

## **CMS PUBLISHES MEDICAID DRUG PAYMENT FINAL RULE**

On July 6, the Centers for Medicare and Medicaid Services (CMS) released a final rule pertaining to the reimbursement of prescription drugs under the Medicaid program. The rule will be published in the Federal Register on July 17, 2007.

The final rule, which implements provisions of the Deficit Reduction Act of 2005 (DRA), establishes a new method of setting limits on what the federal government will reimburse state Medicaid agencies for prescription drug payments. CMS estimates that the final rule will result in a savings of \$8.4 billion over five years.

The DRA and the final rule revise the regulations pertaining to the Average Manufacturers Price (AMP) and increase the transparency of Medicaid prescription drug pricing. For the first time, AMPs will be publicly reported on the Internet. States will be able to use AMP information when establishing their methods for determining reimbursement for drugs under their Medicaid programs. Additionally, drug manufacturers will be required to report AMPs on a monthly as well as a quarterly basis. According to CMS, the frequent



reporting will enable States to make timely adjustments to reimbursement rates. States will also be required to collect information from physicians on drugs they administer in their offices, which, according to CMS, will enable States to collect rebates on certain physician-administered drugs.

According to CMS, the final rule clarifies the definition of AMP by excluding prompt pay discounts to wholesalers from the calculation of AMP; clarifying the definitions of retail pharmacy class of trade, wholesaler, and how to treat sales reimbursed by third party payers; defining what prices should be included in and excluded from the determination of AMP; excluding sales to nursing homes and discounts, rebates, or prices to pharmacy benefit managers (PBMs), except when PBMs act as mail order pharmacies; defining a number of terms for the purposes of the drug rebate program; and explaining how manufacturers should account for price reductions and other pricing arrangements.

The final rule also addresses the establishment of federal upper limits (FUL) for multiple source drugs. Under the DRA, a FUL must be established for each multiple source drug for which the FDA has rated two or more products as therapeutically equivalent. The Secretary is required to use 250 percent of AMP, computed without

considering customary prompt pay discounts extended to wholesalers, for the least costly therapeutic equivalent as the formula for establishing a FUL on a multiple source drug. Under the final rule, there is an “outlier policy” which excludes any drug in a FUL that is priced significantly lower than other drugs in that category from AMP calculations.

Two of the final provisions in the rule, including the definition of AMP and the “outlier policy” have a comment period. Comments on these provisions are due 180 days from the publication date of the final rule.

The final rule will become effective on October 1, 2007. The final rule can be viewed at <http://www.cms.hhs.gov/MedicaidGenInfo/Downloads/CMS2238FC.pdf>.

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