OLR Bill Analysis

sHB 6669

AN ACT PROTECTING PATIENTS AND PROHIBITING UNNECESSARY HEALTH CARE COSTS.

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SUMMARY

A section-by-section analysis follows.

EFFECTIVE DATE: Various, see below

§ 1 — DRUG DISCOUNT CARD PROGRAM

Requires the state comptroller to establish a Drug Discount Card Program for state residents and allows him to join with other states or a regional consortium to pool prescription drug purchasing power

This bill requires the state comptroller to establish the Drug Discount Card Program and make it available to all state residents. Through this program, the comptroller may cooperate with other U.S. states and territories or regional consortia to pool prescription drug purchasing power to do the following:

1. lower prescription drug costs;

2. negotiate discounts with drug manufacturers;

3. centralize drug purchasing; and

4. establish volume discount contracting (i.e., a negotiated drug

purchase in a large quantity for a lower cost).

The bill requires the comptroller to adopt regulations to implement the program, including establishing program criteria and procedures. Regardless of the Uniform Administrative Procedure Act's (UAPA) regulation adoption process, in order to carry out the bill's purposes, the comptroller must issue policies and procedures to implement the program before adopting regulations. He must do so by January 1, 2024, and these policies and procedures have the force and effect of law.

The bill requires the comptroller, at least 15 days before the policies and procedures take effect, to post them on the comptroller's website and submit them to the Secretary of the State (SOTS) to be posted on the eRegulations system. A policy or procedure is no longer effective once the final regulation is adopted or, if the regulations have not been submitted to the Regulation Review Committee, on July 1, 2027, whichever occurs earlier.

EFFECTIVE DATE: October 1, 2023

§ 2 — PRESCRIPTION DRUG MONITORING PROGRAM EXPANSION

Expands the state's prescription drug monitoring program to include not just controlled substances but other prescription drugs, non-prescription drugs, and medical devices; makes related changes to the program, including (1) temporarily reducing the required reporting frequency for pharmacies and other dispensers and (2) adding to the information they must report

Under current law, the state's prescription drug monitoring program collects prescription data on most controlled substances into a centralized online database to prevent improper or illegal drug use or improper prescribing. Pharmacies and other dispensers must report certain information for inclusion in the database, such as the dispensing date, dispenser identification and prescription number, and certain patient identification data.

The bill expands the program to include other legend (i.e., prescription) drugs, non-legend drugs, and legend and non-legend devices. It also expands the program's statutory purposes to include improving prescribers' ability to identify medications that should be

discontinued, deprescribed, or modified in the patient's best interest.

Additionally, the bill requires the program to collect transaction information for covered products that have been electronically deprescribed and sent to licensed pharmacies and nonresident pharmacies (i.e., an out-of-state pharmacy that ships prescription products into the state).

The bill makes several conforming changes to expand the program's scope to include all dispensed drugs and devices (legend and non-legend). In most respects, the bill extends current law's provisions to these other types of drugs and devices, such as:

1. excluding product samples dispensed by physicians and products dispensed to hospital inpatients;

2. procedures for prescribers to designate authorized agents, and pharmacists to designate pharmacy technicians, to review program information on their behalf; and

3. required Department of Consumer Protection (DCP) regulations.

The bill also generally extends to these other products current provisions on the confidentiality and allowable disclosures of program information (other than certain provisions that concern research on opioid abuse or controlled substance overdoses).

However, the bill does not extend to these other products current requirements for prescribing practitioners or their authorized agents to (1) review a patient's records in the program before prescribing more than a 72-hour supply of a controlled substance and (2) periodically review patient records on a specified schedule when prescribing controlled substances for continuous or prolonged treatment.

As described below, the bill also (1) temporarily reduces the required reporting frequency for pharmacies and other dispensers and (2) adds to the information they must report.

