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E-ALERT | Health Care

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HEALTH CARE REFORM: 340B DRUG PRICING PROGRAM

On March 23, 2010, President Obama signed into law Pub. L. No. 111-148, the Patient Protection and Affordable Care Act (PPACA). Shortly afterwards, on March 30, 2010, President Obama signed into law Pub. L. No. 111-152, the Health Care and Education Affordability Reconciliation Act of 2010 (the Reconciliation Amendments), amending PPACA. PPACA, as now amended by the Reconciliation Amendments (collectively the Act), will have far-reaching effects for the entire health care sector.

This alert, part of a series explaining the impact of the Act on life sciences companies, will summarize the provisions of the Act relating to changes to the drug pricing program under section 340B of the Public Health Service Act (the 340B Program). These provisions can be found in sections 7101-7103 of PPACA and 2302 of the Reconciliation Amendments.

Executive Summary

- The Act changes the 340B Program by expanding the universe of covered entities, deepening required discounts, and creating additional compliance obligations and dispute resolution mechanisms.
- The Act does not include some of the major changes to the 340B Program contemplated in earlier versions of health care reform legislation (including expansion to inpatient drugs and relaxation of the group purchasing organization (GPO) prohibition).

Amendments to 340B of the Public Health Service Act

- **NEW 340B PARTICIPANTS.** The Act extends participation in 340B discounts to new entities, including certain additional children's hospitals, cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals (collectively New 340B Participants).
- **NEW DISCOUNTS AMOUNTS.** The Act makes changes to the Medicaid rebate amounts which determine the amount of the 340B discount, increasing the minimum manufacturer rebate on innovator products from 15.1% to 23.1% of average manufacturer price (AMP) and increasing the manufacturer rebate on non-innovator products from 11% to 13% of AMP.
- **EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES.** Under the Act, New 340B Participants, are not entitled to 340B discounts on "orphan drugs" designated by the Food and Drug Administration for the treatment of a rare disease or condition.
- **HEIGHTENED COMPLIANCE MEASURES.** The Act requires the Secretary of the Department of Health and Human Services (HHS) to create additional mechanisms for monitoring and enforcing manufacturer and covered entity compliance, and provides for new sanctions for noncompliance with 340B Program requirements. Heightened compliance requirements noted in the Act include

requirements for manufacturers to provide covered entities with access to previously unpublished manufacturers' ceiling prices, and to "true up" for changes in Medicaid calculations.

- DISPUTE RESOLUTION PROCESS. HHS must promulgate regulations within 180 days of PPACA's enactment to establish and implement an administrative process for the resolution of overcharge claims by covered entities and claims by manufacturers alleging duplicate discounting or the unauthorized resale or transfer of covered outpatient drugs.
- GAO REPORT. Within 18 months of enactment, the Government Accountability Office (GAO) must submit a report to Congress to address health care services provided by covered entities, the expansion of the 340B Program, the impact of the 340B Program on patient access, and the use of funds by covered entities.

Effective Date

- The amendments to the 340B Program are effective as of January 1, 2010 and apply to drugs purchased on or after January 1, 2010.

Outstanding Issues and Implementation Challenges

- HHS must clarify how and when the Act's revisions to the Medicaid rebate calculation will affect 340B prices and must determine how to implement changes to required discounts/ceiling prices.
- HHS must announce whether the changes to the 340B Program will necessitate the execution of new manufacturer agreements.
- HHS must clarify how and when it will implement the language in the Act regarding manufacturer "true-up" of the discounts provided to covered entities if and when the manufacturer restates the prices reported for Medicaid rebate purposes.
- It is not clear whether the Act treats orphan drugs as "covered outpatient drugs" with respect to certain covered entities but not with respect to others. If orphan drugs are to be treated differently depending on the acquiring covered entity, HHS must develop a mechanism to take this difference into account.
- HHS must determine how to implement the inclusion of New 340B Participants.
- HHS must establish and implement complex new compliance and dispute resolution processes, including determining how to provide covered entities with access to ceiling prices for covered drugs in a manner that assures the protection of manufacturers' pricing data and how to administer any true up obligations.

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There are many detailed changes in the Act. We would be pleased to discuss these changes and their potential impact on your industry, company, or customers.

If you have any questions concerning the material discussed in this client alert, please contact the attorneys listed below:

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