

August 7, 2007

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

On July 17, 2007, the Centers for Medicare & Medicaid Services (CMS) published a final rule with comment period that implements sections of the Deficit Reduction Act of 2005 (DRA) regarding Medicaid drug pricing and reimbursement.¹ The final rule addresses a broad range of issues related to the determination of average manufacturer price (AMP), determination of best price, treatment of authorized generics, and new reporting requirements for manufacturers.

This client alert is intended to give an overview of the rule's most important provisions and thus necessarily cannot address all of the rule's nuances and ambiguities.

Unless otherwise stated, the changes mandated by the final rule are effective October 1, 2007. CMS requests additional comments regarding the AMP and federal upper limit (FUL) outlier provisions of the rule; comments are due by January 14, 2008.

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."² The final rule provides the following additional guidance regarding the determination of AMP:

- Definition of Manufacturer: CMS adopts 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 final rule generally considers 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 are two exceptions to the requirement that a manufacturer possess legal title to the NDC. With respect to an authorized generic, the term "manufacturer" also includes the original holder of the new drug application (NDA). With respect to drugs subject to private labeling arrangements, the term includes manufacturing entities that do not possess legal title to the NDC.
- Retail Pharmacy Class of Trade: The final rule defines the "retail pharmacy class of trade" to include sales to entities that dispense drugs to the general public. The definition includes "any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public." The rule specifies that the following are to be included in AMP:

¹ 72 Fed. Reg. 39141 (July 17, 2007).

² SSA § 1927(k)(1); 42 U.S.C. § 1396r-8(k)(1).

1. Sales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any excluded entities.
2. Sales to retail pharmacies.
3. Sales to specialty pharmacies.
4. Sales to mail-order pharmacies.
5. Sales to pharmacy benefit managers (PBMs) for their mail order pharmacy purchases.
6. Sales to physicians.
7. Sales to outpatient facilities, such as clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers.
8. Sales to home infusion providers.
9. Sales to home health care providers.
10. Direct and indirect sales to hospitals, where the drug is used in the outpatient pharmacy, except those sales that cannot be identified with adequate documentation as being used in the outpatient pharmacy for outpatient use.
11. Sales directly to patients.
12. Sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements.
13. Sales at nominal prices (less than 10% of AMP) to any entity except a covered entity described in section 340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR), or a state-owned or -operated nursing facility.
14. Rebates, discounts, or other price concessions associated with the sales listed above.
15. Sales of drugs reimbursed by third-party payers including the Medicare Part D Program, a Medicare Advantage prescription drug plan (MA-PD), a Qualified Retiree Prescription Drug Plan, State Children's Health Insurance Program (SCHIP), state pharmaceutical assistance programs (SPAPs), health maintenance organizations (HMOs) (including managed care organizations (MCOs)) that do not purchase or take possession of drugs, TRICARE Retail Pharmacy Program (TRRx), and Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade.

The rule specifies that the following are to be excluded from AMP:

1. Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a state home receiving funds under 38 U.S.C. § 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the SSA (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

2. Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA) (as administered by the VA).
3. Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.
4. Direct and indirect sales to hospitals, where the drug is used in the inpatient setting or in the outpatient pharmacy for outpatient use where the sales cannot be identified with adequate documentation.
5. Sales to HMOs (including MCOs, and HMO/MCO-operated pharmacies) that purchase or take possession of drugs.
6. Sales to long-term care facilities, including nursing facility pharmacies, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.
7. Sales to hospices (inpatient and outpatient).
8. Sales to veterinarians.
9. Sales to prisons.
10. Sales outside the 50 states and the District of Columbia.
11. Sales to state, county, and municipal entities.
12. Sales to patient assistance programs.
13. Sales to wholesalers where the drug is distributed to the non-retail pharmacy class of trade.
14. Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number.
15. Rebates, discounts, or other price concessions associated with the sales listed above.
16. Manufacturer coupons redeemed by a consumer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.
17. Manufacturer vouchers.
18. Manufacturer-sponsored drug discount card programs.
19. Free goods, not contingent upon any purchase requirement.
20. Bona fide service fees.
21. Customary prompt pay discounts extended to wholesalers.

