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CLIENT ADVISORY

CMS ISSUES FINAL RULE IMPLEMENTING MEDICAID PROVISIONS OF DEFICIT REDUCTION ACT

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On July 6, 2007, the Centers for Medicare and Medicaid Services ("CMS") released a final rule with comment period implementing Sections 6001-6003 of the Deficit Reduction Act of 2005 ("DRA"), relating to the Medicaid Drug Rebate Program. Under the statute, CMS was required to issue a rulemaking relating to the Average Manufacturer Price ("AMP"), a component of the Medicaid rebate formula, by July 1, 2007. CMS published its proposed DRA rule in the Federal Register on December 22, 2006. Like the proposed rule, the final rule covers a broad range of topics concerning the calculation and use of AMP and Best Price ("BP"), including issues not specifically addressed in the DRA. The final rule contains new requirements for calculation of AMP and BP, clarifies a number of issues on which there had not previously been clear guidance, and raises questions on other issues.

The final rule provides that, unless otherwise indicated, the changes mandated by the final rule will become effective October 1, 2007. CMS explains, however, that "existing requirements that remain unchanged in this final rule will continue in force," and that "this rule is not designed to delay the effective date with respect to statutory provisions, regulations or policies that are already in effect." In the final rule, CMS requests additional comments regarding its AMP and Federal Upper Limit ("FUL") outlier regulations. Comments will be due to CMS on those two issues 180 days after the final rule is published in the Federal Register. (Publication of the final rule is anticipated on July 17, 2007, which would provide a comment deadline of January 14, 2008.)

This client advisory provides a top-level overview of selected key final rule provisions regarding definitions of terms, inclusions and exclusions from AMP and BP, so-called "authorized generics," base date AMP, reporting requirements, the FUL, and treatment of physician administered drugs for Medicaid rebate purposes. Because the final rule includes additional details and numerous other requirements, drug manufacturers are encouraged to consult with counsel regarding the full implications of this rule.

DEFINITIONS

Best Price. In the final rule, CMS defines BP as "the lowest price [of a single source or innovator multiple source drug] 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 the AMP is computed." BP includes "all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation." Although the final rule provides greater detail than the Medicaid Rebate Agreement, the two definitions are functionally similar. CMS noted that it will issue future clarifications to the definition of BP, as necessary, through the issuance of program releases and by posting clarifications on the CMS website.

Bona Fide Service Fee. For Medicaid purposes, CMS has adopted the definition of bona fide service fee it had previously established for Average Sales Price ("ASP") calculations for Medicare Part B purposes. The final rule defines the term "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." The final rule also provides that bona fide service fees meeting this definition should be excluded from AMP and BP calculations and adopts the interpretive guidance that CMS issued in the CY 2007 Physician Fee Schedule Rule concerning treatment of bona fide service fees for ASP.

Bundled Sale. The Medicaid Rebate Agreement (under which manufacturers agree to provide Medicaid rebates to the states) defines "bundled sales" as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately." The final rule modifies the language of the definition of bundled sale to: "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), 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 the bundled arrangement." In the preamble to the final rule, CMS asserts that this definition "clarifies" the Medicaid Rebate Agreement definition and imposes "no new obligations that did not already exist under the rebate agreement." The final rule also describes the methodology that manufacturers must use to apportion bundled sales.

Customary Prompt Pay Discounts. As required by the DRA, effective January 1, 2007, AMP must be determined "without regard to customary prompt pay discounts extended to wholesalers." According to the final rule, the term "customary prompt pay discount" means "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 timeframe and consistent with customary business practices for payment." In the preamble to the final rule, CMS explains that this definition "is consistent with customary business practice regarding a routine discount extended to all purchasers for payment within a set time period; for

example, 30, 60, or 90 days and that would be flexible and accommodate prompt pay policies for standard sales. Discounts that do not meet this standard which are used for other purposes (for example, marketing, sales, and promotional strategies, special package discounts, incentives, and performance based discounts) are not considered customary prompt pay discounts and should not be excluded from AMP."

