

## Massachusetts “All Payor” Anti-Kickback Statute Amended to Not Prohibit Certain Drug and Biologic Coupons and Discount Programs

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On July 8, 2012, Massachusetts Governor Deval Patrick signed into law the fiscal year 2013 state budget<sup>1</sup> (“**Budget**”), which included, among other things, amendments to the Massachusetts “all-payor” anti-kickback statute—Mass. Gen. Laws ch. 175H §3 (“**Massachusetts Anti-Kickback Statute**” or “**Statute**”). The Massachusetts Anti-Kickback Statute generally prohibits the solicitation of, and improper inducements for the use of, goods, facilities, services, or products for which payment is or may be made, in whole or in part, by a health care insurer. The changes effectuated by the Budget may have significant implications for pharmaceutical coupons/discount programs.

The Budget included an exception to the Statute for certain coupons. Specifically, the following language was added to the Statute:

[The Massachusetts Anti-Kickback Statute] shall 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 [any biologic product or prescription drug] 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

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<sup>1</sup> See Conference Committee, Fiscal Year 2013 Budget Recommendations, H. 4200, §§ 129-31, 201, 226 (Mass. 2012), available at <http://www.malegislature.gov/Budget/FY2013/Senate/ChamberActions>. The bill was approved by the Massachusetts House of Representatives and Senate on June 28, 2012, and then signed by the Governor on July 8, 2012.

or favor any pharmacy in the redemption of such discount, rebate, product voucher or other expense reduction offer to a consumer.<sup>2</sup>

With respect to the new exception, the Budget further clarified its scope. Specifically, this exception

shall not: (i) restrict a pharmaceutical manufacturing company with regard to how it distributes a prescription drug, biologic or vaccine; (ii) restrict a carrier or a health maintenance organization, ... with regard to how its plan design will treat such discounts, rebates, product voucher or other reduction in out-of-pocket expenses; or (iii) affect the obligations of practitioners and pharmacists pursuant to the [Massachusetts] generic substitution statute.<sup>3</sup>

However, the amendment enacted to the Massachusetts Anti-Kickback Statute includes certain restrictions on the types of discounts, coupons, and free product vouchers that are excepted. Specifically, the Budget provision amending the Statute prohibits manufacturers “from offering any discount, rebate, product voucher or other reduction in an individual’s out-of-pocket expenses, including co-payments and deductibles, for any prescription drug that has an AB rated generic equivalent as determined by the United States Food and Drug Administration.”<sup>4</sup> Additionally, the amendment states that “nothing in this section shall be deemed to require or allow the use or disclosure of health information in any manner that does not otherwise comply with [the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)].”<sup>5</sup>

Significantly, the Budget adds a “sunset” date of **July 1, 2015**, to the Statute.<sup>6</sup> In the interim, the Massachusetts Division of Health Care Finance and Policy (“**Division**”), in consultation with the Massachusetts Department of Public Health, has certain obligations to analyze how the use of discounts and rebate, product voucher, or other reductions now permitted under the amendment to the Statute will affect the impact on health care costs for the period from August 1, 2012, to July 31, 2014. The Division is required to issue a report to the Massachusetts Legislature addressing at least the following:

(i) the total number coupons and discounts redeemed in the commonwealth; (ii) the total value of coupons and discounts redeemed in the commonwealth; (iii) an analysis of the types of biological products and prescription drugs for which coupons and discounts were most frequently redeemed; (iv) a comparison of any change in utilization of generic versus brand name prescription drugs; (v) a comparison of any change in utilization of among therapeutically-equivalent brand name drugs; (vi) the effect on patient adherence to prescribed drugs; (vii) patient access to innovative therapies; (viii) an analysis of the availability of the coupons or

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<sup>2</sup> *Id.* § 130.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* §§ 231, 226.

discounts upon renewals; (ix) an analysis of the cost impact to consumers upon expiration of the coupon or discount; (x) an analysis of the impact on commercial health insurance premiums, attributed to both employers and individuals; (xi) an analysis of the impact on any health care cost containment goals adopted by the commonwealth; (xii) and an analysis of the impact on premiums associated with the group insurance commission.<sup>7</sup>

The Division may contract with a vendor to conduct this analysis. In connection with the analysis, the Division “may require that manufacturers of biological products and prescription drugs report on the number and types of coupons which such manufacturers have issued and which have been redeemed in the commonwealth.” Upon completion of the analysis, the Division will file a findings report with the Massachusetts Legislature.

### Key Considerations

- In light of the amendments to the Massachusetts Anti-Kickback Statute, pharmaceutical and biologic manufacturers should reevaluate the structure and organization of any coupons, vouchers, and/or discount program terms with respect to Massachusetts.<sup>8</sup>
- Specifically, carve-outs should be reviewed product by product and program by program, keeping in mind:
  - statutory restrictions on the exception (e.g., restriction on generic drug coupons, HIPAA),
  - the statutory language (e.g., what does it mean that a “retail pharmacy provides” the coupon?),
  - the “sunset date,”
  - other potentially applicable laws, and
  - recent enforcement trends regarding coupons.
- Manufacturers should also consider updating relevant policies, procedures, training documents, and applicable vendor contracts.

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*This Client Alert was authored by **Kathleen A. Peterson** and **Wendy C. Goldstein**. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

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<sup>7</sup> *Id.* § 201.

<sup>8</sup> Separately, patients and prescribers should be aware that the amendment to the Massachusetts Anti-Kickback Statute does not mean that all manufacturer coupons are now valid in Massachusetts—the validity of any particular coupon is ultimately determined by the program terms, and some manufacturers may continue to carve out Massachusetts for some or all of their product coupons.

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