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CLIENT ADVISORY

CMS Issues Proposed Rule to Implement DRA Medicaid Drug Provisions

On December 18, 2006, the Centers for Medicare and Medicaid Services (CMS) published a highly anticipated proposed rule that would implement sections of the Deficit Reduction Act of 2005 (DRA) on Medicaid drug rebates and reimbursement. The proposed rule will be published in the *Federal Register* on December 22. Comments will be due 60 days from the date of publication in the *Federal Register*. The DRA requires CMS to issue a final rule no later than July 1, 2007.

The proposed rule covers a broad range of topics concerning the calculation and use of average manufacturer price (AMP) and best price. In addition to addressing topics that are specifically addressed in the DRA, the proposed rule also seeks to clarify a number of issues that have been sources of confusion in the past. In particular, the rule proposes new definitions for, among other things, bona fide service fees, bundled sales, and nominal price. It proposes a procedure to account for sales of so-called "authorized generics" in AMP and best price. And, it proposes a method for reporting of AMP on a monthly basis and for calculating the federal upper limit for multiple source drugs. When finalized, this rule will alter the method by which Medicaid rebates are calculated and the way in which Medicaid claims for multiple source drugs are reimbursed.

Provided below is a brief summary of CMS' proposals, organized by relevant subheadings from the proposed regulation.

DETERMINATION OF AMP

Currently, the Medicaid Rebate Act (MRA) defines AMP as "the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade." As required by the DRA, effective January 1, 2007, AMP must be determined "without regard to customary prompt pay discounts extended to wholesalers." In its report last June, the OIG reported that, due to the lack of clear guidance, manufacturers had adopted inconsistent approaches to calculating AMP, and recommended that CMS issue guidance clarifying how AMP should be calculated. In offering a new definition of AMP in the proposed rule, CMS outlined its reasoning with respect to several issues.

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- ***Retail Pharmacy Class of Trade:*** At present, there is no formal definition of retail pharmacy class of trade. CMS has provided guidance in Medicaid Rebate Releases 28 and 29 as to which customers should be accounted for in a manufacturer's AMP. The proposed rule would redefine the "retail pharmacy class of trade" to include sales to entities that dispense drugs to the general public. In addition to traditional retail pharmacies, this would include entities such as mail order pharmacies and pharmacy benefit managers (PBMs). This definition would exclude sales to long-term care facilities, including nursing home pharmacies, because they do not sell or provide drugs to the general public. Price concessions to entities within the retail pharmacy class of trade, including PBMs, would be included in AMP. CMS invites comments as to whether the inclusion of PBM rebates in the AMP calculation is "operationally feasible."
- ***Bona Fide Service Fees:*** The proposed rule would define "bona fide service fee" as "a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the advance of the service arrangement, and that is not passed in whole or in part to a client or customer of an entity, whether or not an entity takes title to the drug." Fees that do not satisfy the proposed definition would have to be included in AMP calculations. This is the same definition of bona fide service fee CMS recently adopted for Average Sales Price purposes.
- CMS requests comments on whether it should provide more specific guidance regarding the kinds of fees that would qualify as bona fide services fees as opposed to price concessions. CMS does not offer a definition of "fair market value" but invites comments on how this term should be defined.
- ***Customary Prompt Pay Discounts:*** The DRA revises the definition of AMP to exclude customary prompt pay discounts extended to wholesalers. The proposed rule would define a customary prompt pay discount 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 of the payment due date."
- ***Medicaid Sales:*** The proposed rule would require manufacturers to include sales reimbursed by Medicaid in their AMP calculations. (Medicaid rebates would not be included in the AMP calculation.) CMS reasons that the Medicaid program does not purchase drugs directly; rather, those drugs are purchased from entities in the distribution chain, which usually will be in the retail pharmacy class of trade.
- ***Medicare Part D Sales:*** CMS proposes that sales reimbursed by a Medicare Part D plan or a qualified retiree prescription drug plan should be included in AMP. Rebates to these plans would be included in AMP. As with Medicaid sales, CMS reasons that sales to Part D beneficiaries will generally be made through entities that are within the retail pharmacy class of trade.
- ***State Pharmaceutical Assistance Programs (SPAPs):*** CMS proposes to include prices (rebates) to SPAPs in the AMP calculation. Again, CMS reasons that drugs reimbursed by SPAPs are purchased through entities that are in the retail pharmacy class of trade.
- ***Prices to Other Federal Programs:*** CMS proposes that prices to the IHS, VA, DOD, PHS, a 340B entity, or a state veterans home should be excluded from AMP. CMS also proposes that prices charged under the federal supply schedule, any depot prices (including the DoD TRICARE

system), and single award prices of a federal agency should be excluded from AMP. CMS reasons that these prices are not available to the retail pharmacy class of trade.

