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MEDICAID REBATE PROGRAM REFORM
WHAT IT REALLY MEANS FOR DRUG MANUFACTURERS

On Feb. 8, 2006, President Bush signed the Deficit Reduction Act (DRA) into law. Title VI imposes changes to the formula for state reimbursement of prescription drugs and changes to the Medicaid rebate program. These changes will have a significant impact on drug manufacturers, increasing rebate liability, impacting reporting obligations and resources required for compliance with the law, and affecting sales and business practices. In addition, Health and Human Services' regulations on the methodology for calculating average manufacturer price (AMP) will create a new basis for enforcement actions and expose manufacturers to greater liability for noncompliance.

REBATE LIABILITY WILL INCREASE

Overall rebate liability will increase for all manufacturers of covered drugs, whether brand or generic. How much of an increase depends on individual circumstances and answers to questions by CMS.

- Prompt Pay. AMP will exclude customary prompt pay extended to wholesalers, which means it will increase by almost 2%. Accordingly, whether the unit rebate amount (URA) is based on the minimum percentage or the difference between AMP and best price (BP), rebate liability will increase, depending on the extent to which manufacturers sell through wholesalers and whether CMS will apply its broad rebate agreement definition of wholesalers in this context.
- Baseline. The penalty calculation, based on increases to the baseline AMP in excess of the consumer price index all urban consumers, could trigger liability if an accommodation is not made for effective increases to AMP resulting from the exclusion of prompt pay discounts.
- Authorized Generics. For manufacturers that authorize other companies to sell their innovator drugs under a generic label, the requirement to include these authorized sales in AMP and BP will substantially increase rebate liability while there are still significant sales of the brand.
- Nominal Price. The statute limits the nominal price exemption from BP to sales to 340B entities, intermediate-care facilities, state owned or operated nursing facilities, and other safety-net providers designated under specific criteria. Thus, to the extent a manufacturer continues to offer nominal prices to other customers, these transactions will create a best price.

REPORTING WILL BE MORE BURDENSOME

The DRA modified subparagraph 1927(b)(3)(A)(i) of the Social Security Act to require manufacturers to begin reporting AMP and BP monthly and to include in the report customary prompt pay discounts extended to wholesalers. At the same time, the statute strikes this entire subparagraph and replaces it with one that retains the old language for filing 30 days after the last day of the rebate period. Assuming the monthly reporting provision is deemed the law, what is to be reported is far from clear because the statute did not change the definition of a rebate period, thus prompting several questions:

- Does report mean calculate a monthly AMP? Must manufacturers calculate an AMP for the month or may they simply report AMP from the last rebate period?
- Shouldn't AMP be final if used to set prospective rates?
- How should the AMP for the rebate period be calculated? Should the manufacturer report a monthly AMP and a quarterly AMP in the third quarter? Should the AMP for the rebate period be a weighted average derived from the three monthly calculated AMPs, or should it use data for the entire quarter?

In addition, there is the antitrust problem of obtaining authorized generic sales data from competing companies as a way to include those prices in the reported calculations of AMP and BP.

THE AFFECT ON SALES, BUSINESS PRACTICES

Multiple source drug has been redefined so that one rated generic equivalent is sufficient to trigger the federal upper limit (FUL). Although the exception for drugs certified as medically necessary has been retained, in general, this change means sales of brands will erode more quickly after generics first appear on the market. In addition, because of the impact on best price, it is likely that provisions addressing authorized generics and nominal prices will serve as deterrents to the practices of authorizing sales of labeled generic drugs and strategic sales at nominal price, which is the intended policy goal.

Finally, the public disclosure of AMP will likely impact business because pharmacies will be reimbursed for multiple source drugs, based on 250% of the lowest AMP for the drug. This scheme is likely to lead to downward price pressure from pharmacies wishing to maximize their reimbursement.

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