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E-ALERT | Health Care

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HEALTH CARE REFORM: MEDICAID PRESCRIPTION DRUG REIMBURSEMENT

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 Medicaid prescription drug coverage. These provisions can be found in sections 2501 to 2503 of PPACA and sections 1101 and 1206 of the Reconciliation Amendments.

Executive Summary

- **MEDICAID REBATES.** The Act increases the minimum manufacturer rebate on innovator products from 15.1% to 23.1% of average manufacturer price (AMP) and increases the manufacturer rebate on non-innovator products from 11% to 13% of AMP. It also provides a new methodology for calculating the additional rebate on new formulations of innovator drugs and caps the maximum total rebate amount at 100% of AMP. Finally, it requires manufacturers to pay Medicaid drug rebates for drug utilization by Medicaid managed care organization (MCO) enrollees.
- **AVERAGE MANUFACTURER PRICE.** The Act revises the definition of AMP to apply to "retail community pharmacies," rather than the retail pharmacy class of trade, and revises the list of entities whose prices are statutorily excluded from AMP.
- **PUBLIC DISCLOSURE.** The Act requires the Centers for Medicare & Medicaid Services (CMS) to disclose online the weighted average of the most recently reported monthly AMP for multiple-source drugs.
- **FEDERAL UPPER LIMIT (FUL).** The Act changes the FUL for multiple-source drugs to no less than 175% of the weighted average of the most recently reported monthly AMP for products that are available for purchase by retail community pharmacies on a nationwide basis.
- **ELIMINATION OF EXCLUDABILITY FROM COVERAGE FOR CERTAIN CLASSES OF DRUGS.** The Act removes smoking cessation drugs, barbiturates, and benzodiazapines from Medicaid's excludable drug list.

Drug Manufacturer Rebates

- **CURRENT LAW.** Under current law, drug manufacturers must pay a basic rebate. For innovator products, the basic rebate is the greater of 15.1% of AMP or the difference between AMP and the best price for the product. For non-innovator products, the basic rebate is 11% of AMP. In addition, manufacturers must pay an additional rebate on an innovator product if the increase in the product's AMP over its base date AMP is greater than the increase in the urban consumer price index (CPI-U) during the same period of time.
- **INCREASED MINIMUM BASIC REBATE.** Under the Act, the minimum basic rebate for innovator products will increase to 23.1% of AMP. The Act includes an exception for clotting factors and drugs approved exclusively for pediatric indications. For these drugs, the minimum basic rebate will increase to 17.1%. The minimum rebate for non-innovator products will increase to 13% of AMP.
- **INCREASED ADDITIONAL REBATE FOR LINE EXTENSIONS.** The Act increases the additional rebate (paid in cases where AMP rises faster than the CPI-U) for new formulations of oral solid dosage forms of innovator drugs, referred to as "line extensions." Under the Act, the additional rebate for a line extension is the greater of (1) the additional rebate under current law or (2) the product of the AMP for the line extension and the highest additional rebate (calculated as a percentage of AMP) for any strength of the original drug.
- **MAXIMUM REBATE.** The Act caps the total rebate (basic plus additional rebate) for an innovator drug at 100% of AMP.
- **REBATES ON MEDICAID MANAGED CARE UTILIZATION.** Under the Act, manufacturers will be required to pay rebates on drugs dispensed to individuals enrolled in Medicaid MCOs. Medicaid MCOs will also be required to report their drug utilization to states, which will report these data to CMS.

Calculation of Average Manufacturer Price

- **CURRENT LAW.** Current law defines AMP as "the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade." CMS defines a wholesaler as "any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug." It also defines the retail pharmacy class of trade to include sales to entities that dispense drugs to the general public, including "any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."
- **REVISED DEFINITION.** The Act narrows the definition of AMP to sales to "retail community pharmacies," rather than the retail pharmacy class of trade, and to wholesalers for drugs distributed to "retail community pharmacies." Retail community pharmacies include independent pharmacies, chain pharmacies, supermarket pharmacies, and mass merchandisers that are licensed by the state as a pharmacy and that dispense medications to the general public at retail prices. Retail community pharmacies do not include mail-order pharmacies, hospital pharmacies, clinics, charitable pharmacies, government pharmacies, or pharmacy benefit managers (PBMs). The Act also narrows the definition of wholesaler to an entity that actually conducts wholesale distribution of drugs, including manufacturers, repackagers, chain drug warehouses, and distributors. Because the new definition of AMP excludes some of the entities that tend to be able to negotiate greater price concessions, this revised definition is likely to result in higher AMPs and higher rebates.

