Senate

General Assembly

File No. 354

February Session, 2022

Substitute Senate Bill No. 355

Senate, April 6, 2022

The Committee on Insurance and Real Estate reported through SEN. LESSER of the 9th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT ESTABLISHING THE 340B DRUG PRICING NONDISCRIMINATION ACT.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2022*) (a) For the purposes of this section and section 2 of this act:

(1) "Covered drug" means a drug purchased by a 340B covered entity that is subject to the federal pricing requirements set forth in 42 USC 256b, as amended from time to time.

(2) "340B covered entity" means a provider participating in the federal 340B drug pricing program authorized by 42 USC 256b, as amended from time to time.

(3) "Drug manufacturer" means the following:

(A) An entity described in 42 USC 1396r-8(k)(5) that is subject to the pricing limitations set forth in 42 USC 256b; and

(B) A wholesaler described in 42 USC 1396r-8(k)(11) engaged in the distribution of covered drugs for an entity described in 42 USC 1396r-8(k)(5) that is subject to the pricing limitations set forth in 42 USC 256b.

(4) "Payer" means a pharmacy benefits manager.

(5) "Pharmacy benefits manager" has the same meaning as provided in section 38a-479aaa of the general statutes and includes a wholly or partially owned or controlled subsidiary of a pharmacy benefits manager.

(6) "Specified pharmacy" means a pharmacy owned by, or under contract with, a 340B covered entity that is registered with the 340B discount drug purchasing program set forth in 42 USC 256b to dispense covered drugs on behalf of the 340B covered entity, whether in person or by mail.

(b) A payer shall not impose any requirements, conditions or exclusions that:

(1) Discriminate against a 340B covered entity or a specified pharmacy in connection with dispensing covered drugs; or

(2) Prevent a 340B covered entity from retaining the benefit of discounted pricing for the purchase of covered drugs.

(c) Discrimination prohibited pursuant to subsection (b) of this section includes:

(1) Payment terms, reimbursement methodologies, or other terms and conditions that distinguish between covered drugs and other drugs, account for the availability of discounts under the 340B discount drug purchasing program set forth in 42 USC 256b in determining reimbursement or are less favorable than the payment terms or reimbursement methodologies for similarly situated entities that are not furnishing or dispensing covered drugs;

(2) Terms or conditions applied to 340B covered entities or specified

pharmacies based on the furnishing or dispensing of covered drugs or their status as a 340B covered entity or specified pharmacy, including restrictions or requirements for participating in standard or preferred pharmacy networks or requirements related to the frequency or scope of audits;

(3) Requiring a 340B covered entity or specified pharmacy to identify, either directly or through a third-party, covered drugs or covered drug costs;

(4) Refusing to contract with or terminating a contract with a 340B covered entity or specified pharmacy, or otherwise excluding a 340B covered entity or specified pharmacy from a standard or preferred network, on the basis that such entity or pharmacy is a 340B covered entity or a specified pharmacy or for reasons other than those that apply equally to entities or pharmacies that are not 340B covered entities or specified pharmacies;

(5) Retaliation against a 340B covered entity or specified pharmacy based on its exercise of any right or remedy under this section; or

(6) Interfering with an individual's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or via direct delivery, mail or other form of shipment.

(d) The provisions of this section do not apply to the federal Medicare program and HUSKY Health program, but do apply to entities that contract with the HUSKY Health program or the federal Medicare program if such entities are a payer and have discretion to negotiate or establish rates of payment for drugs.

Sec. 2. (NEW) (*Effective October 1, 2022*) (a) A drug manufacturer shall comply with federal pricing requirements set forth in 42 USC 256b when selling covered drugs to 340B covered entities located in this state and shall not impose any preconditions, limitations, delays or other barriers to the purchase of covered drugs that are not required under 42 USC 256b.