EFFECTIVE DATE: October 1, 2023

Reporting Frequency and Information

Current law requires pharmacists and most other dispensers to report to the program, in a DCP-approved electronic format, by the next business day after dispensing a covered drug. If the program is not operational, they must report by the next business day (i.e., the next day that the pharmacy is open) after regaining access to the program.

The bill gives pharmacists and most other dispensers more time to report to the program from October 1, 2023 (when these provisions take effect), through June 30, 2024. During that period, it requires them to report not less than weekly, in an electronic format or another DCP-approved format if the pharmacy does not maintain electronic records. Starting July 1, 2024, the bill reverts back to the current deadlines as described above (i.e., the next business day unless the program is not operational).

As under current law, the bill requires, both before and after July 1, 2024, that (1) veterinarians report at least weekly and (2) pharmacists and other dispensers report diabetes-related drugs and devices at least daily. (The current program already reaches beyond controlled substances to include diabetes-related products.)

From October 1, 2023, through June 30, 2024, the bill specifically expands the program's scope to include drugs or devices dispensed by prescribing practitioners instead of just pharmacies as under current law. Starting October 1, 2023, it also adds the following to the information that must be reported: (1) prescribing practitioner's national provider identification number and (2) date the prescription (until June 30, 2024) or drug or device (starting July 1, 2024) was delivered to the patient.

§ 3 — ACADEMIC DETAILING PROGRAM FRAMEWORK

Requires the DCP commissioner, in consultation with UConn's School of Pharmacy, to submit a report that may include a framework to create an academic detailing program for physicians, APRNs, and pharmacists participating in collaborative drug therapy management agreements

The bill requires the DCP commissioner, in consultation with UConn's School of Pharmacy, to report to the Public Health Committee

by January 1, 2025. The report may include a framework for establishing an academic detailing program for physicians, advanced practice registered nurses (APRNs), and pharmacists who participate in collaborative drug therapy management agreements (see *Background*). The bill defines "academic detailing" as the process of (1) identifying the best evidence-based practices for a particular medical condition and appropriate treatments and (2) giving this information to prescribing practitioners and qualified pharmacists participating in collaborative drug therapy management agreements to advance patient care.

Under the bill, the report must provide recommendations to ensure that these agreements' participants are aware of cost-effective treatments for patients based on current practice. It may include suggestions for cost-effective implementation and evaluation of an academic detailing program.

EFFECTIVE DATE: Upon passage

Background — Collaborative Drug Therapy Management Agreements

By law, certain pharmacists may enter into written protocol-based collaborative drug therapy agreements with physicians or APRNs (providers) to manage a patient's drug therapy and medical devices. These agreements can authorize a pharmacist to implement, continue, modify, discontinue, or deprescribe a drug therapy the provider prescribes; take similar actions for medical devices (except they may not modify them); order associated lab tests; and administer drugs. The agreements may include guideline-directed management rather than be patient-specific (CGS § 20-631).

§§ 4-8 — PHARMACEUTICAL REPRESENTATIVES

Requires pharmaceutical representatives to be licensed by DCP; establishes reporting requirements for licensees; allows DCP to adopt implementing regulations; requires these representatives to disclose certain information to prescribers when marketing prescription drugs, such as the wholesale acquisition cost; and prohibits them from taking certain actions, such as providing drug samples

The bill requires pharmaceutical representatives to be licensed by DCP and makes several related changes.

Under the bill, a "pharmaceutical representative" is anyone, such as a sales representative or medical science liaison, who markets, promotes, or gives legend drug information to prescribing practitioners and is employed or compensated by a pharmaceutical manufacturer.

A "pharmaceutical manufacturer" is anyone (including a virtual manufacturer) who directly or indirectly produces, prepares, cultivates, grows, propagates, compounds, converts, or processes controlled substances by natural substance extraction, chemical synthesis, or a combination, or packages or repackages controlled substance containers under the person's own name, trademark, or label to sell it.

Generally, existing law defines "virtual manufacturer" as anyone who (1) manufactures drugs, devices, or cosmetics for which the person owns certain rights through a contract with a manufacturing organization, but (2) is not involved in the physical manufacturing and does not physically possess the items at any time (CGS § 20-571).

