



KEY PROVIDER ISSUES IN HEALTH CARE REFORM

June 2010 **SELECT MEDICAID DRUG COVERAGE PROVISIONS**

The health reform law makes substantial changes to Medicaid programs. Under the law Medicaid coverage will be expanded to all individuals under age 65 with incomes up to 133% Federal Poverty Level (FPL) based on modified adjusted gross income. Additionally, the law presents changes for the pharmaceutical industry including increasing the minimum Medicaid rebate, calculation of oral solids rebates, extension of rebates to Managed Medicaid, and the reduction of federal share for generic drugs. Also created in the law is a new audit for 340(b) drugs.

Medicaid Rebate Increase

Retroactively to January 2010, the minimum federal rebate increases from 15.1% to 23.1% of average manufacturer price (AMP) for brand drugs. Generic drugs will increase to 13% of AMP. Certain clotting factors and drugs for exclusive pediatric use will increase from 15.1% to 17.1%. This provision also clarifies the calculation of AMP to exclude customary prompt pay discounts, service fees and reimbursement for unsalable returned goods that manufacturers make to wholesalers. Additionally, it provides a definition for “retail community pharmacy” to exclude mail-order and institutional pharmacies.

Rebates on New Formulations of Existing Drugs

For brand name oral solid drugs that are new formulations (line extension) of existing drugs, the rebate is based on the AMP and other existing rebates of the original product. The total rebate for brand drugs are capped at 100% of AMP.

Managed Medicaid Rebates

Under the law, drug companies will now be required to pay the same rebates for Managed Medicaid lives as they do for Medicaid FFS lives. The law is not clear but it appears to be in addition to what the manufacturers are paying directly to the Medicaid Managed Care Organizations (MCO's) by way of individual contract agreements and it appears that supplemental rebates paid by manufacturers for Preferred Drug List (PDL) placement are not included in the total amount.

Federal Share of Generics

The law reduces the federal share of payments to states for generic drugs. Reductions from 250% of the AMP of the least costly therapeutic alternative to 175% will begin on October 1, 2010. The share percentage will be based on the weighted average (based on utilization) of the most recently reported monthly AMP for therapeutically equivalent drugs.

340(b) Pricing

Section 340(b) prescription drug discounts (i.e., Medicaid equivalent pricing) for hospitals serving low-income populations are extended to certain critical access hospitals, cancer hospitals, and other entities under the new law. The 340(b) related provisions also make a technical correction to clarify existing access through children's hospitals. The Medicaid equivalent pricing for these providers excludes drugs purchased through group purchasing organization and exempts orphan drugs from required discounts for new 340B entities. The law also establishes a new auditing, reporting and compliance requirements for HHS, pharmaceutical manufacturers and 340(b) covered entities.

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