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S. 1932, The Deficit Reduction Act of 2005 and Drug Manufacturers

Today, the House approved S. 1932, The Deficit Reduction Act of 2005. Today's action clears the \$38.8 billion budget reconciliation measure for signature by the President. Included within S. 1932 are several provisions which will impact the operations of drug manufacturers in 2006.

Federal Upper Payment Limit for Multiple Source Drugs and Other Drug Payment Provisions, Section 6001

Modification of federal upper payment limit for multiple source drugs; definition of multiple source drugs

Current Law – States set the amounts to pay pharmacies for outpatient prescription drugs provided to Medicaid enrollees. States pay those amount to pharmacies and then seek reimbursement of the federal share of those payments. Federal reimbursements to states for state spending for certain outpatient prescription drugs are subject to ceilings called federal upper limits (FULs). Pharmaceutical manufacturers whose drugs are available to Medicaid beneficiaries must provide state Medicaid programs with rebates.

Change – The conference agreement applies FULs to multiple source drugs for which the FDA has rated 2 or more products to be therapeutically and pharmaceutically equivalent. For those drugs, the FUL would be equal to 250 percent of the average manufacturer price computed without regard to prompt pay discounts for the lowest cost drug.

Disclosure of price information to states and the public

Current Law – The average manufacturer's price ("AMP") and best price data are required to be

reported by manufacturers to CMS no later than 30 days after the date of entering into a rebate agreement and then no later than 30 days after the last day of each rebate period. Those prices are required to be kept confidential except for the purpose of carrying out the requirements of Medicaid rebates, or to permit the Comptroller General and the Director of the Congressional Budget Office to review the information.

Change – S. 1932 would increase the required reporting of AMP and best prices. AMP would be reported and calculated on a monthly basis. In addition, the agreement allows states to have access to reported AMP data for multiple source drugs for the purpose of carrying out the Medicaid programs and would require the Secretary to disclose such information through a website accessible to the public. The provision also requires the Secretary to provide AMPs to States on a monthly basis and to update information posted to the website on at least a quarterly basis.

Definition of AMP

Current Law – The AMP is defined as the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. CMS instructs manufacturers to exclude certain federal drug purchases as well as free goods from the computation of AMP. Sales at nominal prices are excluded from the best price computation. Manufacturers are required to report, for each rebate period, the AMP for all Medicaid covered outpatient drug products and the best price for single source and innovator multiple source drugs to CMS.

Change – S. 1932 amends the definition of AMP to exclude customary prompt pay discounts

extended to wholesalers from those amounts. In addition, the agreement modifies the price reporting requirements so that manufacturers would be required to submit, not later than 30 days after the last day of each rebate period, the customary prompt pay discounts extended to wholesalers in addition to the AMP and best price reporting required under current law.

Exclusion of sales at a nominal price from determination of best price

Current Law - In addition to the AMP, pharmaceutical manufacturers are required to report to the Secretary of HHS the 'best price' at which the manufacturer sells each of its drug products to certain purchasers for the purpose of calculating the rebate amounts. Prices that are nominal in amount are excluded from best price reporting. Nominal prices are defined by CMS to be those that are below 10 percent of the average manufacturer's price.

Change – S. 1932 modifies the manufacturer price reporting requirements so that for calendar quarters beginning on or after January 1, 2007, manufacturers would be required to report information on sales of Medicaid covered drugs that are made at a nominal price.

Retail survey prices; state payment and utilization rates; and performance rankings

Current Law – No provision.

Change – S. 1932 allows the HHS Secretary to contract for services for the determination of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for drugs.

Collection and Submission of Utilization Data for Certain Physician Administered Drugs, Section 6002

Current Law – Manufacturers are required to provide rebates to states for all outpatient prescription drugs with some exceptions. Outpatient prescription drugs provided through managed care organizations are explicitly exempted from the rebate requirement. In addition, outpatient drugs dispensed by a hospital and billed at no more than the hospital's purchasing costs are exempt from the rebate requirement. Certain drugs administered by physicians in their offices or in another outpatient setting, such as chemotherapy, have often been excluded from the drug rebate program although there is no specific statutory exclusion. This is because providers use Healthcare Common Procedure Coding System (HCPCS) J-codes to bill the Medicaid program for injectable prescription drugs, including cancer drugs. The HCPCS J-codes do not, however, provide States with the specific manufacturer information necessary to enable them to seek rebates. CMS has concluded that because of this coding, many state Medicaid programs have not collected rebates on these drugs, resulting in millions of dollars in uncollected rebates.

Change – For drugs administered on or after January 1, 2006, states are required to provide for the collection and submission of utilization and coding information for each Medicaid single source drug that is physician administered. For drugs administered on or after January 1, 2008, states are required to provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered. Submissions from states will be based on National Drug Codes unless the Secretary specified an alternative coding system.

Children’s Hospital Participation in Drug Discount Program, Section 6004

Current Law – Section 340(B) of the Public Health Service Act allows certain health care providers, including community health centers and disproportionate share hospitals, access to prescription drug prices that are similar to the prices paid by Medicaid agencies after being reduced by manufacturer rebates.

Change – S. 1932 includes a provision adding Children’s Hospitals to the list of providers that may have access to 340(B) discounted prices. The provision would become effective for drugs purchased on or after the date of enactment.

Prohibition on Restocking and Double Billing of Prescription Drugs, Section 6034

Current Law – No provision.

Change – S. 1932 would prohibit federal matching payments for the ingredient cost of a covered outpatient drug for which the pharmacy has already received payment (other than a reasonable re-stocking fee). It would become effective on the first day of the first fiscal quarter beginning after enactment.

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