EFFECTIVE DATE: October 1, 2023

Licensure Application and Renewals (§ 5(b)-(e))

The bill requires anyone seeking licensure as a pharmaceutical representative to (1) apply to DCP on a commissioner-provided form, (2) pay a nonrefundable $550 application fee, and (3) submit evidence of completing five hours of professional education requirements (see below). The commissioner must issue a license to anyone who meets these requirements.

Licenses may be renewed annually by June 30. The renewal fee is also $550, and renewal applicants must certify that they have met the bill's continuing education requirements.

The bill requires licensees to inform the commissioner within five business days after changing their name, address, or other licensure contact information.

Professional Education (§ 5(f)-(h))

The bill requires licensure or renewal applicants, before applying, to

provide satisfactory evidence to the commissioner of having completed at least five hours of continuing professional education. This must include training in ethical standards, health equity, whistleblower protections, pharmaceutical marketing laws and regulations, and any other commissioner-approved training published on DCP's website. Applicants and licensees must (1) keep records of completing this training for at least three years after doing so and (2) give the records to DCP upon request.

Under the bill, continuing professional education training programs are subject to the commissioner's review and approval. The commissioner must publish a list of approved programs on the department's website.

Programs must meet the following standards:

1. they may not be provided by the applicant's or licensee's employer;

2. they may not be funded by entities in the pharmaceutical industry or a third party paid by them; and

3. the provider must disclose any conflicts of interests, such as personal conflicts of interest that would interfere or prevent the provider from conducting the training honestly, objectively, and effectively.

Annual Reporting Requirement (§ 5(i))

The bill requires pharmaceutical representatives to annually report specified information to DCP for the previous calendar year, on a commissioner-prescribed form. They must report when renewing their license, or by July 31 if not renewing it. The reports must include:

1. the total number of contacts (see below) the licensee had with prescribing practitioners;

2. the names and specialties of these prescribing practitioners;

3. the location and length of each contact;

4. the name and a description of each legend drug marketed to each contact;

5. a description of each gift, voucher, coupon, or other compensation of any value given to prescribing practitioners or staff in their offices; and

6. any other information the commissioner requests.

For this purpose, a "contact" is any in-person, phone, email, text, or other electronic communication between a pharmaceutical representative and a prescribing practitioner to promote or provide information about a legend drug.

Disciplinary Actions (§ 5(j))

The bill allows the DCP commissioner to revoke, suspend, or annul a pharmaceutical representative's license, after notice and a hearing, if the commissioner determines that the licensee (1) obtained the license by fraud or misrepresentation or (2) violated the provisions above or related implementing regulations.

Regulations and Policies and Procedures (§ 6)

The bill allows the DCP commissioner to adopt regulations implementing these licensure provisions. It also allows the commissioner, regardless of the UAPA's regulation adoption process, to issue policies and procedures before adopting regulations. These policies and procedures have the force and effect of law.

At least 15 days before the policies and procedures take effect, the commissioner must post them on DCP's website and submit them to SOTS for posting on the eRegulations system. A policy or procedure is no longer effective once the final regulation is adopted or, if the regulations have not been submitted to the Regulation Review Committee, on October 1, 2027, whichever occurs earlier.

Required Disclosures to Prescribers (§ 7)

The bill requires pharmaceutical representatives marketing legend drugs in Connecticut to disclose certain written information to

prescribing practitioners at the time of each contact with them. Specifically, they must disclose the following information related to these drugs:

1. the drug's wholesale acquisition cost, based on its dose and quantity as described in the medication package insert;

2. the names of at least three drugs from the same, or a similar, therapeutic class for the disease or condition for which the marketed drug has federal Food and Drug Administration approval; and

3. information, if available, on whether the drug's effectiveness varies for different racial and ethnic groups.

