

New California law limits drug manufacturer co-pay cards and other discounts in California

October 16, 2017

In the most recent salvo by states eager to show an effort to contain prescription drug costs, California's governor has signed into law a [bill that will prohibit](#), with some limited exceptions, pharmaceutical manufacturers from offering patients co-pay assistance and other common discounts off their out-of-pocket insurance expenses for prescription drugs if a lower-cost equivalent is covered by the individual's insurance or the active ingredient for the drug is available at a lower cost without a prescription. For those drugs, the new law prohibits manufacturers from offering any discounts, repayments, product vouchers, or other reductions in an individual's out-of-pocket expenses. The new prohibition, however, does not apply to free product or to assistance provided to a patient by an "independent charity patient assistance program."

A Limited Prohibition

The new law (AB-265) prohibits pharmaceutical manufacturers from offering discounts on patients' out-of-pocket expenses associated with their health insurance or other health care coverage, but only if one of two conditions is triggered:

1. a lower cost generic drug that the FDA has designated as therapeutically equivalent to the brand name drug and that drug is covered under the individual's health insurance plan on a lower cost-sharing tier¹; or
2. the active ingredients in the brand name drug are contained in products that are available without prescription at a lower cost, and that are not otherwise contraindicated for treatment of the condition for which the prescription drug is approved.

Escape Hatches

Even when the prohibition on patient assistance applies to a drug, the law includes exceptions that would allow pharmaceutical manufacturers to offer discounts or other financial assistance if:

- the individual has completed applicable step therapy or prior authorization requirements for the branded prescription drug, as mandated by the individual's health insurer;

¹ The prohibition on discounts for branded prescription drugs with a therapeutic equivalent does not take effect until the therapeutically equivalent drug has been nationally available for three calendar months.

- such payments are required under an FDA Risk Evaluation and Mitigation Strategy (REMS) for the purpose of monitoring or facilitating the use of the prescription drug, consistent with the approved labeling of the prescription drug;
- the discount is for a single-tablet drug regimen for the treatment of HIV/AIDS that is as effective as a multi-tablet regimen, unless the multi-tablet regimen is clinically equally effective or more effective and is more likely to result in adherence to the drug regimen;
- the discount is not associated with an individual's health insurance, health service plan, or other health coverage (e.g., a discount for self-pay patients); or
- the discount is a rebate received by a state agency.

The law also does not prohibit manufacturers from offering pharmaceutical product free of cost, whether as part of a patient assistance program or not, so long as the product is free of cost to both the patient and the patient's insurer.

Independent Charities Allowed – But Strictly Defined

The new prohibition does not apply to discounts or other financial assistance provided through an independent charity patient assistance program, but imposes a strict definition of independence that is consistent with the hard line the federal government has taken in assessing charitable patient assistance programs under the federal anti-kickback statute. Under the California law, assistance through independent charity patient assistance programs is permitted only if:

- the independent PAP does not allow a pharmaceutical manufacturer or affiliate (including employees, shareholders, wholesalers, and pharmacy benefit managers) to exert any direct or indirect influence or control over the charity or subsidy program;
- the independent PAP awards assistance in a truly independent manner that severs any link between a manufacturer's funding and the beneficiary;
- the independent PAP awards assistance without regard to the manufacturer's interest and without regard to the beneficiary's choice of product, provider, practitioner, or insurance;
- the independent PAP awards assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied consistently; and
- the pharmaceutical manufacturer does not solicit or receive data from the independent PAP that would facilitate the manufacturer's correlation of the amount or frequency of its donations with the number of subsidized prescriptions for its products.

Although the California law does not specifically require that the independent PAP be sponsored by a 501(c) charity, the law's similarities to the recommendations made in [OIG's 2005 Special Advisory Bulletin](#) may be read to require the independent PAP to be sponsored by a bona fide 501(c) charity.

Practical Compliance Complications

California's AB-265 shares some features with a law in Massachusetts that allows co-pay assistance and other reductions in a patient's out-of-pocket expenses on prescription drugs unless there is an AB-rated generic available.² However, California's law prohibits discounts when there is a prescription drug designated as therapeutically equivalent and covered by the

² M.G.L. ch. 175H, § 3.

individual's insurer on a lower cost-sharing tier. This seemingly more narrow application presents manufacturers with a decision – they may either choose to screen out all California residents from receiving discounts on prescription drugs with therapeutic equivalents or they do so based on a patient-specific determination of the individual's insurance coverage. The former approach is simpler to administer, but may be over-inclusive. The latter, however, presents operational burdens that may outweigh any benefit.

The California law, however, creates an exception for the restriction that is absent from the Massachusetts law: manufacturers may continue to offer assistance to patients who can satisfy their insurance plan's step therapy or prior authorization requirements for the prescription drug. Applying this exception, however, would present the same dilemma above: adopt a uniform approach or make the effort to determine whether each patient is eligible for the exception.

Another practical issue for manufacturers that is not addressed by the law is how to determine whether the alternative drug or product is available at a lower cost than the prescription drug. The law does not clarify whether the lower cost calculation is based on dosage; based on the cost of the drug, wholesale or otherwise, as compared to the over-the-counter price; or based on the patient's co-pay as compared to the over-the-counter price.

While future interpretations or regulations may clarify some of these concerns, we encourage all drug manufacturers to review the new California law and put appropriate policies, procedures, and training in place to promote compliance with the new limitations. California's AB-265 appears to go into effect on January 1, 2018.

If you have any questions related to California AB-265, please contact one of the lawyers listed on this client alert, or the Hogan Lovells lawyer with whom you normally work.

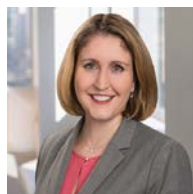
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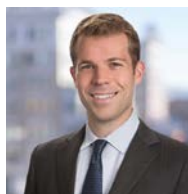
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