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BY HAND DELIVERY

Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicaid Program: Prescription Drugs (CMS-2238-P)

Dear Ms. Norwalk:

Reed Smith LLP welcomes the opportunity to comment on behalf of one of our pharmaceutical manufacturer clients concerning CMS's proposed rule pertaining to prescription drugs under the Medicaid program (the "Proposed Rule"), 71 Fed. Reg. 77,174 (Dec. 22, 2006). We appreciate this opportunity to share our client's views on some of the important issues addressed in the Proposed Rule.

Our client is one of the world's leading pharmaceutical companies, with a strong commitment to developing treatment options for debilitating diseases and improving patient lives. In keeping with this commitment, our client manufactures numerous drugs, many of which are reimbursed under Medicaid, and is a long-standing participant in the Medicaid rebate program. As such, it is important to our client that CMS develop and implement the rebate program's provisions, including those addressing the calculation and reporting of best price ("BP") and average manufacturer price ("AMP") in a manner that promotes consistency and accuracy among manufacturers so as to preserve access to a broad range of medicines for Medicaid patients. Our client believes that the Proposed Rule is a good first step toward accomplishing this goal but requests that CMS consider additional refinements to certain key aspects of the rule. In making the recommendations discussed herein, our client's objectives are to seek clarity by eliminating "gray areas" that could be open to interpretation and confusion, seek consistency to ensure a level playing field with rules that are applied equally across and within industries, and, to the extent possible, minimize the administrative, operational and financial disruptions that could result from changes to existing rebate policy.

I. Definitions – Section 447.502

A. Bundled Arrangements

The Proposed Rule inappropriately broadens the current definition of bundled sales and otherwise requires clarification. Section 447.502 of the Proposed Rule would establish a new definition of “bundled sales” for purposes of the rebate program which differs from the current definition provided in CMS’s national rebate agreement. Specifically, the Proposed Rule would define bundled sales to include arrangements “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 National Drug Code (“NDC”) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary)” 71 Fed. Reg. at 77195. This proposal should be modified and/or clarified in several respects. Further, because this proposal, if adopted, would reflect a change in the definition of bundled sales from the rebate agreement, it should only apply prospectively.

First, our client recommends that CMS amend the bundled sale definition to clarify that, in order to qualify as a bundled sale, an arrangement must involve multiple products. The current language could be construed to include any arrangement in which a price concession is conditioned on a performance requirement, including arrangements where only a single product is involved. Clearly, offering a discount on a single product based on the satisfaction of a purchase requirement or other performance criteria related to that same product does not constitute a bundled sale.

On the other hand, not all discounted pricing arrangements involving multiple products will qualify as bundles. For example, a contract under which Product A could be purchased at a 15% discount (or rebate) conditioned solely on a minimum quantity or market share of Product A purchases or utilization, and Product B could be purchased at a 30% discount (or rebate) conditioned solely on a minimum quantity or market share of Product B purchases or utilization, should not constitute a bundle because the pricing for each product is determined without regard to the pricing of the other. This contract type in essence represents an “a la carte” menu of unrelated product discounts rather than a bundled sale. The bundled sale definition should not be used to undermine transactional efficiencies associated with using a single contract to cover multiple products.

Further, the bundled sale definition should not be construed as defining “drugs of different types” by reference to the 9-digit NDC code (e.g., such that different strengths or dosage forms of the same product would be considered different products). As a practical matter, managed care formulary pricing contracts and pharmacy and therapeutics (“P&T”) approvals made as part of payor plan activities rarely differentiate among different strengths of a product, and instead focus on the chemical entity in question. Thus, in circumstances such as this, manufacturers should be able to presume that the arrangement does not involve a bundled sale.