Prohibited Actions; License Presentation (§ 8)

The bill prohibits pharmaceutical representatives from the following actions in relation to legend drugs:

1. engaging in any deceptive or misleading marketing practices, such as concealing, suppressing, omitting, misrepresenting, or misstating any material fact;

2. using a drug title or designation that could reasonably mislead prescribing practitioners or their employees or representatives; or

3. transporting or giving drug samples to prescribing practitioners or their employees or representatives.

The bill also requires pharmaceutical representatives to present a copy of their license at each visit to these people.

§ 9 — OHS STUDY OF PHARMACY BENEFIT MANAGERS

Requires OHS, in consultation with the Insurance Department, to evaluate and report on PBMs' prescription drug distribution practices in Connecticut and other states

The bill requires the Office of Health Strategy (OHS), in consultation with the Insurance Department, to report to the Insurance and Real Estate Committee by December 24, 2024.

The report must include (1) an analysis of pharmacy benefit managers' (PBMs) prescription drug distribution practices, including spread pricing arrangements, manufacturing rebates, and transparency and (2) an evaluation of PBMs' prescription drug distribution practices in other states. It must make recommendations to reduce consumers' prescription drug costs and regulate in-state PBMs.

EFFECTIVE DATE: Upon passage

Background — Related Bill

sSB 1159 (File 347), reported favorably by the Insurance and Real Estate Committee, requires the Insurance Department to report on similar subjects.

§ 10 — DRUGS WITH SUBSTANTIAL COSTS TO THE STATE

Allows a wider range of drugs to be included on OHS's annual list of 10 drugs that are provided at substantial cost to the state, and gives manufacturers the opportunity, following a public comment period, to show that a drug does not meet inclusion criteria

Existing law requires OHS, in consultation with the comptroller and the commissioners of public health and social services, to annually identify up to 10 outpatient prescription drugs that are provided at substantial state cost, considering their net cost, or critical to public health. Manufacturers of identified drugs must give OHS certain information on the (1) factors that led to an increase in the drug's wholesale acquisition cost and (2) company's research and development costs and other capital costs.

Current law establishes certain parameters for what drugs may be included on this list, requiring both a minimum (1) cost increase percentage over prior years and (2) total cost for a specified supply or course of treatment. As shown in the table below, the bill lowers the minimum required cost increase and total cost that qualifies for inclusion.

Table: Minimum Requirements for List of Outpatient Prescription Drugs

	Current Law	***The Bill***
Cost Increase	At least 20% over the prior year or 50% over the prior	At least 16% cumulatively during the prior two years

	Current Law	***The Bill***
	three years	
Cost for Course of Treatment	At least $60 for a 30-day supply or shorter course of treatment	At least $40 for a course of treatment of unspecified duration

Under current law, the drugs are evaluated based on their wholesale acquisition cost, minus all associated rebates paid to the state during the prior year. Presumably, these rebates are still factored in under the bill.

The bill requires the OHS executive director, before publishing the annual list, to prepare a preliminary list and make it available for public comment for at least 30 days. During that period, the manufacturer of any drug on the preliminary list may give OHS documentation showing that the drug's wholesale acquisition cost, less all rebates paid to the state for it during the prior calendar year, did not exceed the bill's limits shown in the table above. If this documentation establishes this to the executive director's satisfaction, then she must remove the drug from the list before publishing the annual list. She must remove it within 15 days after the comment period closes.

EFFECTIVE DATE: October 1, 2023

§ 11 — FACILITY FEES

Makes various changes affecting hospital or health system facility fees, such as generally allowing providers to bill these fees only if the services are provided at a hospital campus, hospital emergency department, or freestanding emergency department

Current law limits when hospitals, health systems, and hospital-based facilities may charge facility fees for outpatient services provided off-site from a hospital campus. The bill makes various changes to these provisions, such as further limiting the locations where health care providers may charge facility fees and the procedures for which they charge them.

