OHS executive director determines that the average annual percentage change in total health care expenditures for the prior year exceeded the benchmark for that year, she must identify each health care entity or payer (as defined above) that exceeded the benchmark. She must do so by April 1.

The executive director may require that any health care entity found to be a significant contributor to health care cost growth in the state during the prior year participate in the public hearing described above (see § 4). They must provide (1) testimony on issues identified by the executive director and (2) additional information on actions taken to reduce their contribution to future statewide health care costs.

Within 30 days after the executive director identifies each health care entity or payer that exceeded the benchmark, she must send them a notice that, at a minimum, discloses:

1. that she has identified the entity or payer as exceeding the benchmark;

2. the factual basis for her determination; and

3. that the entity or payer must file a proposed performance improvement plan, subject to the extension and waiver provisions described below.

Extension or Waiver Request

Under the bill, any health care entity or payer that OHS identifies as having exceeded the benchmark may request (1) an extension to file a proposed performance improvement plan or (2) a waiver from the requirement. They may file the request up to 30 days after OHS sends the notice described above.

The entity or payer must set forth the reasons for the requested extension or waiver. Within 30 days after the request is filed, the executive director must (1) approve or deny it based upon those reasons and (2) send a notice to the entity or payer of the decision and the reasons for it. If the executive director denies the request, the notice must state that the entity or payer can request a hearing (see below). If she grants an extension, the notice must provide the new due date for the proposed improvement plan.

Hearing

The bill allows any health care entity or payer that OHS identifies as having exceeded the benchmark to request a hearing. They may do so up to 30 days after OHS sends notice (1) of the identification or (2) denying an extension or waiver request. The hearing must be conducted as a contested case hearing under the Uniform Administrative Procedure Act (UAPA).

Performance Improvement Plan

Under the bill, entities or payers required to file proposed performance improvement plans must do so by the earlier of the following:

1. 30 days after the executive director sent the notice disclosing that they exceeded the cost growth benchmark;

2. the due date that the executive director set, if she granted an extension; or

3. 30 days after notice of a final decision following a public hearing.

The plan must include an implementation timetable.

The executive director must review each such proposed performance improvement plan to determine whether it is reasonably likely that (1) the plan will address the cause of the entity's or payer's excessive cost growth and (2) the entity or payer will successfully implement it. After this review and based on this criteria, she must approve or deny the plan.

Within 30 days after her decision, the executive director must send a notice to the entity or payer that discloses her decision. If she denied the proposed plan, she must disclose the reasons and require the entity or payer to file amendments as necessary to satisfy the approval criteria. They must file the amendments within 30 days after the executive director sends notice of the denial.

Under the bill, OHS must post on its website:

1. the name of each health care entity or payer that files, and receives approval for, a proposed performance improvement plan and

2. that such entity or payer is implementing the plan.

Plan Implementation. The bill requires any health care entity or payer whose plan was approved to immediately make good faith efforts to implement it. They may amend their plans during the

implementation timetable with the OHS executive director's approval.

OHS must provide assistance to these entities and payers as the executive director deems necessary and appropriate for the plans' successful implementation.

Required Reporting and Further Action. Under the bill, health care entities and payers with approved performance improvement plans must report to OHS on the outcome of the plans' implementation. They must do so within 30 days after the last date specified in the implementation timetable.

Based on that report, if the executive director determines that the entity or payer successfully implemented its plan, she must (1) notify them of that determination and (2) remove from OHS's website the notice that the entity or payer is implementing such a plan.

If she determines that the entity or payer failed to successfully implement its plan, she must notify them of that and of her actions in response. The bill gives her the discretion to:

1. extend the plan's implementation timetable;

2. require the entity or payer to file plan amendments as she determines necessary for successful implementation;

3. require the entity or payer to file a new plan; or

4. waive or delay the requirement that the entity or payer file any future proposed plan until she determines that they have successfully implemented the initial plan.

The executive director may establish additional reporting requirements for entities and payers to ensure that they successfully implement their approved plans.

Document Confidentiality. The bill requires OHS to keep confidential all nonpublic clinical, financial, operational, or strategic documents and information that parties file with or submit to OHS

under these provisions.