Reasonable Assumptions. CMS guidance allows manufacturers to make reasonable assumptions regarding calculation of AMP and best price where no CMS guidance addresses an issue. In the preamble to the final rule, CMS defines reasonable assumptions as those assumptions "made by manufacturers consistent with [the] Medicaid drug rebate statute, regulation, and general business practice." This standard will continue to apply in those areas where CMS has not provided guidance.

Retail Pharmacy Class of Trade. The final rule defines AMP as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade," and defines "retail pharmacy class of trade" as "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 Medicaid Rebate Agreement and prior CMS guidance did not define the term "retail pharmacy class of trade," but did specify some of the kinds of sales that manufacturers should include in, and exclude from, AMP.

Wholesaler. According to the preamble, CMS has revised this definition in order to make it "consistent with current law [and to] reflect recommendations made … by the OIG and relevant comments." A wholesaler is defined in the final rule as "any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug." This definition is functionally the same as the definition in the Medicaid Rebate Agreement. The final rule, however, differs from the proposed rule in an important respect. Unlike the proposed rule, the final rule does not specify that entities which arrange for the sale of a covered outpatient drug are included in the definition of wholesaler.

AMP AND BP INCLUSIONS AND EXCLUSIONS

Pharmacy Benefit Managers. The final rule addresses discounts and rebates offered to pharmacy benefit managers ("PBMs"), an area that previously has been the source of significant confusion. The final rule provides that AMP includes "sales including discounts, rebates, or other price concessions provided to [PBMs] for their mail order pharmacy purchases." Under the final rule, BP excludes "PBM rebates, discounts, or other price concessions except their mail order pharmacy's purchases or where such rebates, discounts, or other price concessions are designed to adjust prices at the retail or provider level." The final rule defines the term "provider" as "a hospital, HMO, including an MCO or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care." However, the final rule does not explain how a manufacturer should treat PBM rebates or discounts where the "design" of the rebate or discount is unknown to the manufacturer.

Patient Assistance Programs. The final rule excludes "sales to patient assistance programs" ("PAPs") from AMP. The preamble to the final rule, however, notes that PAPs "should be excluded from AMP as long as" four additional "criteria are met." These criteria essentially require that: (1) the program focus on extending free products or financial assistance not contingent on any purchase requirement to low income individuals, as "determined by CMS"; (2) each

manufacturer establish the subsidy amount without any negotiation between the manufacturer and any third party; (3) the entire amount of the free product or subsidy is made available to the individual (and not shared with third parties); and (4) the "pharmacy collect[] no additional payment, other than the benefit amount and a bona fide service fee, from the patient assistance program." CMS's DRA regulations also exclude "goods provided free of charge under a manufacturer's patient assistance programs" from BP, and according to the final preamble, PAPs are exempt from BP as long as four criteria are met. These criteria are similar to the AMP criteria, but the BP criteria include the additional limitation that the PAP must be "focused on" providing financial assistance to individuals "who are not otherwise eligible for Medicare and do not have public or private prescription drug coverage." Additionally, unlike the AMP criteria, the BP criteria do not permit exclusion from BP if the manufacturer pays the pharmacy a bona fide service fee for implementation of the PAP.

Coupons and Vouchers. The final rule excludes from AMP and BP sales that are subject to manufacturer coupons that are "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." This guidance is a significant departure from the proposed rule, which would have required inclusion in AMP and BP of all coupon programs unless redeemed directly by the consumer to the manufacturer. The preamble to the final rule identifies four conditions for application of this exclusion with respect to AMP, but does not mention whether these additional limitations apply to the BP exemption. The preamble requires that: (1) the coupon not be contingent upon any purchase requirement; (2) the manufacturer establish the value of the coupon without any negotiation between the manufacturer and any third party; (3) the entire amount of the free product or coupon is made available to the individual (and not shared with third parties); and (4) the "pharmacy collect[] no additional payment, other than the benefit amount and a bona fide service fee, from the coupon." The final rule excludes sales that are subject to voucher programs from AMP, but does not explicitly confirm whether sales subject to voucher programs are excludable from BP (although it appears from the exclusion of free goods and patient assistance programs from BP that sales subject to vouchers also would be excludable from BP).

