CMS Proposed Rules for Reporting AMP and Best Price May Have Impact Beyond Medicaid Drug Rebates

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On February 2, 2012, CMS issued proposed regulations that further refine and define how pharmaceutical manufacturers must calculate Medicaid drug rebates in the wake of health care reform (the Proposed Rule). Specifically, the Proposed Rule changes the definition of "bona fide services fee," which is a key component in determining a manufacturer's Medicaid rebate liability. While these regulations certainly will affect the operations of pharmaceutical manufacturers, they will also impact those who do business with them. Comments on the Proposed Rule are due April 2, 2012.

Generally, under the Medicaid Drug Rebate Program, pharmaceutical manufacturers calculate and report to CMS the Average Manufacturer's Price (AMP) for their outpatient drugs. They also calculate and report to CMS the "Best Price" they charged for those drugs, i.e., their lowest price to any commercial customer. Depending on specific circumstances and the type of drugs involved, the Medicaid drug rebate that pharmaceutical manufacturers must pay to the 51 State Medicaid Programs is either the difference between the AMP and the Best Price for that specific drug and dosage, or is tied to a specific percentage off of the calculated AMP. The Affordable Care Act (ACA) changed how AMP and Best Price must be calculated, and the Proposed Rule expands upon and implements those changes. CMS estimates that the changes made to the Medicaid Drug Rebate Program by ACA and the Proposed Rule will result in a net savings of $17.7 billion for federal and state governments, over a four-year period.

The Proposed Rule is not CMS's first attempt to define bona fide services fees for AMP and Best Price purposes. In July 2007, CMS issued a Final Rule implementing the Medicaid pharmacy provisions of the Deficit Reduction Act of 2005 (the 2007 Final Rule), which provided guidance on how pharmaceutical manufacturers should calculate and report AMP and Best Price, including definitions for the types of bona fide service fees that were to be excluded. However, in 2010, the ACA redefined AMP in a manner that conflicted with the 2007 Final Rule. CMS therefore withdrew the provisions of the 2007 Final Rule relating to AMP in November 2010, which left manufacturers with nothing but the legislative definitions in the ACA and no substantive regulations to define AMP. The Best Price provisions remained intact.

In the 2007 Final Rule, CMS defined bona fide service fees as:

fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug (emphasis added).

Under the Proposed Rule, a bona fide service fee is defined as a fee paid by a manufacturer not to "an entity" but to a wholesaler or retail community pharmacy only, that (i) represents fair market value for an itemized service actually performed, (ii) the manufacturer would have otherwise had to have done itself, and (iii) is not passed on in whole or in part to a client or customer. Examples of such fees are distribution service fees, product stocking allowances, and fees with patient care programs.

The Proposed Rule defines retail community pharmacies as independent pharmacies, chain pharmacies, supermarket pharmacies, and mass merchandiser pharmacies, licensed as pharmacies by the state and dispensing medicine to the general public. The definition specifically excludes mail order pharmacies, institutional pharmacies, clinics, charitable pharmacies and PBMs.

Interestingly, CMS does not propose to define "fair market value" for bona fide service fees, claiming that the market place changes too rapidly. Instead, CMS stated that pharmaceutical manufacturers should determine fair market value for the services by making "reasonable assumptions consistent with adequate documentation that will support their payment for these services as fair market rates sufficient that an outside party can determine the basis for the fair market value determination."

After defining "bona fide service fees" consistent with the ACA, CMS further proposed to extend the bona fide service fee exemption to fees paid to Group Purchasing Organizations, but not to any other entity. CMS did not provide an explanation for this change, and it is unclear how the pharmaceutical industry will react given that the regulation appears to exclude fees paid to health benefit plans, PBMs and others from the scope of bona fide services fees.

In addition to defining bona fide service fees, the Proposed Rule expands other types of fees and transactions that would be exempt from either the AMP or Best Price calculations. For example, AMP calculations would exclude:

- customary prompt pay discounts provided to wholesalers;
- sales to HMOs and MCOs, and HMO or MCO pharmacies;
- sales to long term care facilities and pharmacies;
- sales to mail order pharmacies ;
- sales to clinics and outpatient facilities;
- sales to government, charitable or non-profit pharmacies;
- sales, rebates, discounts and price concessions to insurers;
- direct sales to physicians or patients;
- sales to PBMs and PBM pharmacies; and
- discounts pursuant to manufacturer coupons and vouchers.

Best Price calculations would exclude:

- prices for a 340 B entity for 340 B drugs;
- prices for a designated State Pharmacy Assistance Program;
- prices charged pursuant to negotiations with a prescription drug plan under Medicare Part D or Part C;
- prices negotiated under a manufacturer drug discount card program;
- discounts pursuant to manufacturer coupons provided the full value goes to the consumer;
- discounts pursuant to manufacturer vouchers;
- nominally priced goods which meet the regulatory definition;
- bona fide service fees, as previously defined but paid to GPOs;
- PBM rebates, discounts or other financial transactions, except their mail order pharmacy's purchases or where such rebates, discounts or other financial transactions are designed to adjust prices at the retail level.

The regulations governing AMP and Best Price calculations are of vital interest to pharmaceutical manufacturers. But other entities that contract with these manufacturers – such as HMOs, GPOs, PBMs, pharmacy chains, hospitals, and group practices – should pay close attention to their pricing provisions, which are likely to undergo changes to comport with what may become the new AMP and Best Price rules.