It generally prohibits OHS from disclosing any such document or information without the consent of the entity or payer that provided it. But it allows OHS to disclose the information in summary form as part of an evaluative report if the executive director determines that the public interest supports disclosure after considering any privacy, trade secret, or anti-competitive considerations.

Under the bill, and despite any contrary laws, the documents and information filed with or submitted to OHS under these provisions are not public records under the Freedom of Information Act.

§ 7 — ACTIONS IF OTHER ENTITIES SIGNIFICANTLY CONTRIBUTED TO EXCEEDING THE BENCHMARK

Requires OHS, if the increase in total state health care spending exceeds the benchmark in 2022 or later, to identify other entities (e.g., drug manufacturers) that significantly contributed to that increase, and allows the OHS executive director to require them to participate in a related public hearing

Under the bill, beginning with 2022, if the OHS executive director determines that the average annual percentage change in total health care expenditures for the prior year exceeded that year's benchmark, she must identify certain other entities that significantly contributed to that outcome.

For this purpose, "other entities" are:

1. medical device manufacturers with annual sales of over $10 million to state residents;

2. manufacturers of drugs meeting certain criteria (e.g., certain frequently prescribed drugs and others in a drug class that OHS determines had a substantial impact on prescription drug spending as a percentage of total health care spending); and

3. pharmacy benefit managers.

The executive director, when identifying these entities, must account for costs, net of rebates and discounts.

She must identify which such entities significantly contributed to the excess growth based on certain existing reporting requirements and other data sources. These include:

1. OHS's reports on health status adjusted total medical expenses,
2. pharmacy benefit managers' annual reports to the insurance commissioner,
3. data from certain reports on new drug applications,
4. information from the all-payer claims database, and
5. any other information that the OHS executive director deems relevant.

She may require these entities to participate in the public hearing described above on the growth in total health care expenditures compared to the benchmark. They must provide (1) testimony on issues she identifies and (2) additional information on actions taken to reduce their contribution to future statewide health care costs.

If she requires a drug manufacturer to participate in the hearing regarding a specific drug or drug class, the hearing may, as possible, include representatives from at least one brand name drug manufacturer, one generic manufacturer, and one innovator company less than 10 years old.

§ 8 — QUALITY COUNCIL

Requires the OHS executive director to appoint a quality council to develop, among other things, a proposed standard quality measure set and proposed updates to submit to OHS for possible adoption

The bill requires the OHS executive director to appoint a quality council. The bill does not specify the number of council members, but the executive director must ensure that the council's membership includes people with experience in Connecticut providing health care services and coverage for such services.

Council Duties

The bill requires the council to develop a "proposed standard quality measure set," which, if adopted by OHS, includes measures on health outcomes and enables in-state health care providers, facilities, medical groups, and provider groups to report to the office a standard set of information on health care quality and safety measures.

The council must develop this proposal in consultation with national and state organizations and state residents who are stakeholders in all aspects of the health care system that monitor and develop health care quality and safety measures.

By November 1, 2020, the council must submit the proposed standard quality measure set to OHS and make recommendations to the executive director on adopting it.

The bill also requires the council to develop, on an ongoing basis, proposed updates to any standard quality measure set OHS adopts. Among other things, these updates may include:

1. nationally recognized quality measures recommended by medical and provider groups on appropriate quality measures for their specialties and

2. new health outcome measures which are patient-centered and consider important differences in preferences and clinical characteristics within patient subpopulations.

The council must provide an opportunity for stakeholder engagement and transparency on (1) the measures' development and (2) related research provided by state agencies or third parties that it relied upon concerning access to health care.

Starting by November 1, 2021, the council must annually make recommendations to the OHS executive director on adopting proposed updates to any standard quality measures the office adopted.

Lastly, the council must advise OHS on other matters that the executive director deems appropriate to help the office perform its duties.

§ 9 — OHS REGULATIONS

Allows OHS to adopt regulations implementing various provisions

The bill allows OHS to adopt regulations implementing the provisions on the heath care cost growth benchmark, related hearings and reporting, performance improvement plans, and quality council (§§ 2-8).