22. Returned or replaced goods when accepted or replaced in good faith.
 23. Rebates, discounts, rebates, or other price concessions to PBMs, except for their mail order pharmacy's purchases.
 24. Rebates, discounts, or other price concessions to third-party payers including the Medicare Part D Program, an MA-PD, Qualified Retiree Prescription Drug Plans, SCHIP, SPAPs, HMOs (including MCOs that do not take possession of drugs), TRRx, and Medicaid programs.
 25. Rebates under the national rebate agreement or a CMS-authorized state supplemental rebate agreement paid to state Medicaid agencies.
- Sales Versus Rebates: As set forth above, rebates and other price concessions paid to Medicaid, SPAPs, SCHIP, TRRx, and Medicare Part D are excluded from AMP, according to CMS, because 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. But sales made through the retail class of trade and reimbursed by these programs are included in AMP.
 - Manufacturer Coupons: The final rule excludes manufacturer coupons from both AMP and best price provided that the full value of the coupon is passed on to the consumer and that the receiving pharmacy, agent, or other entity does not receive any price concession. The preamble to the final rule, however, sets forth slightly different criteria with respect to AMP. It states that coupons (and vouchers for free product) are excluded from AMP if: (1) the coupon is not contingent on any purchase requirement; (2) the manufacturer establishes the coupon's benefit amount without any negotiation with a third party; (3) the entire amount of the coupon's value is made available to the individual patient without an opportunity for a third party to reduce the benefit amount or take a portion of it; and (4) the pharmacy collects no additional payment other than the benefit amount and a bona fide service fee.
 - Patient Assistance Programs: Patient assistance programs, including copayment assistance programs and manufacturer-sponsored drug discount programs, are excluded from AMP if: (1) they are focused on extending free products or financial assistance not contingent on any purchase requirement to low-income individuals; (2) the manufacturer establishes the subsidy amount without any negotiation with a third party; (3) the entire amount of the free product or assistance is made available to the individual patient without an opportunity for a third party to reduce the benefit amount or take a portion of it; and (4) the pharmacy collects no additional payment other than the benefit amount and a bona fide service fee.
 - Returned Goods: Returned goods are excluded from AMP provided that the manufacturer acts in good faith. A product would be considered to be returned in good faith when it is returned in accordance with pre-existing manufacturer policies that comply with customary acceptable business practices and applicable laws and regulations.
 - Lagged Price Concessions: CMS defines lagged price concessions as discounts or rebates that are realized after the sale of the drug, except for customary prompt pay discounts, but are not limited to discounts or rebates offered to wholesalers. Manufacturers must use a 12-month rolling average of lagged price concessions when calculating AMP. Smoothing must be undertaken even in the first partial year of sales of new products.

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 the final rule. The SSA defines “best price” 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.”³

- Manufacturer Coupons: As with AMP, the final rule excludes from best price manufacturer coupons, provided that the full value of the coupon is passed on to the consumer and the receiving pharmacy, agent, or other entity does not receive any price concession. The preamble to the final rule does not state whether the additional criteria for excluding manufacturer coupons from AMP also apply to best price.
- PBM Price Concessions: Rebates, discounts, or other price concessions to PBMs are not taken into account in determining best price, except that purchases made through PBM mail-order pharmacies or “such rebates, discounts or other price concessions . . . designed to adjust prices at the retailer or provider level” are included in best price.
- Patient Assistance Programs: The final rule excludes goods provided free of charge under a manufacturer’s patient assistance program. With respect to SPAPs, CMS reiterated that, in order for rebates to an SPAP to be exempt from best price, the SPAP must meet the qualification standards adopted by CMS (set forth in Manufacturer Release 68).
- Nominal Prices: 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 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 final 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.”

Considerations for Both AMP and Best Price

- Customary Prompt Pay Discounts: The DRA revises the definition of AMP to exclude customary prompt pay discounts to wholesalers. The final rule establishes that non-routine discounts used for purposes other than ensuring payment within a specified timeframe, such as marketing, sales, promotional strategies, special package discounts, incentives, and performance-based discounts, are not customary and must be included in AMP and that prompt pay discounts must be earned according to their terms (and not automatically granted despite the timing of payment) in order to be excluded. In its response to a comment requesting that CMS clarify that customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer, CMS

³ SSA § 1927(c)(1)(C); 42 U.S.C. § 1396r-8(c)(1)(C).

disagreed, stating, “Both the customary prompt pay discounts and other price concessions available to the end-customer are to be included in the determination of best price.”