EFFECTIVE DATE: July 1, 2023

Definitions

Under current law, a "facility fee" is any fee a hospital or health

system charges or bills for outpatient hospital services provided in a hospital-based facility that is (1) intended to compensate the hospital or health system for its operational expenses and (2) separate and distinct from the provider's professional fee. The bill specifies that this applies regardless of the treatment modality of the services.

For its facility fee provisions, the bill defines "health care provider" as an individual or entity, whether for-profit or nonprofit, that provides, bills for, or is paid for delivering health care services in the normal course of business, such as a hospital, health system, hospital-based facility, freestanding emergency department, and urgent care center.

These definitions apply to facility fee limits as well as other related provisions in existing law on patient notification requirements, billing statements, reporting, and related matters.

Facility Fee Limits

The bill allows health care providers to charge, bill for, or collect facility fees only for services provided (1) on a hospital's campus, (2) at a facility that includes a hospital emergency department, or (3) at freestanding emergency departments. The bill specifies that urgent care centers licensed as outpatient clinics are not freestanding emergency departments (which are part of licensed hospitals).

It prohibits health care providers from charging, billing for, or collecting facility fees for outpatient evaluation and management or assessment and management services. Current law has a generally similar limitation for hospitals, health systems, and hospital-based facilities for these services provided offsite from a hospital campus.

The bill allows OHS to annually identify outpatient diagnostic and imaging services that may reliably be provided safely and effectively in a non-hospital setting. It prohibits health care providers from charging, billing for, or collecting facility fees for these identified services.

The bill also subjects freestanding emergency departments to the above limits, removing an exemption from current law.

It removes a current limitation on hospitals, health systems, or hospital-based facilities charging more than the Medicare rate for outpatient services provided offsite from a hospital campus.

Despite the above limits, it allows hospitals or health systems to continue to collect insurance reimbursement for otherwise-prohibited facility fees if an insurance contract in effect on July 1, 2023, reimburses these fees. They may continue to do so until the earlier of the contract's expiration, renewal, or amendment.

Additionally, the bill allows certain hospitals to continue to collect Medicaid reimbursement for otherwise-prohibited facility fees, to the extent the Department of Social Services reimburses for them. They may do so for service dates from July 1, 2023, through June 20, 2026. This applies to (1) the John Dempsey Hospital at UConn Health Center and (2) any hospital that is a party to the settlement agreement with the state approved under Special Act 19-1, December Special Session (DSS) (see *Background*).

As under current law, (1) the bill's facility fee limits do not apply to Medicare and Medicaid patients or those receiving services under a workers' compensation plan and (2) a provider that violates these fee prohibitions has committed an unfair trade practice (see *Background*).

Background — 2019 Settlement Agreement

SA 19-1, DSS, approved a settlement agreement between the state and the Connecticut Hospital Association and its member hospitals. The settlement resolved a dispute related to the state's hospital user fee (i.e., hospital provider tax). Generally, the hospitals alleged that they had received inadequate Medicaid supplement payments back from the state in comparison to their tax assessments.

Among other things, the settlement (1) refunded certain tax revenue to the hospitals; (2) reduced the amount of revenue to be collected from the "second hospital user fee" (i.e., the tax on inpatient and outpatient hospital services beginning July 1, 2017); and (3) increased Medicaid payments to hospitals for the covered period.

Background — Connecticut Unfair Trade Practices Act (CUTPA)

By law, CUTPA prohibits businesses from engaging in unfair and deceptive acts or practices. It allows the DCP commissioner to issue regulations defining an unfair trade practice, investigate complaints, issue cease and desist orders, order restitution in cases involving less than $10,000, enter into consent agreements, ask the attorney general to seek injunctive relief, and accept voluntary statements of compliance. It also allows individuals to sue. Courts may issue restraining orders; award actual and punitive damages, costs, and reasonable attorney's fees; and impose civil penalties of up to $5,000 for willful violations and up to $25,000 for a restraining order violation.

