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CMS PROPOSES TO WITHDRAW REGULATIONS ON AVERAGE MANUFACTURER PRICE DETERMINATION, MULTIPLE SOURCE DRUG DEFINITION, AND MEDICAID FEDERAL UPPER LIMITS

September 10, 2010

RESOURCE LINKS

Proposed CMS Rule
http://edocket.access.gpo.gov/2010/pdf/2010-22115.pdf

Medicaid Drug Rebate Program 'Reform': Key Considerations and Implementation Tips for Pharmaceutical and Biotech Manufacturers
http://www.ebglaw.com/showclientalert.aspx?Show=12652

IMPORTANT DATES

OCTOBER 1, 2010
Statutory AMP/multiple source drug/FUL changes take effect*

OCTOBER 4, 2010
(5:00 p.m. EDT): CMS comment period closes

*Note that the impact on FULs will not be on October 1, 2010, despite the fact that the statute requires it. This is because the implementation of the FUL provisions will require the calculation of AMP under the new formula, and CMS will not have this data until November 30, 2010, at the earliest.

On September 3, 2010, the Centers for Medicare & Medicaid Services ("CMS") issued a proposed rule withdrawing regulations governing the determination of "Average Manufacturer Price" ("AMP"), the definition of "Multiple Source Drug," and the application of federal upper reimbursement limits ("FULs") for Multiple Source Drugs (the "Proposed Rule").[1] This withdrawal would impact the applicable regulations finalized by CMS in 2007 and 2008[2] but would leave intact other sections of the 2007 regulations, including, for example, the "Best Price" provisions and certain "definitions" (including the definition of "bona fide service fee"). Comments may be submitted to CMS until 5:00 p.m. EDT on October 4, 2010. We recommend that organizations consider commenting on the impact of the withdrawn regulations, as well as on the open items that have not been addressed under the recent "health reform" legislation.

BACKGROUND

The Proposed Rule is in response to the changes made to the Medicaid Drug Rebate Program statute[3] by recent health reform legislation. As discussed in greater detail in our March 31, 2010, client alert titled *Medicaid Drug Rebate Program 'Reform': Key Considerations and Implementation Tips for Pharmaceutical and Biotech Manufacturers* (http://www.ebglaw.com/showclientalert.aspx?Show=12652), Section 2503 of the Patient Protection and Affordable Care Act ("PPACA")[4] significantly revised the calculation of AMP, the determination of FULs, and the definition of "Multiple Source Drug." Such changes are to take effect October 1, 2010. The definition of AMP was further revised by the Education Jobs and Medicaid Assistance Act, also effective October 1, 2010.[5] The Proposed Rule would replace the current regulatory provisions with the revised statutory provisions set forth in PPACA, as amended (see box for new AMP definition).

THE STATUTORY AMP DEFINITION TO BE EFFECTIVE OCTOBER 1, 2010

(A) In general — Subject to subparagraph (B), the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—

(i) wholesalers for drugs distributed to retail community pharmacies; and

(ii) retail community pharmacies that purchase drugs directly from the manufacturer.

(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—

(i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—

(I) customary prompt pay discounts extended to wholesalers;

(II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

(III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction; and

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy.

(ii) INCLUSION OF OTHER DISCOUNTS AND PAYMENTS.—Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

(C) Inclusion of section 505(c) drugs — In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)], such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

The intent of the Proposed Rule is to ensure that the CMS regulations do not conflict with the amended Medicaid Drug Rebate Program statute. However, CMS' proposed withdrawal, particularly the provision regarding determination of AMP, leaves several open issues. For example, in the Proposed Rule, CMS did not withdraw the definition of "bona fide service fees" set forth in the 2007 regulation, which included:

> . . . 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.[6]

However, PPACA specifies that AMP excludes

> bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs).

If the current CMS regulations continue to modify the amended Medicaid Drug Rebate Statute's use of "bona fide service fees," then in some cases the statutorily itemized "bona fide service fees" might not qualify for exclusion under the regulatory definition. It is unclear whether this outcome is consistent with Congressional intent as there is no formal legislative history to PPACA. To the extent that a manufacturer previously had concluded that a category of fees itemized in PPACA could not be "bona fide service fees," such manufacturer may want to reconsider its position. Additionally, the withdrawn AMP provision in the Proposed Rule would eliminate the regulatory definition of "customary prompt pay discount," thus leaving an ambiguity as to the determination as to whether a discount is "customary."

CONSIDERATIONS

Although helpful in ensuring consistency, the Proposed Rule does not address some of the more difficult interpretation issues in the revised statutory AMP definition that will be effective October 1, 2010. For example, there remains uncertainty regarding the calculation methodology of AMP for products that are not "generally" dispensed through retail community pharmacies, including what the term "generally" means. There also is a lack of clarity regarding the data manufacturers will need in order to determine whether wholesaler sales are "distributed to retail community pharmacies." Additionally, the Proposed Rule does not address whether manufacturers will be permitted to restate baseline AMPs in connection with the revised definitions. In this regard, PPACA requires that Section 2503 take effect on October 1, 2010, with or without CMS regulations. However, CMS states in the Proposed Rule that CMS intends to promulgate additional regulations regarding Section 2503, although no proposed time frame is provided.

Entities involved in the sale, promotion, purchase, or distribution of Medicaid covered drugs should review the Proposed Rule and consider taking advantage of the opportunity to seek CMS

clarification on outstanding issues that may impact their respective businesses. The comment period ends at 5:00 p.m. EDT on October 4, 2010.

For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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1 75 Fed. Reg. 54,073 (Sept. 3, 2010).

2 *See* 42 C.F.R. §§ 447.500-447.520; *see also* preamble at 72 Fed. Reg. 39,142 (July 17, 2007) (pertaining to Medicaid Drug Rebate program generally); 73 Fed. Reg. 58,491 (Oct. 7, 2008) (pertaining to revised "Multiple Source Drug" definition).

3 42 U.S.C. § 1392r-8 (Section 1927 of the Social Security Act).

4 Pub. L. 111–148 (2010).

5 Pub. L. 111–226 (2010).

6 42 C.F.R. § 447.502.

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