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MEDICAID FACT SHEET

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Medicaid Drug Pricing Regulation: A Summary

The Deficit Reduction Act of 2005 (DRA) enacted significant changes to payment for prescription drugs by the Medicaid Program.

Background

The DRA modified several key provisions of law concerning Medicaid prescription drugs. The regulation addresses these changes in the final rule published in the *Federal Register* on July 6. The final rule will become effective October 1, 2007.

The regulation also makes two provisions as final with a comment period: (1) a policy that eliminates from AMP calculations any drug in an FUL that is priced significantly lower than other drugs in that category, the so-called "outlier policy" and (2) definition of AMP. Stakeholders have 180 days from the publication date to submit public comments. CMS will respond to the public comments at a later date. This will allow CMS the benefit of further public comment as actual AMP numbers become available and the FULs are developed.

Major Drug Provisions of the DRA

Determination of Average Manufacturer Price (AMP)

The Social Security Act and the national rebate agreement specify that AMP is the average unit price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade. The DRA amended the AMP definition to exclude customary prompt pay discounts extended to wholesalers.

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In various studies, the Office of the Inspector General (OIG) and the Government Accountability Office noted inconsistencies in the methods used by manufacturers to determine AMP due to confusion about which sales should be included in AMP. This regulation clarifies the definition of AMP.

The final rule:

- excludes customary prompt pay discounts to wholesalers from the calculation of AMP, as required by the DRA;
- clarifies the definition of retail class of trade and wholesaler and how to treat sales reimbursed by third party payers such as Medicaid sales, as recommended by OIG;
- defines what prices should be included in and excluded from the determination of AMP;
- excludes sales to nursing homes and discounts, rebates, or prices to PBMs (except when PBMs act as mail order pharmacies);
- defines the following terms for purposes of the drug rebate program:
 - Retail pharmacy class of trade
 - Customary prompt pay discounts
 - Treatment of sales by third party payers; for example, Medicaid, Medicare Part D, SPAPs, and HMOs/MCOs sales
 - Treatment of Medicare Part D sales
 - SPAP price concessions
 - Prices to other Federal programs
 - Administrative and service fees
 - Returned goods
 - Average unit price
 - Bona fide service fee
 - Bundled sales
 - Net sales
 - Wholesaler
 - Manufacturer coupons
 - Patient Assistance Programs; and
- clarifies how manufacturers should account for price reductions and other pricing arrangements in calculating AMP.

Prior to enactment of the DRA, AMP was used by CMS solely to calculate rebates. The DRA makes AMP available to the States and provides more information for States to consider in determining their methods for setting reimbursement for drugs under the Medicaid Program.

Limitation on Sales at a Nominal Price

Prior to the DRA, sales by a manufacturer of covered outpatient drugs below ten percent of AMP were generally excluded from best price as nominal sales.

- The final rule continues to define nominal sales as those sales at less than ten percent of AMP, but limits the best price exemption to sales to 340B covered entities, intermediate care facilities for the mentally retarded, State-owned or operated nursing facilities.
- The final rule does not incorporate an optional fourth category of entities, which the statute authorizes the Secretary to include in the nominal price exemption.

Determination of Best Price

Prior to the DRA, the statute specified that best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States.

The DRA did not require CMS to clarify the requirements for best price. However, because best price, along with AMP, is essential to the Medicaid Drug Rebate Program, we address it in the final regulation.

We specify the sales and prices which must be included in and excluded from best price, taking into account the best price exclusions listed in section 1927 of the Act. Notably, we specify that PBM rebates, discounts, or other price concessions are excluded from best price.

Authorized Generic Drugs

Prior to the DRA, there were no statutory requirements specifically addressing authorized generics under the Medicaid Drug Rebate Program. For purposes of the Medicaid program, an authorized generic drug is the brand name drug approved by the FDA under a New Drug Application, but relabeled or repackaged to be marketed by a subsidiary or secondary manufacturer.

- Section 6003 of the DRA requires manufacturers to include authorized generics when they report their AMP and best price for covered outpatient drugs to the Secretary.

- We define the term “authorized generic” in the regulation and require the primary manufacturer to include in its best price the sale of that drug to the subsidiary or secondary manufacturer. We also require the primary manufacturer to include in its AMP the sale of that drug when that sale is to a wholesaler.

Federal Upper Limits (FULs)

Prior to the passage of the DRA, we used criteria established in Federal statute and regulation to establish a FUL reimbursement limit on certain multiple source drugs. Under these criteria, an innovator multiple source drug listed in FDA’s “*Approved Drug Products with Therapeutic Equivalence Evaluations*,” that has two therapeutically equivalent drugs, or that has three therapeutically equivalent drugs regardless of other formulations, is evaluated for a FUL.