(b) Preconditions, limitations, delays or other barriers prohibited by subsection (a) of this section include:

(1) Implementation of policies or limitations that restrict the ability of 340B covered entities or specified pharmacies to dispense covered drugs, including restrictions on the number or type of locations through which covered drugs may be dispensed by or on behalf of a 340B covered entity;

(2) Conditioning the sale of covered drugs for 340B covered entities on enrollment with third-party vendors or on the sharing of claims information or other data;

(3) Charging 340B covered entities for covered drugs at amounts above the federal ceiling price, including policies that condition discounts on rebate requests;

(4) Interfering with an individual's choice to receive a covered drug from a 340B covered entity or specified pharmacy, whether in person or via direct delivery, mail or other form of shipment;

(5) Delays in shipping covered drugs compared to drugs that are not discounted; and

(6) Retaliation against a 340B covered entity or specified pharmacy based on such entity's or pharmacy's exercise of any right or remedy under this section.

(c) The Insurance Commissioner shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, to implement the provisions of this section and section 1 of this act.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2022*	New section
Sec. 2	*October 1, 2022*	New section

Statement of Legislative Commissioners:
In Section 1, Subsecs. (b)(1) and (c)(5), the word "and" was changed to "or" for accuracy.

INS *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 23 $	FY 24 $
UConn Health Ctr.	Various - Savings	Significant	Significant
Insurance Dept.	IF - Cost	Up to 50,000	None

Note: IF=Insurance Fund; Various=Various

Municipal Impact: None

Explanation

The bill results in an annual significant savings to the University of Connecticut Health Center beginning in FY 23. The health center has multiple 340B covered entities, including John Dempsey Hospital, and has not been fully benefiting from the provisions of the 340B program due to manufacturer and pharmacy benefits manager (PBM) practices. The health center estimates that the foregone savings due to these practices has reached approximately $7 million to $9 million annually. It is anticipated that the bill will reduce or eliminate the practices it prohibits, and consequently result in greater 340B savings to UConn Health Center.

The bill results in a cost of up to $50,000 to the Insurance Fund in FY 23 for the Insurance Department to adopt implementing regulations. As the agency lacks expertise in the business practices and contracting of PBMs and drug manufacturers, it is anticipated the agency would need

to hire a consultant to assist with developing such regulations.[1]

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to the level of the 340B discount.

[1] The fiscal impact to the Insurance Department for enforcing the provisions of the bill would depend on and be associated with the regulations the agency must adopt under the bill.

OLR Bill Analysis

sSB 355

AN ACT ESTABLISHING THE 340B DRUG PRICING NONDISCRIMINATION ACT.

SUMMARY

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"). 340B covered entities may dispense the discounted drugs to any of their patients.

This 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 (including those that contract with the Medicare or HUSKY Health programs if they negotiate or establish payment rates for drugs) and their subsidiaries.

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

Lastly, the bill requires the insurance commissioner to adopt implementing regulations.

EFFECTIVE DATE: October 1, 2022

§ 1 — ACTIVITIES CONSTITUTING DISCRIMINATION BY PBMS

The bill prohibits PBMs from discriminating against 340B covered entities or their specified pharmacies in connection with dispensing covered drugs. ("Specified pharmacies" are those that the 340B covered entity owns or contracts with, whether the covered drugs are dispensed 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) account for the availability of 340B program discounts when determining reimbursement, or (c) are less favorable than those used for similarly situated entities that are not furnishing or dispensing covered drugs;

2. terms or conditions applicable to 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 identify covered drugs or their costs;

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 specified pharmacies;

5. retaliating against a 340B covered entity or specified pharmacy because it avails itself of a right or remedy under the bill; and

6. 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.

§ 2 — PROHIBITIONS ON DRUG MANUFACTURERS AND WHOLESALERS

The bill specifically prohibits drug manufacturers and wholesalers subject to the 340B Drug Pricing Program's rules 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 preconditions, limitations, delays, or other barriers include 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 covered drugs;

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 the bill.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable Substitute
Yea 16 Nay 1 (03/22/2022)