Second, and very importantly, our client disagrees with the proposal to expand the factors that may “trigger” the bundled sale definition based on certain “other performance requirements.” As noted above, the Proposed Rule appears to provide that merely requiring that multiple products be listed on a formulary as a condition to a discount could trigger the bundled sale definition. The bundled sale definition only should include arrangements in which there is a requirement to actually purchase some quantity of a particular product. A formulary listing, without more, does not constitute a commitment to purchase any quantity of a product, but rather simply an indication that a product will be covered by a particular health plan. For example, if a contract provided for a 15% discount on Product A and a 30% discount on Product B if both products are listed on the formulary of a plan, the plan may have no, or only very limited, utilization of either product, and the prices offered may in fact be consistent with market competitive prices for each product. Similarly, not all contracts with minimum volume or market share requirements should be considered a bundled arrangement. For example, an aggregate volume or market share standard across multiple products would not necessarily require the purchase of any single product in order to achieve the target, and thus would not constitute a purchase requirement with respect to any particular product.

Third, in addition to specifying a new definition of “bundled sale,” the Proposed Rule also provides for a new method of taking bundled sales into account in pricing calculations. Specifically, the Proposed Rule provides that, “For bundled sales, the discounts are allocated proportionally to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle.” 71 Fed. Reg. at 77195.

Notwithstanding our client’s concerns about whether, in some cases, a bundled arrangement even exists (e.g., performance requirements such as formulary status), the reference to the “aggregate value of all the discounts” may be misinterpreted or applied in an overly broad manner to take into account price concessions that are not in fact part of bundled offerings. Specifically, some manufacturers have developed contracts that contain two distinct types of discounts. First, individualized price discounts may be applicable for individual products, without regard to other products. For example, a contract might offer a 15% discount on Product A, and a 30% discount on Product B, without any cross-contingencies between the two products, based on the independent competitive markets for each of those products. As described above, these individual product discounts should not be construed as bundled discounts for the simple reason that the prices relate solely to the individual products. Second, the contract may then contain an “overlay” or “wraparound” discount under which the buyer may earn additional discounts based on a bundled feature. For example, in addition to the basic discounts available for each individual product on a freestanding basis, the contract might provide that, if the customer purchased specified volumes of Product A, the customer will be eligible to receive an additional 3% “overlay” or “wraparound” rebate on both products. In this situation, assuming for the sake of argument that the purchase contingencies triggered the bundling rule, it is only the additional 3% rebate that represents a “bundled” discount, and moreover, since the overlay rebate percentage for both products is the same, the “allocation” of the bundled discount would be relatively simple (i.e., each

product would receive an additional 3% discount for net effective discount percentages of 18% and 33% respectively).

Such a clarification concerning which discounts in an arrangement should be applied to the bundle is economically sound, and in fact may be in the best interests of the Medicaid program. With respect to the former, in the absence of a cross-purchase contingency between products, it is simply incorrect to suggest that the discounts on Product B should be attributed to Product A. Indeed, Product B may be in a more competitive therapeutic category where greater discounts are required. By contrast, if CMS does not provide clarification in the final rule pertaining to prescription drugs under the Medicaid program (the "Final Rule") and the allocation requirement is interpreted to require that all discounts be aggregated, the effect would be that all of the products in the contract would receive the same net effective discount percentage. For example, in the hypothetical above (assuming that the products had approximately equal costs and utilization), the net effective discount for both products would be approximately 25.5% ($18\% + 33\% / 2$). In that scenario, if Product B were a high Medicaid utilization product, the transaction price (and potentially the BP) for Product B could actually increase. In other words, it would be relatively easy for manufacturers, in essence, to "dilute" BPs for significant Medicaid products by simply adding more products to the bundle at lower discount percentages, particularly if the bundling "triggers" were interpreted very liberally as described in these comments. In sum, our client strongly encourages CMS to clarify that it is only "the aggregate value of all the bundled discounts" (*i.e.*, the discounts that are specifically contingent on the purchase of other products) that must be allocated across the drugs in the bundle.