§§ 12-15 — CERTIFICATE OF NEED

Makes various changes to the CON program, such as (1) subjecting a person or facility to civil penalties for failing to comply with a settlement agreement; (2) allowing OHS to retain independent expert consultants when necessary in the CON review process; (3) allowing OHS to issue notices for suspected violations of the CON law and, following a hearing, issue cease and desist orders; and (4) expanding the circumstances under which OHS, through an independent consultant, must conduct a cost and market impact review of CON applications for hospital ownership transfers

Generally, existing law requires certain health care facilities to apply for and receive a certificate of need (CON) from OHS's Health Systems Planning Unit when proposing to (1) establish a new facility or provide new services, (2) change ownership, (3) purchase or acquire certain equipment, or (4) terminate certain services. The bill makes various changes to this process, primarily concerning OHS's enforcement authority and hiring of experts to assist in the CON review process.

EFFECTIVE DATE: October 1, 2023

Civil Penalties (§ 12)

Current law imposes a civil penalty of up to $1,000 per day for any person, health care facility, or institution (hereinafter, "person or facility") who willfully fails to (1) seek CON approval when required or (2) timely file required data or information under the CON law, other laws (such as those on nonprofit hospital conversions or various required filings with OHS), and related regulations and orders. The bill eliminates the current condition that the failure must be willful for the

penalty to apply.

It also extends the penalty to any person or facility that has agreed to resolve a CON application through a settlement and fails to comply with any of the agreement's terms or conditions. It extends existing procedures (and related deadlines) to these penalties, such as prior notice, the right to a hearing, and the right to appeal. It similarly extends an existing provision that makes the failure to pay the penalty after the final assessment potentially lead to a deduction in Medicaid payments.

Application Notice (§ 13(b))

The bill eliminates the requirement that a CON applicant file prior notice in a newspaper with substantial circulation in the area. Instead, it requires the applicant to file this notice on its website, in a clear and conspicuous location that is easily accessed by the public.

As under existing law, the notice must (1) briefly describe the project, (2) list its proposed location, and (3) be published for at least three consecutive days and no later than 20 days before filing the CON application.

Public Hearing Notice (§ 13(f))

Existing law requires the Health Systems Planning Unit to hold a public hearing for CON applications in certain circumstances; the unit has the discretion to hold hearings in other cases. The bill increases, from two to three weeks, the minimum required prior written notice that the unit must give to the applicant.

It eliminates a requirement that the unit publish a newspaper notice, and instead requires the applicant to publish notice on its website in a clear and conspicuous location easily accessed by the public. As under current law, this public notice must be made at least two weeks before the hearing.

Independent Consultants (§ 13(g))

Under the bill, if the unit cannot reasonably review and analyze a CON application without the expertise of an industry analyst or other actuarial consultant, it may retain an independent consultant for

assistance. The consultant must have expertise in the specific health care area under review.

If the unit retains a consultant, it must bill the applicant for the person's services, and the applicant must pay within 30 days after receipt. These bills must be a reasonable amount per application.

The bill specifies that these retainer agreements are not subject to specified existing laws on (1) the Department of Administrative Services, (2) consultant and personal service agreements, and (3) methods for awarding state contracts.

Cease and Desist Orders (§ 14)

The bill allows the OHS executive director, or her agent, to issue a notice to any person or facility if she or her agent has received information or reasonably believes that the person or facility has violated or is violating the CON law, other related laws, or the unit's regulations or orders.

The executive director or agent must notify the person or facility by first-class mail or personal service. The notice must include the following:

1. a reference to the laws, regulations, or orders allegedly violated;
2. a short and plain language statement of the matter;
3. a description of the activity alleged to have violated a law or regulation; and
4. a statement on the person's or facility's right to a hearing and the deadline and manner to request one.

Under the bill, the person or facility has 10 business days after receiving the violation notice to request a hearing. To do so, they must apply in writing to the OHS executive director or her agent. At the hearing, the person or facility may attempt to demonstrate that (1) the violation did not occur, (2) a CON was not required, or (3) the required CON was obtained. The hearing must be conducted as a contested case

proceeding under the UAPA.

