

Client Alert

FDA & Life Sciences Practice Group

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Massachusetts Authorizes Pharmaceutical Companies to Offer Drug Coupons to Massachusetts Residents

On July 8, 2012, Massachusetts Governor Deval Patrick signed into law H.4200, which makes appropriations for the state's fiscal year 2013 budget, and which revises the state's Health Care False Claims Act (M.G.L. c. 175H, s. 3) to now permit pharmaceutical manufacturers to offer drug coupons to Massachusetts residents. The revisions, which relax Massachusetts' strict prohibition on offering or paying any remuneration in cash or in-kind to induce any person to purchase, order, or arrange for or recommend the purchase or order of any good or item for which payment is or may be made by *any health care insurer* (not just government funded health care programs, like Medicare and Medicaid), take effect immediately.

Specifically, sections 128 through 130 of H.4200 provide that Massachusetts' stringent kickback prohibition does not apply to:

any discount or free product vouchers that a retail pharmacy provides to a consumer in connection with a pharmacy service, item or prescription transfer offer or to any discount, rebate, product voucher or other reduction in an individual's out-of-pocket expenses, including co-payments and deductibles, on: (i) any biological product . . . , or (ii) any prescription drug provided by a pharmaceutical manufacturing company . . . , that is made available to an individual if the discount, rebate, product voucher or other reduction is provided directly or electronically to the individual or through a point of sale or mail-in rebate, or through similar means; provided, however, that a pharmaceutical manufacturing company shall not exclude or favor any pharmacy in the redemption of such discount, rebate, product voucher or other expense reduction offer to a consumer.

The relaxation of the prohibition, however, does not apply to discounts, rebates, product vouchers, or other reductions in an individual's out-of-pocket expenses (including co-pays and deductibles), for any prescription drug that has an AB rated generic equivalent (as determined by the Food and Drug Administration).

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The bill also provides that the relaxed restrictions sunset on July 1, 2015. In the interim, the Massachusetts Division of Health Care Finance and Policy must conduct an analysis of the impact on health care costs of the use of discounts, rebates, product vouchers, or other reductions for biological products and prescription drugs during the period August 1, 2012 to July 31, 2014. The report must include, among other things: (1) the total number and value of coupons and discounts redeemed in Massachusetts; (2) an analysis of the types of biological products and prescription drugs for which coupons and discounts were most frequently redeemed; (3) a comparison of any change in utilization of generic versus brand name prescription drugs; (4) a comparison of any change in utilization of among therapeutically-equivalent brand name drugs; (5) the effect on patient adherence to prescribed drugs; (6) an analysis of the availability of the coupons or discounts upon renewals; and (7) an analysis of the cost impact to consumers upon expiration of the coupon or discount. In conducting its analysis, the Division may require that manufacturers report on the number and types of coupons they issue that have been redeemed in Massachusetts. The Division must complete its analysis by December 31, 2014. Presumably, the Massachusetts legislature will use the analysis as it determines whether to extend the sunset date for the relaxed restrictions.

Implications for Manufacturers of Prescription Drugs and Biological Products

Under the relaxed restrictions to the Massachusetts Health Care False Claims Act, manufacturers will now be able to provide coupons, vouchers, and other price reductions for biological products and prescription drugs under certain circumstances. The statutory language, however, is less-than-clear regarding what exactly would be the appropriate circumstances for distributing such price reductions. For example, it is unclear whether manufacturers may distribute coupons, vouchers, etc., to Massachusetts physicians and other prescribers to be passed on for free to patients, given the requirement that such items be provided “directly or electronically to the individual or through a point of sale or mail-in rebate, or through similar means.” It is possible that “similar means” could be interpreted to permit distribution of such price reductions to prescribers, who would then provide them “directly” to patients. This and other ambiguities should be given careful consideration in light of the significant criminal penalties associated with violating the Massachusetts Health Care False Claims Act.

In contrast, it is clearer that any coupons, vouchers, and other price reductions that manufacturers offer to patients must be able to be redeemed at any pharmacy under the same terms and conditions. Similarly, manufacturers will need to ensure that any such items they distribute to Massachusetts residents are not for drugs that have an FDA AB rated generic equivalent.

In addition, it remains unclear how the Massachusetts Division of Health Care Finance and Policy will proceed to conduct its mandated analysis of coupons and vouchers redeemed in Massachusetts, including what might be the required deadline(s) and format for manufacturers to submit information on the number and types of coupons, vouchers, etc., they issue that have been redeemed in Massachusetts. Manufacturers, however, should begin to consider how they would comply with such a requirement, including how they will develop the capability to accurately track information about coupons, vouchers, and other price reductions they make available to Massachusetts residents. Manufacturers should also be cognizant of how the Division will use the information to conduct its analyses (described above), which will be made available to state legislators, and consider instituting a coupon and voucher policy for Massachusetts with that important consideration in mind.

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