- ***Direct Patient Sales:*** CMS proposes that covered outpatient drugs sold to patients through direct programs are to be included in AMP. Commonly in this situation, specialty drugs are distributed to the patient through a third party distributor that stores, delivers and bills for the drug. In the proposed rule, CMS reasons that the distributor in such circumstances is acting as a wholesaler, and that the transaction is therefore through an entity within the retail pharmacy class of trade. CMS invites comments on this proposed policy.
- ***Returned Goods:*** Currently, product returns must be included in AMP calculations. Under the proposed rule, CMS would change this policy to require manufacturers to exclude goods returned in "good faith." According to CMS, goods are returned in good faith when the policies that enable the return are not designed to manipulate or artificially inflate or deflate AMP.
- ***Manufacturer Coupons:*** CMS proposes to include coupons redeemed by any entity other than the consumer in the calculation of AMP. Coupons redeemed by the consumer directly to the manufacturer would be excluded from AMP. The proposed rule is silent on whether coupons redeemed to a vendor under contract with the manufacturer also should be excluded. CMS invites comments on this proposed policy.

DETERMINATION OF BEST PRICE

Although the DRA did not specifically mandate that CMS issue rules addressing best price, the proposed rule includes some important clarifications of best price going forward. Best price is defined 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 AMP is computed" (except exempt sales). As with the discussion of issues related to AMP, CMS also provided its reasoning with respect to a number of topics relevant to best price.

- ***Bundled Sales:*** According to the preamble, best price (as well as AMP) must be adjusted for any bundled sale, which is redefined by the proposed rule. Under the proposed rule, a bundled sale would be "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit NDC level) or some other performance requirement… or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside of the bundled arrangement." The proposed definition would potentially expand the existing definition of bundled sale in several respects, including extending a "bundle" to discounts conditioned on purchases of a different package size of the same drug. Manufacturers would be required to allocate discounts proportionately to the dollar value of the units of each drug sold under a bundled arrangement.
- ***Customary Prompt Pay Discounts:*** Although the DRA requires manufacturers to exclude customary prompt pay discounts from AMP, Congress did not require manufacturers to exclude those discounts from best price. In the proposed rule, CMS explains that, in its view, there is no evidence in the legislative history of the DRA suggesting that Congress intended also to exclude such discounts from best price. Accordingly, CMS proposes to require manufacturers to account for customary prompt pay discounts in best price.

- ***PBM Price Concessions:*** CMS proposes to include PBM rebates, discounts or other price concessions for the purpose of determining best price "where the use of the PBM by manufacturers affects the price available from the manufacturer." Manufacturers would exclude from best price PBM fees that qualify as a "bona fide service fee" under the proposed definition discussed above. CMS invites comments on the issues associated with including PBM rebates in best price.
- ***Administrative and service fees:*** CMS proposes that "administrative fees which include service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates [other than Medicaid rebates] should be included in…best price" if the sales are to a best price eligible entity. CMS proposes to exclude fees that qualify as "bona fide service fees" under the proposed definition discussed above.
- ***Medicare Part D Prices:*** Because the Medicare Modernization Act contains an exemption, CMS proposes to exclude from best price certain prices negotiated by Medicare Part D plans or qualified retiree prescription drug plans.
- ***Manufacturer Coupons:*** CMS states that "redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., the retail pharmacy)." Accordingly, CMS proposes to require manufacturers to include in best price coupons redeemed by any entity other than the consumer. It proposes to exclude coupons redeemed by the consumer directly to the manufacturer. Again, the proposed rule does not address coupons that are redeemed to a vendor acting on behalf of the manufacturer. CMS invites comments on this proposed policy.

AUTHORIZED GENERIC DRUGS

CMS proposes to use the term "authorized generics" in implementing DRA § 6003, and to define this term as "any drug sold, licensed or marketed under a new drug application approved by the [Food and Drug Administration (FDA)] under section 505(c) of the [Federal Food, Drug and Cosmetic Act] that is marketed, sold, or distributed directly or indirectly under a different product code, labeler code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug."

CMS proposes to interpret the DRA as requiring manufacturers of brand name drugs to include in the best price and AMP calculations of the brand drugs the authorized generic drugs that have been marketed by another manufacturer or by a subsidiary of the brand manufacturer. CMS also proposes "to require the NDA holder of the drug to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and best price." The secondary manufacturer or the affiliate of the brand manufacturer would continue to pay Medicaid rebates on its sales of the authorized generic product. Notably, CMS's proposal does not appear to require the brand manufacturer to account for the price at which it sells the product to the secondary manufacturer (or affiliate of the brand manufacturer) in its AMP or best price.

NOMINAL PRICE EXCLUSIONS FROM BEST PRICE

Before the enactment of the DRA, the national Medicaid rebate agreement permitted manufacturers to exclude from their best price determinations outpatient drug prices sold at less than 10 percent of AMP. The DRA narrowed the scope of this "nominal price" exclusion, which (starting in 2007) only encompasses sales to 340B covered entities, intermediate care facilities for the mentally retarded (ICF/MR), or State-owned or operated nursing facilities. The DRA also authorized CMS to identify additional facilities or entities as "safety net providers," to whom sales at nominal prices could be excluded from best price.

