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CMS Issues Proposed Rule to Implement Medicaid Drug Pricing and Reimbursement Provisions of the Deficit Reduction Act

On December 22, 2006, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule that would implement sections of the Deficit Reduction Act of 2005 (DRA) regarding Medicaid drug pricing and reimbursement.[1] The proposed rule addresses a broad range of issues related to the determination of average manufacturer price (AMP), determination of best price, treatment of authorized generics, exclusion of nominal prices from best price, and new requirements for manufacturers. Although the proposed rule was intended to clarify some of the areas of ambiguity in the DRA and some areas of long-standing confusion with respect to AMP and best price, the rule nevertheless leaves a number of questions unanswered.

Comments regarding the proposed rule are due to CMS by February 20, 2007. The DRA requires CMS to publish a final regulation no later than July 1, 2007.

Determination of AMP

The Social Security Act (SSA) 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." The proposed rule would provide additional guidance regarding the determination of AMP.

- Definition of Manufacturer: CMS proposes to adopt a definition of "manufacturer" based on the definition used by the Medicare Part B program in the regulations regarding average sales price (ASP) data. Specifically, the proposed rule generally would consider an entity a manufacturer only if it "possesses legal title to the national drug code (NDC) for a covered drug or biological product" in addition to engaging in manufacturing activities. There would be two exceptions to the requirement that a manufacturer possess legal title to the NDC. With respect to an authorized generic, the term "manufacturer" would also include the original holder of the new drug application (NDA). With respect to drugs subject to private labeling arrangements, the term would include manufacturing entities that do not possess legal title to the NDC.

- Retail Pharmacy Class of Trade: CMS proposes to define the "retail pharmacy class of trade" to include sales to entities that dispense drugs to the general public. The definition would include "any independent pharmacy, chain pharmacy, mail order pharmacy, [or] pharmacy benefit manager (PBM)." It would exclude sales to long-term care facilities, including nursing home pharmacies, because they do not sell or provide drugs to the general public. The proposed rule would include in AMP all rebates, discounts, and other price concessions to entities within the retail pharmacy class of trade, including PBMs. CMS seeks comments on whether all mail order pharmacies should be included in the definition of retail pharmacy class of trade, as well as whether the inclusion of PBM rebates in the calculation of AMP is "operationally feasible."

[1] The proposed rule appears at 70 Fed. Reg. 77173 (Dec. 22, 2006).

- Bona Fide Service Fees: The proposed rule would require all fees, except bona fide service fees, to be included in the calculation of AMP. CMS proposes to use the same definition of "bona fide service fees" in the Medicaid rebate context as it recently adopted for purposes of determining ASP, namely "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 the entity takes title to the drug." CMS invites comments on whether it should provide more specific guidance regarding the kinds of fees that would qualify as bona fide service fees rather than price concessions. The agency also seeks comments on how the term "fair market value" should be defined.

- Customary Prompt Pay Discounts: The DRA revises the definition of AMP to exclude "customary prompt pay discounts" extended to wholesalers, but it does not define the term. CMS proposes to define the term as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for the prompt payment of purchased drugs within a specified time of the payment due date."

- Medicaid, State Children's Health Insurance Program (SCHIP), Medicare Part D, and State Pharmaceutical Assistance Program (SPAP) Sales: CMS proposes to include sales reimbursed by Medicaid, SCHIP (whether through Medicaid or non-Medicaid expansion programs), Medicare Part D plans or qualified retiree prescription drug plans, and SPAPs in the calculation of AMP. The rationale for this decision is that these programs do not purchase drugs directly but instead reimburse for drugs purchased from entities in the distribution chain, which will usually be in the retail pharmacy class of trade. Importantly, Medicaid rebates (including rebates to SCHIP Medicaid expansion programs) paid to the states under SSA § 1927 would be excluded from AMP calculations, but rebates to Part D plans, SPAPs, and SCHIP non-Medicaid expansion programs would be included in AMP.

- Prices to Other Federal Programs: The proposed rule would exclude from AMP prices to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA) or a state veterans home, the Department of Defense (DoD), the Public Health Service (PHS), or a 340B entity. Prices charged under the federal supply schedule, any depot prices (including Tricare), and single award prices of a federal agency would also be excluded from AMP because these prices are not available to the retail pharmacy class of trade.

- Direct Patient Sales: Outpatient drugs sold to patients through direct programs, such as, for example, specialty drug distribution arrangements whereby the manufacturer retains ownership of the drug but pays a third party for the storage, delivery, and billing of the drug, would be included in AMP because the distributor in such circumstances is acting as a wholesaler. As a result, the transaction is through an entity within the retail pharmacy class of trade. CMS proposes to require that any rebates or other price concessions associated with direct patient sales be included in AMP. CMS requests comments regarding this proposed policy.

- Returned Goods: CMS proposes that products returned in good faith would be excluded from AMP. A product would be considered to be returned in good faith when it is returned pursuant to manufacturer policies that are not designed to manipulate or artificially inflate or deflate AMP. This policy would be similar to the exclusion of returned goods in the calculation of ASP.