§ 10 — REINSURANCE PROGRAM

Requires OHS to apply for an innovation waiver from the federal government to establish a state reinsurance program and annually determine the funding needed for the program; requires the insurance commissioner to establish the program and the Health Reinsurance Association to administer it; requires certain health carriers to pay an annual reinsurance fee to fund the program; allows the insurance commissioner to adopt implementing regulations

Section 1332 Innovation Waiver

The bill requires the Office of Health Strategy (OHS) to apply for an innovation waiver under Section 1332 of the federal Affordable Care Act from the U.S. Department of Treasury or U.S. Department of Health and Human Services, as applicable. The waiver is to establish a state reinsurance program.

Notice of Funding Needed

If the federal government approves the Section 1332 innovation waiver, beginning in 2020, OHS must, by September 1 annually, (1) determine the amount needed, up to $30 million annually, to fund the state reinsurance program for the next plan year and (2) inform the Office of Policy and Management (OPM) of the amount. OPM must then inform the insurance commissioner of the amount.

Reinsurance Program and Fee

Reinsurance Fee. The bill requires certain health carriers to pay the insurance commissioner an annual reinsurance fee that he assesses (see below). He must deposit the fees in the Insurance Fund.

The following health carriers must pay the fee: (1) insurers and HMOs doing health insurance business in the state and (2) insurers that administer self-insured health benefit plans and are exempt from having to obtain a third-party administrator license from the insurance

commissioner ("exempt insurers").

Reinsurance Program. Under the bill, the insurance commissioner must use the fees to establish a reinsurance program for the individual health insurance market, if the federal government approves a Section 1332 innovation waiver for that purpose. The bill does not identify what he must use the fees for if the waiver is not approved. However, it specifies that if the waiver ends and is not replaced, the reinsurance fee will also end.

The reinsurance program must be designed to lower premiums by 5% to 10% annually on individual health benefit plans sold on and off the exchange (i.e., Access Health CT).

The bill requires the Health Reinsurance Association (HRA) to administer the reinsurance program. (By law, HRA is a nonprofit legal entity made up of all insurers, HMOs, and self-insurers doing business in Connecticut.)

Fee Assessment Process and Timeline

Covered Lives Report, Late Fee, and Penalty. Under the bill, health carriers subject to the reinsurance fee must report information to the insurance commissioner annually by September 1 on a form he prescribes. The report must include the number of Connecticut people covered as of the prior May 1 under health insurance plans that the carrier issued or administered, but exclude people enrolled in Medicare, state Department of Social Services' medical assistance programs, workers' compensation insurance, or Medicare Part C plans.

Any carrier that does not file the report must pay a $100 late fee for each day the report remains unfiled past September 1.

The bill allows the commissioner to require carriers or other persons to produce records they possess that were used to prepare a covered lives report. He or his designee may examine the records to substantiate the information reported. If the commissioner finds that there is anything other than a good faith discrepancy between the actual number of covered lives and the number reported, the carrier

must pay a civil penalty of up to $15,000 for each inaccurate report.

Commissioner Determines and Assesses Fee. Annually by November 1, the insurance commissioner must determine the reinsurance fee to be assessed to each affected health carrier for the next plan year.

The bill provides the formula for determining the fee, which must be based on the number of covered lives reported and the amount of funding OHS determined was necessary for the reinsurance program (see above).

The fee is calculated by multiplying the number of covered lives by a factor the commissioner determines annually to fully fund the reinsurance program, adjusted as necessary to account for any over or under appropriation, minus the federal pass-through savings available under the Section 1332 innovation waiver. The commissioner must determine the factor by dividing the adjusted amount by the total number of covered lives.

The commissioner, annually by December 1, must send a statement assessing the applicable reinsurance fee to each affected carrier. Each carrier must pay their assessed fee to the commissioner annually by February 1.

A carrier aggrieved by the reinsurance fee assessment may, within one month from when the fee is due, appeal to the New Britain Superior Court.

Overpayment. If a carrier overpays the reinsurance fee in any fiscal year by more than $5,000, the commissioner must apply the overpayment as a credit against the reinsurance fee due for the following fiscal year. For this to happen, the carrier must notify the commissioner by June 1 of the calendar year of the overpayment and provide him with sufficient evidence to prove the overpayment.

Within 90 days after receiving the notice and evidence, the commissioner must determine if the carrier overpaid and notify the

carrier of his determination.

Under the bill, a carrier's failure to timely notify the commissioner of an overpayment waives its demand for the overpayment. A carrier retains its ability to appeal the payment as described above.