- Authorized Generics: The final rule defines 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]; and marketed, sold, or distributed 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.” According to the final rule, a manufacturer must include the price at which it sells an authorized generic to the secondary manufacturer (which may be an inter-company transfer price and must be adjusted for discounts and fees) in its calculation of best price. But prices charged by the secondary manufacturer to its customers do not affect the primary manufacturer’s AMP or best price.
- Direct Patient Sales: Direct sales are those for which the manufacturer exerts control over the distribution of the drug through an exclusive wholesaler/distributor or pharmacy. Outpatient drugs sold to patients through direct programs, such as 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, are 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. Sales directly to patients are also included in best price, except to the extent that the sales are specifically excluded by statute.
- Bundled Sales: The final rule requires best price to be adjusted for any bundled sale. CMS defines 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. CMS asserts that this definition is a clarification of the definition in the national rebate agreement and does not impose new obligations. Manufacturers are required to allocate discounts proportionately to the dollar value of the units of each drug sold under a bundled arrangement.⁴ For bundled sales where multiple drugs are discounted, the aggregate value of the discounts must be proportionately allocated across all the drugs in the bundle. In the preamble to the final rule, CMS illustrates the correct methodology for apportioning bundled sales with the following example: Products A and B are sold under a bundled arrangement and have a combined bundled discount equal to \$200,000 on total undiscounted sales of \$1 million. If Product A has undiscounted sales of \$600,000 and Product B has undiscounted sales of \$400,000, when calculating AMP the manufacturer would allocate 60 percent of the combined bundled discount to product A and 40 percent to Product B. The effective unit price of each product would be calculated by subtracting the discount allocated to each drug product ($\$600,000 - \$120,000 = \$480,000$ for Product A; $\$400,000 - \$80,000 = \$320,000$ for Product B) and dividing the result by the number of units for each drug product in the bundled sale.

⁴ Recognizing that “appropriate consistencies across the calculations of ASP and AMP will result in a lower potential for error and more accurate calculations of both prices,” CMS recently adopted this same allocation methodology for purposes of determining ASP. 72 Fed. Reg. 38122, 38151 (July 12, 2007).

- Bona Fide Service Fees: The final rule requires all fees, except bona fide service fees, to be included in the calculation of AMP and best price. The rule adopts in the Medicaid rebate context the same definition of “bona fide service fees” (and accompanying interpretive guidance) as CMS 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 absence 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 declined, however, to define “fair market value” except to say that it is determined “consistent with generally recognized standards.”

Reporting Requirements

- Base Date AMP: Manufacturers have the option to revise a product’s base date AMP based on the definition of AMP in the final rule. The option may be exercised on a product-by-product basis. Revised base date AMPs must be submitted to CMS within the first four full calendar quarters following publication of the final rule. These recalculations must be based on actual and verifiable pricing records, not on estimates.
- Quarterly and Monthly Reporting: Manufacturers must report AMP to CMS on a monthly basis. In addition, manufacturers must submit quarterly reports of AMP, best price, and the dollar volume of customary prompt pay discounts and nominal price sales. Quarterly AMP must be calculated as a weighted average of the three component monthly AMPs.
- Restatements: Manufacturers must restate quarterly AMP and best price figures for up to 12 quarters from the quarter in which the data were due. Manufacturers must also report revisions to customary prompt pay discounts and nominal prices over the same 12-month period. In addition, they must revise their monthly AMPs for up to 36 months from the month in which the data were due.
- Certifications: All reports and restatements must be certified by the manufacturer’s chief executive officer (CEO), chief financial officer (CFO), an individual who has authority equivalent to a CEO or CFO, or an individual to whom the CEO or CFO has directly delegated certification authority.
- Publication of AMP Data: CMS reiterated in the preamble to the final rule that the DRA removed the confidentiality protection for AMP data as of January 1, 2007. It further stated that it will publish AMP on its website when it finds the data “sufficiently complete and accurate.”

Federal Upper Limits

As required by the DRA, the federal upper limit (FUL) for multiple source drugs is 250% of AMP for the least costly therapeutic equivalent when FDA has rated at least two drugs to be therapeutically and pharmaceutically equivalent. The FUL applies to all drug formulations, including those not proven to be therapeutically equivalent (B-rated). CMS will not use the lowest AMP to establish the FUL for a particular multiple-source drug group if that AMP is a so-called outlier—less than 40 percent of the next highest AMP—unless the FUL group includes only a brand name product and its first generic competitor. CMS is currently accepting comments on this proposed “outlier AMP” formula.

Dispensing Fees

States may also require manufacturers to pay pharmacies a reasonable dispensing fee. This fee is one 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.

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. "Physician-administered drugs" are "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." Under the final rule, FFP is available for physician-administered drugs only when states require providers to submit claims for these drugs using NDC numbers. Providers were required to submit claims beginning January 1, 2007, for single-source drugs, and will be required to submit claims beginning January 1, 2008, for the 20 multiple-source drugs identified by CMS as having the highest value under the Medicaid program.

Proportional Rebates

In the preamble, CMS explicitly rejects the proposition that where the Medicaid program functions as a secondary payor, "the rebate should be proportional to the amount of the claim paid by Medicaid."

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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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