OHS must issue a cease and desist order if (1) the person or facility does not request a hearing by the deadline or (2) after the hearing, OHS finds, by a preponderance of the evidence, that the violation occurred or is occurring. The order is a final decision and may be appealed to Superior Court under the UAPA. The attorney general may go to court to enforce the order.

Cost and Market Impact Review of Hospital Transfers (§ 15)

The bill expands the circumstances under which OHS's Health Systems Planning Unit must conduct a cost and market impact review of CON applications that propose to transfer a hospital's ownership. It requires this review in all cases when the purchaser is a hospital or health system (in-state or otherwise), rather than only when the purchaser had net patient revenue exceeding $1.5 billion in FY 13 as under current law.

Existing law also requires this review in all CON applications to transfer a hospital's ownership to a for-profit purchaser.

By law, the unit must retain an independent consultant to conduct the review at the purchaser's expense (up to $200,000). The unit must complete a preliminary report and then, after giving the transacting parties time to respond, a final report. After the review, the unit must refer its final report to the attorney general for investigation if a transacting party currently or, after the transfer, will likely (1) have a dominant market share and (2) charge prices, or have health status adjusted total medical expenses, that are materially higher than the median for similar providers in the market.

§§ 16-19 — 340B PROGRAM

Makes various changes affecting participants in the federal 340B drug pricing program, such as (1) prohibiting PBMs from discriminating against 340B covered entities in connection with dispensing covered drugs, (2) requiring drug manufacturers to comply with specified federal pricing requirements when selling covered drugs to these entities, (3) allowing covered entities or the attorney general to seek court relief if a PBM seeks to enforce contract provisions that violate the bill, and (4) requiring hospitals that participate in the 340B program to annually report certain related information to OHS

Section 340B of the federal Public Health Service Act (i.e., the 340B Drug Pricing Program) requires drug manufacturers participating in Medicaid to sell certain outpatient prescription drugs ("covered drugs") at discounted prices to health care organizations that care for uninsured and low-income patients. These organizations include federally qualified health centers, children's hospitals, hospitals that serve a disproportionate number of low-income patients, and other safety net providers ("340B covered entities").

The bill prohibits pharmacy benefit managers (PBMs) from (1) discriminating in certain ways against 340B covered entities or their specified pharmacies in connection with dispensing covered drugs and (2) preventing the 340B covered entities from keeping the benefit of the covered drugs' discounted prices. It applies to all PBMs and their subsidiaries.

The bill specifically requires certain drug manufacturers (including wholesalers) to comply with federal 340B pricing and sales requirements when selling covered drugs to 340B covered entities in Connecticut. It also prohibits them from imposing a precondition, limitation, delay, or other barrier to purchasing covered drugs beyond those required by federal law.

The above provisions on covered drugs apply to those that a 340B covered entity (1) purchases under the program and that are subject to the program's pricing requirements or (2) would purchase except for the prohibited conduct.

The bill allows covered entities, or the attorney general, to seek an injunction or other court relief to prevent PBMs or drug manufacturers from enforcing contract provisions that violate the bill's restrictions.

Lastly, the bill requires hospitals that participate in the 340B program to annually file certain related information with OHS's Health Systems Planning Unit.

EFFECTIVE DATE: October 1, 2023

Activities Constituting Discrimination by PBMs (§ 16)

The bill prohibits PBMs from imposing requirements, conditions, or exclusions that (1) discriminate against 340B covered entities or their specified pharmacies in connection with dispensing covered drugs and (2) prevent covered entities from keeping the benefit of the discounted pricing. ("Specified pharmacies" are those that the 340B covered entity owns or contracts with and that dispense drugs on the entity's behalf under the program, whether in person or by mail.)