- Manufacturer Coupons: The proposed rule would exclude from AMP coupons redeemed by the consumer directly to the manufacturer but would include those redeemed by any entity other than the consumer. The plain language of the rule seems to require that coupons redeemed by a consumer to an intermediary under contract with the manufacturer also be included, but manufacturers may wish to submit comments seeking exclusion of such coupons.

Determination of Best Price

The DRA did not specifically require CMS to clarify the requirements for determination of best price, but the agency nevertheless determined that it was reasonable to include certain revisions and clarifications in this proposed rule. "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."

- Bundled Sales: The proposed rule would require best price to be adjusted for any bundled sale. CMS would define a "bundled sale" as an arrangement under which a rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types or upon some other performance requirement (e.g., the achievement of market share, inclusion or tier placement on a formulary), or where the resulting price concessions are greater than those that would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. Manufacturers would be required to allocate discounts proportionately to the dollar value of the units of each drug sold under a bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of the discounts should be proportionately allocated across all the drugs in the bundle.

- Statutory Exclusions: All transactions except those explicitly excluded by SSA § 1927 would be required to be included in the determination of best price. The statutory exclusions are:

    - Any prices charged on or after October 1, 1992, to the IHS, DVA or a state veterans home, DoD, PHS, or a 340B covered entity;
    - Any prices charged under the federal supply schedule;
    - Any prices paid by a SPAP;
    - Any depot prices and single award contract prices;
    - The prices negotiated from drug manufacturers for covered discount card drugs; and
    - Any prices negotiated by a Medicare Part D plan, a Medicare Advantage prescription drug plan, or a qualified retiree prescription drug plan.

- Customary Prompt Pay Discounts: Although the DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers, CMS concludes that Congress did not similarly intend to change the definition of best price to exclude customary prompt pay discounts. CMS therefore proposes that customary prompt pay discounts be included in best price.

- PBM Price Concessions: As with AMP, rebates, discounts, and other price concessions to PBMs would be included in best price determinations. Bona fide service fees (as defined for AMP purposes) would be excluded. The proposed rule does not exclude price concessions to entities outside the retail pharmacy class of trade. CMS seeks comment on the issues associated with including PBM rebates in best price.

- Administrative and Service Fees: The proposed rule would include administrative fees, including service fees and distribution fees, incentives, promotional fees, chargebacks and all discounts or rebates other than Medicaid rebates paid to states under SSA § 1927, in the calculation of best price "if those sales are to an entity included in the calculation of best price." Again, bona fide service fees would be excluded.

- Treatment of Medicare Part D Prices: The Medicare Modernization Act explicitly provides that prices negotiated by Medicare Part D plans and qualified retiree prescription drug plans would not be taken into account in determining best price. Accordingly, the proposed rule excludes these prices from best price.

- Manufacturer Coupons: As with AMP, coupons redeemed by the consumer directly to the manufacturer would be excluded from best price, but those redeemed by any entity other than the consumer would be included. Again, the plain language of the rule indicates that coupons redeemed by a consumer to an intermediary under contract with the manufacturer would also be included, but manufacturers may wish to submit comments seeking exclusion of such coupons. Exclusion of consumer coupons redeemed by intermediaries would be consistent with CMS's most recent prior guidance on this subject.

- Manufacturer Patient Assistance Programs: The proposed rule states that goods provided free of charge under a manufacturer's patient assistance program would be excluded from best price, but it is silent on whether the price would be included if the manufacturer charges a reduced rate for its products under such a program. Manufacturers may wish to seek clarification from CMS on this point.

Authorized Generics

The proposed rule would define the term "authorized generic" as "any drug sold, licensed, or marketed under a new drug application approved by the 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 to require that the AMP calculation for a branded drug include the prices of authorized generics that have been marketed by another manufacturer or subsidiary of the brand manufacturer or NDA holder. The agency also proposes to require the NDA holder to include sales of the authorized generic marketed by a secondary manufacturer or the brand manufacturer's subsidiary in its determination of best price.

The secondary manufacturer or subsidiary of the brand manufacturer would pay the single source or innovator multiple source rebate for the authorized generic based on utilization under its own NDC number.

The plain language of the proposed rule does not appear to require the brand manufacturer to include the price at which it sells the product to the secondary manufacturer or to its subsidiary in its determination of AMP and/or best price. Nor does the proposed rule address the process by which competitors will share data in order to comply with the proposed rule. In addition, it is not clear

whether secondary manufacturers would have any independent price reporting obligation with respect to their products. Manufacturers and other stakeholders may wish to submit comments to CMS seeking clarification of these issues. More generally, CMS invites comments on this proposed policy.

