OLR Bill Analysis

sSB 494

AN ACT CONCERNING PRESCRIPTION DRUG SHORTAGES, PRESCRIPTION DRUG REBATES AND PROHIBITED MANUFACTURER PRACTICES CONCERNING CERTAIN PRESCRIPTION DRUGS.

SUMMARY

This bill makes several changes in laws related to prescription drug prices and prescription drug shortages.

Existing law authorizes the Department of Social Services (DSS) to enter contracts for supplemental rebates for drugs on the department's preferred drug list or formulary. The bill requires DSS to develop and implement a plan, starting July 1, 2026, to increase the number of supplemental rebates by at least 20% and sets a related reporting requirement.

Existing law establishes an ongoing task force to study emergency preparedness and mitigation strategies for prescription drug shortages. The bill adds the Human Services Committee chairpersons to the task force and makes them the task force's chairpersons. Among other things, it sets requirements for member terms and new deadlines to appoint members and meet.

The bill requires the Department of Economic and Community Development (DECD) to expand the Strategic Supply Chain Initiative to include efforts to prevent or mitigate prescription drug shortages.

The bill also generally prohibits drug manufacturers from (1) limiting access to 340B drugs (see below) for pharmacies contracting with covered entities or (2) requiring pharmacies or covered entities to submit claims or utilization data as a condition for receiving 340B drugs. It also establishes a hearing process and penalties for violators.

EFFECTIVE DATE: Upon passage, except provisions on the Strategic Supply Chain Initiative and supplemental rebates are effective July 1, 2026.

§ 3 — SUPPLEMENTAL REBATES

The federal Medicaid Drug Rebate Program requires a drug manufacturer to enter into a rebate agreement in exchange for Medicaid coverage of most of the manufacturer's drugs. States may negotiate with drug manufacturers for supplemental rebates in addition to federal rebates.

Starting July 1, 2026, the bill requires DSS to develop and implement a plan to increase the number of supplemental rebates by at least 20%. It also requires DSS to report to the Human Services Committee annually by January 15 on the number of (1) prescription rebates received the previous calendar year and any increase or decrease from the prior calendar year and (2) supplemental rebates negotiated by DSS and any increase or decrease from the prior calendar year.

§ 1 — TASK FORCE ON PRESCRIPTION DRUG SHORTAGES

Under current law, the House speaker and Senate president pro tempore select the taskforce's chairpersons. The bill adds the Human Services Committee chairpersons to the task force and makes them the taskforce's chairpersons. It changes responsibility for administrative staffing for the task force from the General Law Committee to the Human Services Committee.

Existing law requires legislative leaders to appoint eight task force members and allows the task force's chairpersons to appoint more members as they find necessary (in addition to certain ex-officio members). Under the bill, these appointed members have two-year terms, but subsequent appointments are made on a staggered basis, as follows:

1. two-year terms for members appointed by the House Speaker, Senate president pro tempore, House majority leader, and the Human Services Committee chairpersons; and

2. three-year terms for members appointed by the Senate majority leader, House minority leader, and Senate minority leader.

Under the bill, all initial appointments must be made by August 1, 2026, and the task force must hold its first meeting by September 1, 2026. Its annual report is due January 1, 2027, to the General Law, Human Services, and Insurance and Real Estate, and Public Health committees.

§ 2 — STRATEGIC SUPPLY CHAIN INITIATIVE

The bill requires the DECD commissioner to expand the department's Strategic Supply Chain Initiative to include efforts to prevent or mitigate prescription drug shortages, including task force recommendations (see above).

Under the bill, this initiative is a DECD-administered program to help state-based companies increase their production capacity to win new business and attract out-of-state and international supply chain operations.

§§ 4 & 5 — 340B PROGRAM

Section 340B of the federal Public Health Service Act (the 340B Drug Pricing Program) requires drug manufacturers participating in Medicaid to sell certain outpatient prescription drugs at discounted prices to health care organizations that care for uninsured and low-income patients. Pharmacies may contract with 340B-participating healthcare organizations to also purchase reduced-price outpatient drugs.

The bill prohibits drug manufacturers (including biologics manufacturers), and their agents or affiliates, from directly or indirectly taking any of the following actions:

1. denying or limiting access to 340B drugs for a pharmacy contracting or otherwise working with a covered entity (see below) to obtain them on the entity's behalf, unless the pharmacy's receipt of a drug is federally prohibited, or

2. requiring a covered entity, or pharmacy contracted with a

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

For these restrictions, "covered entities" are the UConn Health Center, federally qualified health centers, family planning clinics, and Ryan White clinics (clinics that receive specified HIV and AIDS-related federal funding). (Federal law allows other organizations to participate in the 340B program, such as hospitals that serve a disproportionate number of low-income patients.)

Also, under these provisions, 340B drugs are those that a 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 subjects violators to civil penalties (see below). It also requires the Department of Consumer Protection (DCP) commissioner to adopt implementing regulations.

The bill specifies that its 340B provisions must not be applied in a way that conflicts with, or is less restrictive than, applicable state and federal laws (including the federal law on drug risk evaluation and mitigation strategies (REMSs); see BACKGROUND).

Violations

Beginning July 1, 2026, the bill subjects drug manufacturers (or their agents or affiliates) to a civil penalty of up to $50,000 per violation if the DCP commissioner has a reasonable belief, based on received information, that they have violated these provisions or regulations.

The commissioner must issue the violation notice by first-class mail or personal service, and it must include:

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

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

3. a description of the activity to cease;

4. the penalty amount that may be imposed; and

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

Under the bill, DCP must hold requested hearings as contested case hearings under the Uniform Administrative Procedure Act (UAPA). If after a hearing, DCP finds by a preponderance of the evidence that there was a violation or that the entity violated any DCP order, the department must issue a final cease and desist order in addition to any civil penalty imposed.

If the manufacturer, agent, or affiliate does not timely request a hearing, DCP must issue a cease and desist order or impose a civil penalty.

BACKGROUND

REMS

Federal law authorizes the FDA to require a drug safety program (called "REMS") for certain prescription medications with serious safety concerns to ensure that the medications are used safely and the risks of serious or life-threatening side effects are minimized for patients, pharmacies, and providers (21 U.S.C. § 355-1).

COMMITTEE ACTION

Human Services Committee

Joint Favorable Substitute
Yea 15 Nay 8 (03/19/2026)