For these purposes, discrimination includes the following:

1. payment terms, reimbursement methodologies, or other terms or conditions that (a) distinguish between covered and non-covered drugs, (b) consider the availability of 340B program discounts when determining reimbursement, or (c) are less favorable than the payment or purchase terms or reimbursement methods for similarly situated entities that are not furnishing or dispensing covered drugs;

2. terms or conditions for 340B covered entities or specified pharmacies based on their (a) furnishing or dispensing covered drugs or (b) status as a 340B covered entity or specified pharmacy, including restrictions or requirements for participating in certain pharmacy networks or audit frequency or scope;

3. requiring 340B covered entities or their specified pharmacies to (a) identify covered drugs or their costs or (b) provide information not sought from other drug purchasers;

4. refusing to contract, or ending a contract, with a 340B covered entity or specified pharmacy, or excluding either from a network, because of its status as a 340B covered entity or specified pharmacy or for any reasons other than those that apply equally to non-340B covered entities and pharmacies;

5. refusing to sell covered drugs to a 340B covered entity or specified pharmacy because of its status as such, or for reasons

that do not apply equally to other entities and pharmacies;

6. retaliating against a 340B covered entity or specified pharmacy because it avails itself of a right or remedy under these provisions; and

7. interfering with a person's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or by direct delivery, mail, or other shipment method.

The bill specifies that these provisions apply to PBM-administered self-insured employee welfare benefit plans under the federal Employee Retirement Income Security Act.

For contracts between PBMs and 340B covered entities, the bill makes any contract provisions that violate the above restrictions void and unenforceable. This applies to contracts entered into, amended, or renewed after October 1, 2023, and despite the existing insurance laws and UAPA.

Prohibitions on Drug Manufacturers and Wholesalers (§ 17)

The bill specifically prohibits drug manufacturers subject to the 340B program's pricing rules, and their wholesalers, from imposing preconditions, limitations, delays, or other barriers on 340B covered entities purchasing covered drugs, unless they are required by federal law. The bill specifies that prohibited conduct includes the following:

1. implementing policies or limitations restricting 340B covered entities' or specified pharmacies' ability to dispense covered drugs, including restricting the number or type of locations that may dispense them;

2. conditioning the sale of covered drugs for 340B covered entities on enrollment with third-party vendors or sharing claims or other data;

3. charging 340B covered entities for covered drugs more than the federal ceiling price, including conditioning discounts on rebate

requests;

4. interfering with a person's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or by direct delivery, mail, or other shipment method;

5. delaying covered drug shipments compared to non-discounted drugs; and

6. retaliating against a 340B covered entity or specified pharmacy because it avails itself of a right or remedy under these provisions.

Injunction or Other Court Relief (§ 18)

The bill allows a covered entity or the attorney general to go to court seeking a temporary or permanent injunction and other appropriate relief to prevent a PBM or drug manufacturer (including a wholesaler) from continuing to enforce contract provisions that violate the bill. The bill allows a court, if it finds such a violation, to grant injunctive relief and other relief that justice may require. The court may set deadlines for compliance.

In these cases, if the PBM or manufacturer appeals, the injunction remains in effect unless the court determines that this would lead to great and irreparable injury.

Hospital Reporting (§ 19)

Starting by January 15, 2024, the bill requires hospitals participating in the 340B program to file certain information with the Health Systems Planning Unit, in a way set by the unit. This includes the following:

1. a list of manufacturers from whom the hospital purchased covered outpatient drugs under the program in the prior year;

2. a list of these drugs purchased from each manufacturer, identified by national drug code (NDC) number and categorized by quantity, actual purchase price, and ceiling price;

3. the reimbursement amount by each payer (other than Medicaid

and Medicare) for these drugs, categorized by manufacturer, quantity, actual purchase price, and ceiling price;

4. the cost difference for each of these drugs (identified by NDC number) due to the difference in the ceiling price or actual price paid and the patient's or payer's actual price paid; and

5. a summary of how this cost difference was applied for the community's benefit.

COMMITTEE ACTION

Public Health Committee

Joint Favorable
Yea 25 Nay 12 (03/20/2023)