- EXCLUSIONS FROM AMP. The Act specifies a number of payments that are excluded from AMP, thereby expanding the list of statutory exclusions from AMP. In addition to customary prompt pay discounts and bona fide service fees paid to wholesalers or retail community pharmacies (such as distribution services, inventory management agreement services, stocking allowances, and administrative services), the Act now excludes from AMP reimbursements for recalled, expired, damaged, and returned goods (and any associated costs). Also specifically excluded are payments from and price concessions offered to PBMs, MCOs, health maintenance organizations, insurers, hospitals, clinics, mail-order pharmacies, long-term care providers, manufacturers, and any other entity that is not a wholesaler or retail community pharmacy. Notwithstanding these exclusions, rebates, discounts, payments and other financial transactions that are received by or passed through to retail community pharmacies are included in AMP.
- SMOOTHING. The Act requires CMS to establish a smoothing process for AMP similar to that used by the Medicare Part B program regarding average sales price (ASP) data. This requirement appears to codify CMS's existing requirement that manufacturers "estimate the impact of [their] lagged price concessions using a 12-month rolling average" in calculating AMP.
- PART D COVERAGE GAP. Under the Act, manufacturers will be required to offer a 50% discount on the negotiated price of branded drugs to Medicare Part D beneficiaries in the coverage gap (donut hole) who do not qualify for the low-income subsidy. These coverage gap discounts are excluded from AMP and best price.

Disclosures to the Public

- CURRENT LAW. Current law requires CMS to provide AMP information to state Medicaid agencies and post reported AMPs on a website accessible to the public; these requirements have been enjoined by a court.
- REVISED DISCLOSURES. The Act requires CMS to disclose online the weighted average of the most recently reported monthly AMP for multiple-source drugs, rather than each manufacturer's AMP. The Act also requires manufacturers to report to CMS the total number of units used to calculate the monthly AMP for covered multiple-source outpatient drugs so CMS may determine the weighted averages.

Federal Upper Limit

- Current Law. Current law requires CMS to establish an upper reimbursement limit for multiple source drugs, known as the federal upper limit (FUL). The Deficit Reduction Act of 2005 (DRA) set the FUL at 250% of AMP for the least costly therapeutic equivalent when the Food and Drug Administration (FDA) has rated at least two drugs to be therapeutically and pharmaceutically equivalent, although this requirement is not yet in force due to ongoing litigation regarding the implementing rule issued by CMS.
- Revised FUL. Under the Act, the FUL applies to multiple-source drugs when FDA has rated at least three drugs to be therapeutically and pharmaceutically equivalent. The Act further provides that the FUL for multiple-source drugs will be no less than 175% of the weighted average (based on utilization) of the most recently reported monthly AMP for products that are available for purchase by retail community pharmacies on a nationwide basis.

Elimination of Excludability from Coverage for Certain Classes of Drugs

- CURRENT LAW. Current law excludes certain classes of drugs from mandatory Medicaid coverage, giving states the option of whether to cover those classes.

- **ELIMINATION OF EXCLUDABILITY.** The Act removes smoking cessation drugs, barbiturates, and benzodiazapines from Medicaid's excludable drug list.

Effective Dates

- The changes to the rebate amounts, including the alternative additional rebate for line extensions, are effective for rebate periods beginning after December 31, 2009.
- The requirement that manufacturers pay rebates on drugs dispensed to Medicaid MCO enrollees appears to be effective as of March 23, 2010.
- The changes to the FUL are effective October 1, 2010.
- The removal of certain drugs from Medicaid's excludable drug list is effective January 1, 2014.

Outstanding Issues and Implementation Challenges

- **LINE EXTENSIONS.** The revisions to the additional rebate for line extensions leave open a number of questions regarding the definition of a line extension and how the additional rebate is determined if the original product is no longer marketed, or if it is marketed by a company other than the company that markets the line extension.
- **FUL.** The fact that the FUL will be "no less than" 175% of the weighted average of AMP suggests that CMS could exercise its discretion to establish a higher FUL.
- **DETERMINATION OF AMP.** Because price concessions are included in AMP if they are received by or passed through to retail community pharmacies, customary prompt pay discounts would presumably be included in AMP if they are made to or passed through to a retail community pharmacy. The Act does not specify whether manufacturers may assume that these discounts and service fees have not been passed on or whether they are required to determine conclusively that they have not been passed through to a retail community pharmacy.
- **BASE DATE AMPS.** It is not clear whether CMS will allow manufacturers the opportunity to restate base date AMPs using the revised AMP definition. Unless the base date AMP can be restated, the difference between AMP and base date AMP is likely to increase, resulting in greater additional rebates.
- **MEDICAID MANAGED CARE.** While the percentage of Medicaid beneficiary enrollment in MCOs is generally high, some states may have exempted their Medicaid drug benefits from managed care arrangements in order to receive rebates. Thus, it is not clear how much additional utilization will now be eligible for rebates.
- **POLICIES AND PROCEDURES.** As a result of the changes to the definition of AMP and the statutory exclusions, drug manufacturers will likely need to revise their government price reporting policies and standard operating procedures for calculating AMP and assigning a class of trade to customers.
- **RETROACTIVE EFFECTIVE DATES.** As described above, several of the changes to the Medicaid rebate program are retroactive to rebate periods beginning after December 31, 2009. Retroactive compliance could be challenging for drug manufacturers and states, which may not have the systems to implement this change in time for their first quarter 2010 rebates.

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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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