

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Affairs Office

FACT SHEET

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MEDICAID DRUG PRICING REGULATION PROPOSED

- * HHS Secretary Mike Leavitt today announced proposed changes in the payment for certain prescription drugs in the Medicaid program. These changes implement provisions of the Deficit Reduction Act of 2005 (DRA) and are expected to save taxpayers \$8.4 billion in state and federal funds over five years.
- * The DRA changes how the federal government limits payments to state Medicaid agencies for the aggregate costs of prescription drugs when a generic substitute is available. Currently, Federal Upper Limits (FULs) are calculated based on published drug prices. Approximately 600 drugs are currently subject to the FULs. Some of the most commonly prescribed drugs on the FULs include such drugs for the treatment of asthma, hypertension, pain relief, and depression. They also include vitamin supplements, antibiotics, and anti-ulcer medications. According to the most recent data, drugs subject to the FUL account for approximately 8.3% of outpatient drug expenditures under Medicaid.
- * The DRA establishes a new FUL calculation that is based on 250% of the lowest AMP in a drug class. The FUL does not mandate prices for individual drugs; rather, the FUL is based on the aggregate costs of all the drugs. States will retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists, and may pay above or below the FUL as long as overall payments for drugs subject to a FUL are under the annual aggregate cap. States can also vary reimbursement levels. For example, states can target more favorable reimbursement to pharmacists in rural or inner city areas or to independent pharmacists.
- * In a major step towards providing greater transparency in the cost of health care, the DRA also requires the Centers for Medicare & Medicaid Services (CMS) to disclose the AMP of drugs. The DRA requires CMS to publicly post AMPs on at least a quarterly basis, to better inform the states and the public about the true market price of prescription drugs. The goal of this DRA provision is to capture the most accurate pricing data possible to assure that the Federal government and state Medicaid programs are paying appropriately for generic drugs. CMS expects that these will be available to the states and public in late spring.
- * As required by DRA, the proposed rule includes a proposed definition of AMP on which CMS requests public comment. The definition of AMP will have an impact on the rebate payments drug manufacturers are required to make to the states and federal government.

* The proposed rule also would help Medicaid in collecting rebates from drug manufacturers for drugs administered by physicians. Currently, some state Medicaid programs are unable to collect rebates on drugs dispensed by doctors and hospital outpatient departments because of insufficient information. The proposed rule outlines new steps to allow Medicaid agencies to bill for these rebates.

* The proposed rule will also ensure that drug manufacturers include so-called “authorized generic” drugs in the calculation of their rebate amounts. Authorized generics are those drugs that continue to be made by the original manufacturers or are licensed to another drug company under the Food and Drug Administration’s original new drug approval.

* Until CMS issues new FULs, states may continue to rely upon the FULs published prior to January 1, 2007.

* The comment period on this proposed rule will run through 60 days from publication in the Federal Register. CMS will publish a final regulation after considering these comments and revising it to reflect comments accepted. The DRA requires that the final regulation be promulgated by July 1, 2007.

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