II. Determination of AMP – Section 447.504

A. PBM Rebates

The Proposed Rule requires manufacturers to include all pharmacy benefit manager ("PBM") rebates, discounts or other price concessions "associated with" sales of products to the retail class of trade in the calculation of AMP. The preamble to the Proposed Rule further discusses this requirement and requests comments on whether CMS should define which rebates, discounts, or price concessions should be included in AMP and how to best measure them. Inclusion of PBM rebates "associated with" sales of products through the retail class of trade could be interpreted as applying to all PBM price concessions paid on units that are dispensed by networks and mail order pharmacies. On the other hand, the requirement could be interpreted to require the inclusion only of those PBM price concessions that are paid on units that, at the end of the day, are distributed through the retail class of trade. This interpretation could encompass a smaller subset of PBM price concessions and require greater data tracking to ensure the proper characterization of the concession as being associated with an included or excluded entity (*e.g.*, the exclusion of PBM price concessions associated with long term care ("LTC") pharmacy sales and the inclusion of PBM price concessions associated with sales to traditional retail pharmacies). In the case of PBM rebates, such data often is not readily available.

Accordingly, CMS should clarify that the AMP calculation includes all PBM rebates. Our client believes that such a requirement would be administratively less burdensome to implement and would not materially affect the overall value of manufacturer AMP calculations as compared to differentiating among retail and non-retail PBM utilization. Conversely, requiring additional granularity in allocating PBM rebates could require manufacturers to make significant modifications to existing systems and could result in inaccurate AMP calculations. In addition, under the theory that discounts for products that flow through the retail class of trade are included in AMP, CMS also should include rebates paid to health plans by manufacturers under contracts directly with those health plans, unless the health plan is a staff model HMO.

B. Characterization of SPAP Rebates in AMP

In the Proposed Rule, CMS directs manufacturers to include sales associated with State pharmaceutical assistance programs (“SPAPs”) in the calculation of AMP, and specifically, to reduce AMP revenue by the amount of manufacturer rebates to such entities to the extent the sales flow through an entity included in the retail pharmacy class of trade. CMS justifies this requirement by pointing to the fact that SPAPs do not directly purchase drugs. In contrast, however, CMS proposes to expressly exclude from BP sales associated with SPAPs.

CMS should treat SPAP sales consistently for AMP and BP purposes by excluding them from both calculations. The purpose of the AMP is to reflect market transactions. However, where prices are excluded from the BP determination, manufacturers may provide concessions that do not reflect commercial considerations. This is particularly true in the case of SPAPs, where prices or rebates provided to SPAPs are generally the result of state law rather than market negotiations. Because including prices set by statute in the AMP calculation undermines this purpose, CMS should exclude these amounts from the AMP calculation.

C. Bona Fide Service Fees

The Proposed Rule requires bona fide services fees, as defined in the final Average Sales Price (“ASP”) rule, to be excluded from AMP and BP. CMS should make clear that it is also adopting the final ASP rule’s preamble which contained helpful commentary on many elements of the definition.

In addition, CMS should clarify an issue that the preamble to the final ASP rule left open – specifically, whether fees paid to group purchasing organizations (“GPOs”) and PBMs would come within the definition of bona fide service fees. In the ASP preamble CMS deferred to manufacturers to make this determination based on documented, reasonable assumptions, stating: “We are continuing to develop our understanding of the variety of agreements made with entities such as PBMs and GPOs and the possible effects of these arrangements on the calculation of ASP and provider acquisition costs.” 71 Fed. Reg. 69,624, 69,669 (Dec. 1, 2006).

Fees paid to PBMs and GPOs should receive the same treatment as other administrative and service fees for the purpose of the AMP and BP calculations. As part of the services they provide, these entities often negotiate contracts between manufacturers and purchasers but do not purchase the product themselves. The preamble to the final ASP rule provides that “[i]f a manufacturer has determined that a fee paid meets the other elements of the definition of “bona fide service fee,” then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity.” *Id.* Assuming the preamble to the final ASP rule applies to the Proposed Rule, this presumption alleviates some of the administrative complications associated with monitoring and controlling whether an entity has passed on any portion of its fee to another entity. However, in the absence of definitive guidance on the treatment of GPOs and PBMs under the ASP definition, it may be difficult to ascertain whether GPO and PBM entities have passed on fees to their members or clients because the clients are ultimately purchasers. Accordingly, CMS should clarify in the Final Rule that such arrangements do not constitute price concessions or discounts to purchasers and should not require the manufacturer to ascertain if the fee is passed on.