Although the Institute of Medicine (IOM) recommended that CMS define safety-net providers as "providers that by mandate or mission organize and deliver a significant level of healthcare and other health-related services to the uninsured, Medicaid and other vulnerable populations," CMS concluded that the entities specified in the statute "are sufficiently inclusive and capture the appropriate safety net providers" and declined to exercise this authority. As a result, the proposed rule would only exempt sales below 10% of AMP that are made to the three categories of entities identified in the DRA as falling within the nominal price exemption.

REQUIREMENTS FOR MANUFACTURERS

The changes to AMP required by the DRA added a number of new requirements for drug manufacturers, which are proposed for adoption in the proposed rule.

- ***Reporting Requirements:*** CMS interprets the DRA to require manufacturers to calculate and report AMP on a monthly basis beginning January 1, 2007, and to submit this information to CMS no later than 30 days after the last day of the prior month. In addition, the proposed rule would require manufacturers to submit quarterly reports to CMS no less than 30 days after the end of the rebate period that include quarterly figures for AMP, best price, and the respective aggregate dollar amounts for customary prompt pay discounts and prices within the nominal price exclusion. While the proposed rule would prohibit manufacturers from reporting a revised monthly AMP, it requires manufacturers to report revisions to quarterly AMP, best price, customary prompt pay discounts, or nominal prices for a rebate period within 12 quarters of the rebate period for which they were reported. Since monthly AMP may not be restated, the proposed rule requires manufacturers to calculate it using "the best data available…at the time of submission" and the preamble makes clear this permits manufacturers to use estimates of quarterly rebates or price concessions that would not otherwise be reflected in the monthly data set.
- CMS also requests comments on whether the monthly or quarterly AMP should be calculated using a 12-month "rolling average" estimating methodology similar to that used in ASP calculations.
- ***Recalculation of Base Date AMP:*** Medicaid rebates for innovator drugs are calculated by determining a basic rebate amount and an additional rebate amount. The additional rebate amount is calculated by subtracting the "base date AMP as adjusted for inflation" from the current quarter AMP. The base date AMP generally is the AMP for the first full quarter in which the drug was marketed. Because the DRA and the proposed rule will change the methodology that manufacturers must use to calculate AMP, the difference between the current quarter AMP and the inflation-adjusted base date AMP could increase unfairly, thus causing an unintended increase in manufacturer rebate liability. For this reason, CMS proposes to allow manufacturers to recalculate their base date AMP to conform to the updated AMP definition, and to submit the recalculated value to CMS with their data submission for the first full calendar quarter following the publication of the final rule.
- ***Certification of Pricing Reports:*** As with the Average Sales Prices submitted in connection with the Medicare Part B program, the proposed rule would require all pricing reports, restatements, and submissions to be certified by the manufacturer's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual with delegated authority to sign for the CEO or CFO and who also reports directly to either of them.
- ***Recordkeeping Requirements:*** Manufacturers must retain for 10 years from the date of submission

to CMS written or electronic records of submitted data and any other materials associated with the calculation of AMP, best price, customary prompt pay discounts, and nominal prices, including any assumptions used in calculating these figures. Records must be retained for more than 10 years if they are subject to an audit or government investigation related to pricing data of which the manufacturer is aware or if the findings of such an audit or investigation have not been resolved.

- ***Required Data Reporting Format:*** The proposed rule would require manufacturers to use one uniform electronic data transmission format to transmit and collect the relevant data. CMS indicated that it will issue further guidance regarding electronic data submission requirements.

UPPER LIMITS OF PAYMENT

CMS has the authority to set Federal upper limits (FULs) of payment in certain instances where different formulations of a multiple source drug are rated as therapeutically equivalent by FDA. The DRA revised the previous formula used by CMS to set FULs and, as a result, CMS proposes to set the FUL for multiple source drugs at 250 percent of AMP for the least costly alternative "when at least two suppliers (e.g., manufacturers, wholesalers, re-packagers, or re-labelers) list the drug in a nationally available pricing compendia." This formula will be based on AMP calculated at the nine-digit NDC level and will utilize the reported monthly AMP. Additionally, to ensure that the FUL is not established on the basis of an outlier AMP, CMS proposes to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP. This "FUL benchmark" would be used unless the FUL group includes only the innovator single source drug and the first new generic in the market, including an authorized generic. An established FUL will not be applied where a physician certifies that a specific brand is medically necessary for the patient.

PHYSICIAN ADMINISTERED DRUGS & FEDERAL FINANCIAL PARTICIPATION

The DRA amended the Medicaid Rebate Act to require that States collect rebates on certain physician-administered drugs, as a condition of federal financial participation. In the proposed rule, CMS proposes to define "physician-administered drugs" as covered outpatient drugs that are typically furnished incident to a physician's service. The proposed rule expressly provides that no Federal financial participation would be available for physician-administered drugs unless a State requires the submission of claims using codes that sufficiently identify the drug being billed. It also would establish a schedule for implementation of this requirement.

The proposed rule also mandates that States require providers to submit claims for physician-administered single source and the 20 multiple source drugs identified by the Secretary using NDC codes by January 1, 2007. States requiring extra time to come into compliance with the regulation could apply to CMS for an extension.

If you have questions about this advisory, or other related issues, please feel free to contact your Arnold & Porter attorney or:

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