Nominal Price. The final rule retains the Medicaid Rebate Agreement's definition of nominal price, namely, "a price that is less than ten percent of the AMP in the same quarter for which the AMP is computed." However, as required by the DRA, the final rule excludes from BP sales at nominal prices only if made to certain entities: (1) covered entities under Section 340B of the Public Health Service Act; (2) intermediate care facilities for the mentally retarded providing services under 42 C.F.R. § 440.150; and (3) state-owned or operated nursing facilities providing services as set forth in 42 C.F.R. § 440.155. Under the final rule, sales at nominal prices are included in AMP, so long as these prices are not offered to these three types of entities.

The following table provides a partial list of additional kinds of sales that the final rule includes in, or excludes from, AMP and BP reports.

Sales / Arrangements	Include in AMP?	Include in BP?
Sales to wholesalers	Yes, except for sales that can be identified with adequate documentation as being subsequently sold to any excluded entities	Yes
Sales to other manufacturers who act as wholesalers and do not repackage/ relabel under the purchaser's NDC, including private labeling agreements	Yes	Yes
Direct and indirect sales to hospitals	Yes, except exclude sales that cannot be documented as used in the hospital's outpatient	Yes
Sales to mail order pharmacies	Yes (including purchases by PBM's for use in the PBM's mail order pharmacy operation)	Yes
Sales directly to patients	Yes	Yes
Sales to outpatient facilities	Yes (including clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers)	Yes
Sales to home infusion providers	Yes	Yes (fall within the definition of "provider")
Sales to specialty pharmacies	Yes	Yes ("provider")
Sales to HMOs that take possession of drugs	No	Yes
Sales to physicians	Yes	Yes
Sales of drugs reimbursed by 3rd party payors	Yes (where 3rd party payors includes Medicare Part D plans, Qualified Retiree Prescription Drug Plans, SCHIP, State pharmaceutical assistance programs "SPAPs", HMOs that do not take possession of drugs, TRICARE Retail Pharmacy "TRRx" Program, Medicaid Programs)	Not explicitly addressed, but "prices to providers" are included in BP, and providers are defined as including HMOs, MCOs, and entities that provide "coverage"; also, the definition of BP includes all sales and associated rebates unless explicitly exempted, and there are only specific exemptions for covered Part D drug prices negotiated by a Medicare Part D plan or a Qualified Retiree Prescription Drug Plan and sales to designated SPAPs
Associated rebates, discounts, or other price concessions to 3rd party payors	No (where 3rd party payors include the same entities listed immediately above)	See immediately above.
Sales to long-term care facilities including nursing facility and contract pharmacies	No	Yes (BP includes prices to providers, including nursing facilities)
Sales to hospices (inpatient and outpatient)	No	Yes ("provider")
Sales to prisons	No	Yes (unless otherwise excluded)
Sales to wholesalers or distributors where the drug is relabeled under the wholesalers' or distributors' NDC number	No	Yes, if the relabeler is also an HMO or other non-excluded entity
Returned or replaced goods	No, if accepted or replaced in good faith	Yes (See Section 447.505(e)(1))

AUTHORIZED GENERICS

Section 6003 of the DRA requires that manufacturers of innovator drugs with authorized versions marketed under New Drug Applications ("NDAs") account for these authorized versions in their AMP and BP calculations. In the final rule, CMS interprets this requirement as applying to "authorized generics," which it defines as "any drug sold, licensed, or marketed under an NDA approved by the FDA under section 505(c) of the FFDCA [Federal Food Drug and Cosmetic Act]; and marketed, sold, or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand drug."