As CMS stated in connection with the final ASP rule, “manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value of drug distribution services for which they contract.” *Id.* CMS should clarify that this also applies in the AMP context. Given the complexity of the drug market, it is critical for manufacturers to retain sufficient flexibility in making these determinations. However, CMS should consider adopting a threshold standard, such as that articulated in the GPO safe harbor (*i.e.*, 3% of the value of the product), by which any service fee below that threshold would constitute fair market value for the purpose of the definition of bona fide service fees.

Similarly, CMS stated in the final ASP Rule, that “in certain circumstances, it may be appropriate to calculate fair market value for a set of itemized bona fide services, rather than fair market value for each individual itemized service, when the nature of the itemized services warrants such treatment.” *Id.* CMS should adopt the same approach for the purposes of AMP. If manufacturers are required to itemize the value of each individual service included in a service agreement it would significantly and inappropriately impair their flexibility in negotiating service agreements based on the fair market value of a group of services. CMS should clarify that it will not interpret “itemized services” so narrowly as to exclude groups of services from the definition. *See e.g.*, GPO safe harbor regulation to the anti-kickback statute at 42 C.F.R. § 1001.952(j).

D. Direct Patient Sales

The Proposed Rule requires a manufacturer to include direct sales to patients in the calculations of AMP and BP. CMS states that it considers such sales to be “to the retail pharmacy class of trade” even where the manufacturer retains ownership over the product until it is purchased by the patient and uses third party distributors simply to store, deliver, and bill for the product on behalf of the manufacturer, pursuant to a service agreement. CMS should reconsider this rationale, because the statute does not

contemplate that patients are within the classes of purchasers used to determine AMP and BP. With regard to AMP, the patients are purchasing the drugs for personal use and thus are not within the retail class of trade. CMS has explained that "retail pharmacy class of trade" includes only entities that purchase drugs from manufacturers in order to distribute the product to the general public. With regard to BP, patients are not among those entities listed in section 1927(c)(1)(C)(i) of the Social Security Act defining BP. Furthermore, distributors with whom manufacturers contract in order to conduct transactions directly with patients are not "wholesalers" who purchase and resell the product, as CMS suggests. They are simply agents of the manufacturer with regard to conducting transactions directly with patients, and store or ship the product as the manufacturer itself would do, but for the service contract. A service contract with a distributor does not change the nature of the sales transaction at issue or the parties thereto. It is simply the method a manufacturer may use to conduct direct patient sales. Accordingly, direct patient sales should be excluded from AMP and CMS should reexamine its view of service arrangements with distributors in the context of direct patient sales.

E. Coupons and Other Consumer Programs

CMS proposes to exclude only those coupons redeemed by a consumer directly to a manufacturer from the calculations of AMP and BP. CMS reasons that the redemption of coupons by the consumer directly to the manufacturer is not included in the retail pharmacy class of trade for purposes of AMP and, for BP, does not ultimately affect the price paid by an entity.

Notwithstanding the concerns about CMS's proposed treatment of coupons discussed below and the fact that point of sale should not be dispositive, CMS should provide further guidance concerning what arrangements it considers to constitute "coupons directly redeemable to the manufacturer." It is unclear whether CMS intends for the term "coupon" only to cover coupon arrangements in their traditional sense or whether the term also is intended to cover other types of consumer subsidies. For example, consumer offerings may be implemented through various types of mechanisms that resemble coupons (*i.e.*, discount cards, trial scripts, vouchers, or similar programs) which take advantage of more efficient point-of-sale claims processing mechanisms. Our client believes that, in light of current industry practices, the latter, more expansive treatment of the term may be warranted.

As a policy matter, the proposed treatment of coupons in the Proposed Rule could have a chilling effect on manufacturers' willingness to offer coupons and other consumer subsidies. Manufacturers may be unwilling to continue supporting coupon programs that have an unintended AMP or BP effect. Further, even in cases where coupons are directly redeemable to manufacturers and arguably are excluded from AMP and BP calculations, manufacturers may discontinue them if they do not have established capabilities for processing the coupons without assistance from vendors or retailers. Such results could impede patient access to important life-improving medications.