Retaliatory Charge

Under the bill, if another jurisdiction imposes a retaliatory charge on a Connecticut domiciled insurer, HMO, or other domestic entity because of the reinsurance fee imposed under the bill, the entity may appeal to the insurance commissioner within 60 days after receiving notice of the retaliatory charge for verification that the reinsurance fee is subject to retaliation.

If the commissioner determines that the reinsurance fee is subject to retaliation by another jurisdiction, then he must not assess the reinsurance fee on nondomestic health carriers.

Any domestic entity aggrieved by the commissioner's decision may appeal to the New Britain Superior Court.

Regulations

The bill authorizes the insurance commissioner to adopt regulations to implement the reinsurance program and fee provisions.

§§ 11-19 — CANADIAN DRUG IMPORTATION PROGRAM

Requires the DCP and DPH commissioners to apply for federal approval and, if received, to establish and operate a program to import prescription drugs from Canada

The bill requires the Department of Consumer Protection (DCP) commissioner, in consultation with the Department of Public Health (DPH) commissioner, 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.

Application for Federal Approval. By January 1, 2021, the DCP commissioner, after consulting with the DPH commissioner, must submit a request to the federal Health and Human Services (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 DPH commissioner and the Appropriations, General Law, Human Services, and Public Health committees that the request was approved, and

2. in conjunction with the DPH commissioner, begin operating the program within 180 days of the approval date.

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

Importation. 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 such drugs if they:

1. meet federal Food and Drug Administration (FDA) standards for safety, effectiveness, misbranding, and adulteration; and

2. are not (a) controlled substances, (b) biologics, (c) infused, (d) intravenously injected, (e) inhaled during surgery, or (f) parenteral drugs that HHS determines pose a public health threat.

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

Wholesalers may import prescription drugs to a pharmacy or institutional pharmacy, or to a DPH-registered laboratory to perform analytical testing.

Track-and-Trace. The bill requires Canadian suppliers and participating wholesalers to comply with all applicable track-and-trace requirements (e.g., document the manufacture, supply, and distribution chain) and prohibits them from distributing, dispensing, or selling any imported drugs outside of Connecticut.

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

Safety. 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 all federal labeling requirements;

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

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

state laws.

The bill requires wholesalers to maintain these records for at least three years.

Wholesaler Records. The bill requires each wholesaler to maintain for each imported drug:

1. the drug's name, quantity, and 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, in consultation with the DPH commissioner, requires for the protection of public health.

This information must be submitted to the DCP commissioner upon his request.

Supplier Records. 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, and the drug's manufactured date, location 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 DCP

commissioner, in consultation with the DPH commissioner, requires for the protection of public health.

This information must be submitted to the DCP commissioner upon his request.

Commissioner Enforcement. 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 he 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.

The commissioner 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 commissioner issues such an order against a wholesaler or supplier, he must notify the wholesaler or supplier that (1) the order has been issued, along with its legal and factual basis, and (2) that they may make a written request for a hearing, provided the request is received within 30 days of the notice.

If the commissioner receives a request for a hearing, he must convene it under the UAPA within 30 days of receiving the request, and must issue a final decision vacating, modifying, or affirming the order within 60 days. Any supplier or wholesaler aggrieved by a final decision may appeal it in accordance with existing UAPA provisions.

Regulations. The bill authorizes the DCP commissioner to adopt implementing regulations.

Reporting. Starting by July 1, 2020, 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, including any information prescribed in applicable regulations.

§§ 20 & 21 — MAIL ORDER PRESCRIPTION DRUGS

Allows individual and group health insurance policies or contracts to require a person to obtain maintenance prescription drugs through a mail order pharmacy

The bill allows individual and group health insurance policies or contracts to require a covered person to obtain maintenance prescription drugs (as described in the policy or contract) through a mail order pharmacy as a condition of obtaining coverage for the drugs. This applies to health carriers (e.g., insurers and HMOs) delivering, issuing, renewing, amending, or continuing an individual or group health insurance policy or contract that provides prescription drug coverage. Current law prohibits carriers from requiring a person to obtain any prescription drugs from a mail order pharmacy as a condition of obtaining coverage for the drugs.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 11 Nay 8 (03/19/2019)

Appropriations Committee

Joint Favorable
Yea 29 Nay 19 (05/02/2019)