According to the final rule, a "manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler," and must include the BP of an "authorized generic drug in its computation of BP for a single source or innovator multiple source drug during a rebate period **to any manufacturer**, wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States." (Emphasis added.) Thus, unlike CMS's proposed DRA rule, prices charged by the secondary manufacturer to its customers **would not** affect the innovator's AMP or BP. But the innovator's transfer price to the authorized generic manufacturer would affect BP. The final rule explains that, for BP purposes, the transfer price that the innovator manufacturer charged to the secondary manufacturer (including any discounts or fees) must be accounted for in the innovator's BP for the authorized generic drug.

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. In the proposed rule, CMS proposed to allow manufacturers to recalculate their base date AMPs to conform to the new 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. Under the final rule, a manufacturer may report a revised base date AMP to CMS within the first four full calendar quarters following publication of the final rule (Q4 2007 through Q3 2008). These base date AMP recalculations must "only reflect the revisions to AMP as provided for in §447.504" (the final rule's AMP provisions), must be based only on "actual and verifiable pricing records" (i.e., manufacturers cannot recalculate based on estimates or correlation factors), and may be made on a product-by-product basis.

REPORTING REQUIREMENTS

Quarterly and Monthly Reporting. In addition to quarterly AMP and BP reports, manufacturers must also report customary prompt pay discounts and nominal price sales quarterly to CMS, and must report monthly AMPs to CMS.

Pricing Restatements. In the final rule, CMS has retained the current requirement that manufacturers must restate quarterly AMPs and BP for up to twelve quarters from the quarter in which the data were due. Manufacturers also must report revisions to customary prompt pay discounts and nominal prices over this same period, and must revise monthly AMP reports for a period not to exceed 36 months from the month in which the data were due. CMS notes that revised monthly AMPs will not affect reimbursement and therefore it is incumbent on manufacturers to ensure as best as possible that the initial monthly AMP reports are accurate.

Rolling Average Methodology For Lagged Discounts. The final rule requires manufacturers to use a twelve-month rolling average of lagged price concessions when calculating monthly and quarterly AMP, but does not offer details regarding the formula that should be used.

Recordkeeping. In addition to existing recordkeeping requirements, manufacturers must retain records used in calculating the customary prompt pay discounts, nominal prices, and monthly AMPs reported to CMS for at least ten years from the date the manufacturer reports data for the relevant reporting period.

Certifications. The final rule requires that all Medicaid pricing reports, restatements, and submissions be certified by a manufacturer's Chief Executive Officer ("CEO"), Chief Financial Officer ("CFO"), an individual other than a CEO or CFO who has authority equivalent to a CEO or a CFO, or an individual with directly delegated authority to sign for these individuals.

FEDERAL UPPER LIMIT ("FUL")

CMS must set FULs for payment when FDA rates two or more drugs as therapeutically equivalent. The DRA revised the previous formula used by CMS to set FULs. Under the final rule, CMS will create an FUL for every multiple source drug for which the FDA has rated at least two products as therapeutically and pharmaceutically equivalent, regardless of whether all formulations are so rated, if at least two suppliers meet this requirement. The FUL will generally equal 250 percent of AMP for the least costly therapeutic equivalent. CMS will not use the lowest AMP to establish the FUL for a particular multiple-source drug group if that AMP is less than 40 percent of the next highest AMP, unless the FUL group includes only a brand name drug and its first generic competitor, including an authorized generic drug. This is the so-called "outlier AMP" formula on which CMS has extended the comment period.

PHYSICIAN-ADMINISTERED DRUGS

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 ("FFP"). The final rule notes that, in order to receive FFP, a state must have required providers to submit claims for physician-administered single source drugs as of January 1, 2007. Additionally, for the twenty multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid program, the state must require providers, as of January 1, 2008, to submit claims using NDC numbers for these twenty multiple source physician-administered drugs "in order to secure rebates."

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