Before the DRA, three suppliers must list the drug in price compendia and the drug must be available for sale nationally. CMS set the FUL at 150 percent of the published price for the least costly therapeutic equivalent using all available national price compendia.

The DRA modified the current regulatory methodology used to establish a FUL on multiple source drugs. Based on these statutory provisions, we are establishing the following requirements:

- A FUL will be established for each multiple source drug for which the FDA has rated two or more products as therapeutically equivalent, regardless of other formulations. Section 6001(a)(3) of the DRA changed the definition of multiple source drug to include a covered outpatient drug for which there is at least one other drug product which is rated as therapeutically equivalent.
- At least two suppliers meet the above criteria in order for CMS to establish a FUL.
- The Secretary will use 250 percent of AMP (as computed without regard to 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.

To ensure that a drug is for sale nationally, we are also establishing the following criteria to be used when determining the FUL for a multiple source drug:

- The AMP of a terminated NDC will not be used to set the FUL beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.
- Outlier AMPs will be excluded. The lowest AMP in a FUL group will be excluded if it is less than 40 percent of the next highest AMP. (The outlier policy will not be applied

- when the FUL group consists of the innovator single source drug and the first new generic only.)

In order to give stakeholders an opportunity to comment on the “40 percent rule,” we are publishing this requirement as a final rule with comment period. We will accept comments for 180 days from the publication date of the final rule with comment period.

Requirements for Manufacturers

Prior to the DRA, manufacturers were required to report AMP and best price to CMS on a quarterly basis. The DRA amended these reporting provisions by requiring manufacturers to report customary prompt pay discounts and nominal prices to CMS on a quarterly basis. It also requires manufacturers to report AMP to CMS on a monthly basis.

Under current Federal regulations, manufacturers are required to report changes to AMP and best price to CMS for a period not to exceed twelve quarters from the quarter in which the data were due. Federal regulations also require manufacturers to retain pricing data for ten years from the date the manufacturer reports that period’s data to CMS.

The final rule:

- requires manufacturers to report pricing data to CMS on a quarterly basis. This pricing data includes AMP, best price, customary prompt pay discounts, and nominal price;
- requires manufacturers to submit monthly AMPs to CMS. Monthly AMPs are calculated in the same manner as the quarterly AMP, except the period covered is one month. Further, manufacturers must estimate the impact of lagged price concessions using a 12-month rolling average;
- revises the recordkeeping provisions by adding the requirement that manufacturers must also retain records used in calculating the customary prompt pay discounts and nominal prices reported to CMS;
- allows manufacturers to recalculate and report their base date AMPs to CMS during the first four full calendar quarters after publication of the final rule. The rule allows manufacturers to recalculate their base date AMPs on a product-by-product basis; however, any recalculations must be based on auditable data;
- requires manufacturers to certify their quarterly and monthly pricing reports. The reports must be certified by the manufacturer’s chief executive officer (CEO), chief financial officer (CFO), another individual with a different title who holds similar authority to a CEO or CFO, or an individual with the directly delegated authority to perform the certification on behalf of one of these individuals; and

- requires that all product and pricing data be submitted to CMS in an electronic format.

Physician-Administered Drugs

Prior to the DRA, most States did not collect rebates on physician-administered drugs because drug claims typically did not contain national drug codes (NDCs), which are necessary for the State to invoice drug manufacturers for rebates. An Office of Inspector General (OIG) report, “*Medicaid Rebates for Physician Administered Drugs*” (April 2004, OEI-03-02-00660), stated that 24 States were able to collect NDC numbers for some physician-administered drugs for the purpose of billing manufacturers for rebates. Of those States, only four were able to collect rebates for all physician-administered drugs for which a State payment was made to providers.

The regulation requires States to collect NDC numbers from providers to enable them to collect rebates on certain physician-administered drugs.

- In order to receive Federal financial participation (FFP) for physician-administered drugs, States must require that providers submit claims using NDCs.
- Effective January 1, 2006, States must require providers to submit claims for single source, physician-administered drugs using HCPCS codes or NDC numbers that allow States to bill for rebates.
- Effective January 1, 2007, States must require providers to submit claims for single source physician-administered drugs and 20 Secretary-specified, multiple source physician-administered drugs using NDC numbers. (FFP will not be available beginning January 1, 2008.)
- States that require additional time to comply with the requirements of this section may apply to the Secretary for a hardship waiver.

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