

## Assembly Bill No. 265

### CHAPTER 611

An act to add Division 114 (commencing with Section 132000) to the Health and Safety Code, relating to public health.

[Approved by Governor October 9, 2017. Filed with  
Secretary of State October 9, 2017.]

#### LEGISLATIVE COUNSEL'S DIGEST

AB 265, Wood. Prescription drugs: prohibition on price discount.

Existing law regulates the packaging, labeling, and advertising of drugs and devices.

This bill would generally prohibit a person who manufactures a prescription drug from offering in California any discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses associated with his or her health insurance, health care service plan, or other health coverage, including, but not limited to, a copayment, coinsurance, or deductible, for any prescription drug if a lower cost generic drug is covered under the individual's health insurance, health care service plan, or other health coverage on a lower cost-sharing tier that is designated as therapeutically equivalent to the prescription drug manufactured by that person or if the active ingredients of the drug are contained in products regulated by the federal Food and Drug Administration, are available without prescription at a lower cost, and are not otherwise contraindicated for the condition for which the prescription drug is approved. The bill would specify exceptions to these prohibitions, including, among other things, if the individual has completed any applicable step therapy or prior authorization for the prescription drug as mandated by the individual's health insurer, health care service plan, or other health coverage, or if a rebate is received by a state agency. The bill would also clarify that it does not prohibit an entity, including a manufacturer of prescription drugs, from offering a pharmaceutical product free of any cost, if the product is free of cost to both the patient and his or her health insurer, health care service plan, or other health coverage, that it does not affect a pharmacist's ability to substitute a prescription drug, and that it does not prohibit or limit assistance to a patient provided by an independent charity patient assistance program, as defined.

*The people of the State of California do enact as follows:*

SECTION 1. Division 114 (commencing with Section 132000) is added to the Health and Safety Code, to read:

## DIVISION 114. PRESCRIPTION DRUG DISCOUNT PROHIBITION

132000. (a) Except as provided in Section 132004, a person who manufactures a prescription drug shall not offer in the state a discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses associated with his or her health insurance, health care service plan, or other health coverage, including, but not limited to, a copayment, coinsurance, or deductible, for a prescription drug if a lower cost generic drug is covered under the individual's health insurance, health care service plan, or other health coverage on a lower cost-sharing tier that is designated to be therapeutically equivalent as indicated by the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations."

(b) The prohibition in subdivision (a) shall not apply to a branded prescription drug, until the time that the first drug designated in the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" as therapeutically equivalent to that branded prescription drug has been nationally available for three calendar months.

132002. Except as provided in Section 132004, a person who manufactures a prescription drug shall not offer in the state a discount, repayment, product voucher, or other reduction in the individual's out-of-pocket expenses associated with his or her health insurance, health care service plan, or other health coverage, including, but not limited to, a copayment, coinsurance, or deductible, for a prescription drug if the active ingredients of the drug are contained in products regulated by the federal Food and Drug Administration, are available without prescription at a lower cost, and are not otherwise contraindicated for treatment of the condition for which the prescription drug is approved.

132004. The prohibitions in Sections 132000 and 132002 shall not apply to any of the following:

(a) A discount, repayment, product voucher, or other payment to a patient or another person on the patient's behalf for a prescription drug required under a United States Food and Drug Administration Risk Evaluation and Mitigation Strategy for the purpose of monitoring or facilitating the use of that prescription drug in a manner consistent with the approved labeling of the prescription drug.

(b) A single-tablet drug regimen for treatment or prevention of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS) that is as effective as a multitablet regimen, unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally effective or more effective and is more likely to result in adherence to the drug regimen.

(c) The individual has completed any applicable step therapy or prior authorization requirements for the branded prescription drug as mandated by the individual's health insurer, health care service plan, or other health coverage.

(d) A discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses is not associated with his or her health insurance, health care service plan, or other health coverage.

(e) Rebates received by a state agency.

132006. This division does not prohibit an entity, including an entity that manufactures prescription drugs or a patient assistance program that is solely funded by one or more manufacturers, from offering a pharmaceutical product free of any cost, if the product is free of cost to both the patient and his or her health insurer, health care service plan, or other health coverage.

132008. (a) This division shall not be deemed to affect a pharmacist's ability to substitute a prescription drug pursuant to Section 4073 of the Business and Professions Code.

(b) (1) This division shall not prohibit or limit assistance to a patient provided by an independent charity patient assistance program.

(2) For purposes of this section, "independent charity patient assistance program" means a program that meets all of the following requirements:

(A) The program does not allow a pharmaceutical manufacturer or an affiliate of the manufacturer, including, but not limited to, an employee, agent, officer, shareholder, contractor, wholesaler, distributor, or pharmacy benefits manager, to exert any direct or indirect influence or control over the charity or subsidy program.

(B) Assistance is awarded in a truly independent manner that severs any link between a pharmaceutical manufacturer's funding and the beneficiary.

(C) Assistance is awarded without regard to the pharmaceutical manufacturer's interest and without regard to the beneficiary's choice of product, provider, practitioner, supplier, health insurance, health care service plan, or other health coverage.

(D) Assistance is awarded based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner.

(E) The pharmaceutical manufacturer does not solicit or receive data from the program that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.