Nominal Price Exclusions from Best Price

Sales made at nominal prices (less than 10% of AMP) have traditionally been excluded from best price calculations. The DRA limited the nominal price exclusion to exclude nominal price sales to only certain entities and safety net providers: 340B covered entities, intermediate care facilities for the mentally retarded, and state-owned or -operated nursing facilities. It also authorized CMS to identify other safety net providers to which sales at a nominal price would be excluded from best price. In the proposed rule, however, CMS declines to do so, reasoning that "the entities specified in the statute are sufficiently inclusive and capture the appropriate safety net providers."

CMS also expresses concern that manufacturers will continue to use the nominal price exclusion as a marketing tool. It explains that "using nominal price for marketing is not within the spirit and letter of the law." The agency is considering crafting guidance to address this issues and seeks comments regarding this issue.

In accordance with the DRA, the restriction on nominal price sales would not apply to sales by a manufacturer of covered outpatient drugs that are sold under a Department of Veterans Affairs master agreement.

Requirements for Manufacturers

CMS proposes a number of additional requirements for manufacturers:

- Reporting Requirements: Manufacturers would be required to report AMP on a monthly basis. In addition, they would be required to submit quarterly reports that contain AMP and best price data, as well as aggregate dollar amounts for customary prompt pay discounts and prices within the nominal price exclusion. The monthly AMP would be calculated in the same manner as the quarterly AMP except that manufacturers would not be permitted to report a revised monthly AMP. Instead manufacturers would be required to calculate monthly AMP using "the best data available" at the time of submission. CMS requests comments on whether either the monthly or quarterly AMP should be calculated using "12-month rolling average estimates of all lagged discounts."

- Base Date AMP Recalculation: CMS proposes to allow manufacturers to submit a revised base date AMP that would reflect the changes to AMP set forth in the DRA. Manufacturers would be given the option to decide whether to recalculate and submit to CMS a revised base date AMP or to continue to use their existing base date AMP. Those wishing to submit a revised base date AMP would do so with the data submission for the first full calendar quarter following publication of the final rule.

- Certification Requirements: 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 who has delegated authority to sign for and who reports directly to the CEO or CFO. This requirement would mirror that adopted for ASP filings in the Medicare Part B program.

- Recordkeeping Requirements: CMS proposes to require manufacturers to maintain AMP and best price data and any materials associated with the calculation of AMP, best price, customary prompt pay discounts, and nominal prices for 10 years. Records that are subject to an audit or government investigation must be retained pending the resolution of such inquiry.

- Reporting Format: All monthly and quarterly product and pricing data would be required to be submitted to CMS in an electronic format. CMS plans to issue operational instructions to provide guidance regarding this electronic submission requirement.

Federal Upper Limits

As required by the DRA, CMS proposes to set the federal upper limit (FUL) for multiple source drugs at 250% of AMP for the least costly therapeutic equivalent when at least two suppliers list the drug in a nationally available price compendium. The FUL will apply to all drug formulations, including those not proven to be therapeutically equivalent (B-rated).

The FUL would also include a reasonable dispensing fee, which would be defined as a fee that (1) is incurred at the point of sale and pays for expenses other than the ingredient cost each time the drug is dispensed, (2) includes only pharmacy costs associated with ensuring that the drug is dispensed to a Medicaid beneficiary, and (3) does not include administrative costs incurred by the state. This definition of the term is similar to that in the Medicare Part D program.

The calculation of the FUL would be determined using the monthly AMP. As with AMP, the FUL would be based on the nine-digit NDC and would be specific only to the product code, combining all package sizes of the drug into the same computation. CMS is requesting comments on the alternative approach of using the 11-digit NDC to calculate both AMP and the FUL.

To ensure that a drug is nationally available at the FUL price, CMS proposes to disregard the AMP of an NDC that has been terminated. CMS also proposes to set the FUL based on the lowest AMP that is not less than 30% of the next highest AMP. Use of this percentage calculation as a benchmark would prevent an outlier price from determining the FUL. In situations where the FUL group includes only the innovator and the first new generic, including an authorized generic, the 30% rule would not apply because the agency "believe[s] the DRA intends that a FUL be set when new generic drugs become generally available so as to encourage greater utilization of a generic drug when the price is set less than its brand name counterpart." CMS invites comments on whether 30% is an appropriate measure to use in establishing this benchmark.

Physician-Administered Drugs

The DRA requires states to collect rebates on certain physician-administered drugs in order for federal financial participation (FFP) to be available for these drugs. CMS proposes that FFP be available for physician-administered drugs only when states submit claims for these drugs using codes that sufficiently identify the drug being administered. The agency also proposes to require that providers submit claims for the physician-administered single source drugs and the 20 multiple source drugs identified by CMS as most costly to the Medicaid program. "Physician-administered drugs" would be defined as "covered outpatient drugs . . . that are typically furnished incident to a physician's service, . . usually injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting." This rule would affect liability for single source drugs immediately. The 20 multiple source drugs will be identified in 2007 (the DRA requires the list to be published by January 1, 2007, but the proposed rule states that the list "will be developed . . . and published on the CMS Web site"); rebate liability for these drugs will begin January 1, 2008.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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