CMS Makes Significant Changes in AMP and Best Price Reporting

On July 17, 2007, the Centers for Medicare & Medicaid Services (CMS) published its highly anticipated final rule regarding both the calculation of average manufacturer price (AMP) and the best price (BP) reporting requirements.[1] The final rule implements provisions of the Deficit Reduction Act of 2005 (DRA) and contains significant changes that will impact pharmaceutical manufacturers, pharmacies, and other entities.[2] The final rule took effect October 1.

The final rule was issued under the DRA, and it changes how the federal government pays state Medicaid agencies for aggregate costs of prescription drugs when a generic substitute is available. The rule includes a new method of setting limits on how much the federal government will reimburse state Medicaid agencies for medications with the goal of controlling "inflated drug product payments," and it sets forth several important Medicaid prescription drug definitions in regulations for the first time. CMS estimates that implementation of the final rule will result in savings of $8.4 billion for the federal government and state agencies over the next 5 years.[3]

The final rule is the result of a policy change by Congress, in part in response to a series of reports issued in 2004 by the Government Accountability Office (GAO) and the Department of Health and Human Services Office of Inspector General (OIG) "showing that Medicaid payments to pharmacies for generic drugs were much higher than what pharmacies were actually paying for those drugs."[3] Both the GAO and OIG reports found that states were paying too much for drugs because they were using commercial drug pricing guides to set state reimbursement levels. An investigation of these drug guides found that the prices "were artificially inflated, especially for generic drugs."[3] CMS found that pharmacies made the most profit on generic drugs with the highest markups, which created an incentive to dispense those drugs.[3]

Requirements for Manufacturers

As mandated by the DRA, the final rule establishes a number of record-keeping and submission requirements for manufacturers to increase the transparency of Medicaid drug pricing.[4] In particular, manufacturers, who currently report AMP quarterly, will now be required to report AMP monthly.[5] In addition, for the first time, CMS will make the quarterly and monthly AMP publicly available on the CMS Web site.[6] States will be able to use AMP information to determine reimbursement for drugs under their Medicaid programs, and the frequent reporting will enable states to make timely adjustments of reimbursement rates. States will also be required to collect information from physicians concerning the medications that they administer in their offices, which will enable states to collect rebates on certain physician-administered drugs.[7]

Determination of AMP

The final rule defines AMP as the "average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."[8] The rule also provides guidance on the AMP calculation. Of note, in determining AMP, CMS has defined "retail pharmacy class of trade" to include independent and chain retail pharmacies and also mail-order pharmacies but has excluded nursing home sales because these pharmacies do not serve the general public.[9]

The term "customary prompt pay discount" is defined as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time frame and consistent with customary business practices for payment."[10] The rule specifies that these discounts, including PBM rebates, discounts, or other price concessions for drugs provided to the retail pharmacy class of trade, are to be included in the AMP calculation. The rule provides additional guidance on how manufacturers should account for price reductions and other pricing arrangements.

Determination of Best Price

The final rule defines BP as the "lowest price available from the manufacturer during the rebate period to any entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed."[11] Included in the BP cal-

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culation are customary prompt pay discounts. While CMS recognizes that there may be "difficulties of including certain PBM rebates, discounts, or other price concessions in best price, excluding these price concessions could result in an artificial inflation of best price."[12] In addition, the final rule specifies that BP includes certain administrative and service fees, such as distribution fees; incentives; promotion fees; chargebacks; and all discounts or rebates, other than rebates provided under the Medicaid Drug Rebate Program.[13]

Federal Upper Limits

The final rule also addresses the establishment of federal upper limits (FUL) for multiple source drugs.[14] The FUL is the maximum the federal government will pay to states in matching funds or federal financial participation (FFP) for multisource drugs, meaning generics, dispensed through state Medicaid programs. The DRA requires the FUL to be calculated at 250% of the lowest AMP in a generic drug class.[15] States may pay above or below the FUL for individual drug classes and still receive the full FFP as long as overall payments for multisource drugs subject to a FUL are under the annual aggregate cap.

Some members of Congress and trade associations representing pharmacies have complained that this new methodology will result in a significant reduction in Medicaid payments for generic drugs dispensed by pharmacies. Independent and chain community pharmacies are seeking legislative relief on the FUL provisions in the final rule.

Conclusion

The final rule makes many significant changes to the Medicaid program and should be carefully reviewed by pharmaceutical manufacturers, pharmacies, and their business partners. ■

References

1. 72 *Federal Register* 39142 (2007).
2. Deficit Reduction Act of 2005, Pub L No 109-171, §6001, §6002, §6003 (2006).
3. New Medicaid Drug Payment Rule. CMS press release. July 6, 2007. See also 72 *Federal Register* 39223 (2007).
4. 72 *Federal Register* 39169 (2007).
5. 42 CFR §447.510(a).
6. 72 *Federal Register* 39194 (2007).
7. 42 CFR §447.520.
8. 42 CFR §447.504(a).
9. 42 CFR §447.504(e). See also 72 *Federal Register* 39146 (2007).
10. 42 CFR §447.504(c).
11. 42 CFR §447.505(a).
12. 72 *Federal Register* 39150 (2007).
13. 42 CFR §447.505(e).
14. 42 CFR §447.512, §447.514.
15. Deficit Reduction Act of 2005, Pub L No 109-171, §6001 (2006).