

Health Care Reform Resolves Heated Dispute Over Medicaid “Average Manufacturer’s Price” Reimbursement Methodology in Favor of Retail Pharmacies

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The intense battle over Medicaid prescription drug pricing that began with the passage of the Deficit Reduction Act of 2005 (DRA) and continued with contentious litigation and subsequent legislative maneuvering finally was resolved in favor of retail pharmacies on March 23, 2010 when President Barack Obama signed the Patient Protection and Affordable Care Act (PPACA) into law. The DRA lowered retail pharmacy reimbursement for certain Medicaid outpatient prescription drugs by calculating the “federal upper limit” (FUL) based on 250% of the average manufacturer’s price (AMP) for a drug’s least costly therapeutically equivalent version, a methodology trade organizations claimed resulted in reimbursement to retail pharmacies lower than acquisition costs and had the potential of dramatically reducing beneficiary access to drugs. The new methodology in the PPACA calculates the FUL as no less than 175 percent of the weighted average of the AMP.

Rather than purchasing drugs directly from pharmaceutical manufacturers and dispensing them to Medicaid beneficiaries, state Medicaid programs reimburse retail pharmacies for providing this service. State Medicaid programs receive matching funds from the federal government to offset their expenditures, but the federal contribution is capped by the FUL. Pre-DRA studies found that the FUL methodology in place at the time ineffective at controlling costs, and the Congressional Budget Office determined that applying a new methodology - the DRA AMP methodology - would reduce spending by approximately \$11.8 billion during the 2007 through 2015 period.

Leading pharmacy trade groups, including the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (DCPA), argued the DRA methodology set reimbursement levels so low that they fell below acquisition cost, adversely impacting the profitability of retail pharmacies across the board. These and other trade groups argued that certain community pharmacies, particularly those in poor regions with high Medicaid populations, were disproportionately impacted by the rule and may be forced to either terminate Medicaid participation or close operations, diminishing beneficiary access.

In large part because of these claims, several studies conducted after the DRA’s passage assessed the reimbursement impact of the AMP methodology on retail pharmacies. Most recently, at the request of United States Senator Charles E. Grassley, Ranking Member of the Committee on Finance, the United States Government Accountability Office (GAO) evaluated AMP-based FULs against pharmacy acquisition costs. The sample of drugs reviewed included a total of 83 multiple-source outpatient prescription drugs, comprised of 32 with the highest Medicaid utilization,

34 with the highest Medicaid expenditures, and 17 that fell into both categories. The study concluded that the AMP-based FULs would have been lower than average retail acquisitions for 54 of the 83 drugs. Reimbursement for 44 of the drugs would have been at least 25% below acquisition costs. The general conclusions of the Grassley report were consistent with findings in prior reports published by the GAO in 2006 and DHHS Office of the Inspector General in 2007.

NACDS and DCPA initiated litigation on November 7, 2007 to prevent application of the DRA AMP methodology, and, on December 19, 2007, the United States District Court for the District of Columbia enjoined the implementation of the final rule issued by the Centers for Medicare and Medicaid Services (CMS). On the federal legislative front, the Medicare Improvements for Patients and Providers Act of 2008 further prohibited CMS from implementing the DRA AMP methodology through October 1, 2009. The PPACA now definitively resolves the issue (pending further congressional action) and establishes reimbursement for Medicaid prescription drugs at no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail pharmacies on a nationwide basis.