Most importantly, our client does not support CMS's focus on the mechanism for redemption ("directly to the manufacturer") as the touchstone for determining whether a consumer coupon is exempt from pricing calculations. Rather, the more appropriate inquiry is whether the concession (regardless of redemption mechanism) represents a concession to the patient or a discount on the purchase price of a redeeming entity. From an economic perspective, consumer savings arrangements that do not affect the ultimate price paid for a drug by a non-consumer purchaser (such as a retailer) should not be viewed as discounts to that purchaser and, as related to the Medicaid rebate program, should be AMP and BP exempt. Established law supports the principle that consumer coupons are not price concessions to redeeming entities. In reviewing an alleged antitrust violation, for example, the U.S. District Court for the Western District of Pennsylvania held that consumer coupons are not an element of "price."¹ The coupon at issue in that case granted price reductions on coffee to residents in the Cleveland and Pittsburgh areas. The court found that the coupons were solely of benefit to the consumer and did not reduce price to retailers because the retailers "received absolutely no price concession and served merely as redemption agents for Folger."²

CMS's proposal to rely on the method of redemption to determine whether consumer concessions are to be included in price calculations is also inconsistent with the agency's historic practices. Specifically, the agency has issued a number of letters to manufacturers concerning various patient savings cards implemented through point-of-sale mechanisms, which confirm that the savings under those programs do not affect AMP and BP. In each of those cases, CMS determined that, notwithstanding the mechanism for patients to realize the savings, the amounts in question, which were based on standard commercial reimbursement rates, passed through to the benefit of the patient and did not constitute price concessions to the retail pharmacy class of trade.

In our view, the salient test for exclusion from AMP and BP, and one that is consistent with existing law and CMS's prior position, should be whether a coupon or other type of consumer subsidy is solely of benefit to the consumer. If it affects the price realized by the commercial purchaser and not just the consumer, then inclusion in AMP and BP calculations may be appropriate. If it does not, then the coupon or consumer subsidy should be excluded from AMP and BP even if the coupon or subsidy is redeemed by a third party that is not the manufacturer.³ Therefore, while the Proposed Rule addresses one type of coupon structure that may be of benefit only to the consumer and not affect a purchaser's price (*i.e.*, coupons redeemed by a consumer directly to the manufacturer), it may exclude other types of arrangements that are similar in end result. For example, it is not uncommon for a manufacturer to contract with a vendor to administer a coupon program. In such cases, a patient may redeem a coupon from the

¹ See *Indian Coffee Corp. and Penn-Western Food Corp. v. The Procter & Gamble Company and the Folger Coffee Company*, 482 F. Supp. 1104 (Jan. 16, 1980).

² *Id.* at 15.

³ As discussed in the separate comment above relating to direct patient sales, the rebate statute does not contemplate that arrangements directly involving consumers should be included in AMP and/or BP.

vendor and not “directly to the manufacturer.” The vendor is clearly “standing in the shoes” of the manufacturer and the vendor’s participation does not substantively change the nature of the arrangement. Even in cases where a consumer redeems a coupon from a “purchaser,” such as a retail pharmacy, the redemption should not affect the price realized by the purchaser on the product at issue. Indeed, such coupons are not “targeted” to the pharmacies, but rather to the consumers, and the pharmacies are merely redemption entities. This should be the case even where the manufacturer pays a service fee to the retailer in return for the retailer’s role in processing the coupon. CMS should clarify in the Final Rule that these types of situations may be excluded from AMP and BP.

III. Determination of BP – Section 447.505

A. BP “Stacking”

The Proposed Rule generally defines BP as the lowest price available from a manufacturer to any entity that is not otherwise excluded from the BP determination. However, the Proposed Rule goes on to say that BP shall be calculated “to include all sales and associated 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.” CMS should clarify that the references to “all sales and associated discounts” and “to any entity” are not intended to require a manufacturer to aggregate discounts offered to different entities when determining BP.

Unlike AMP, which clearly contemplates that prices be aggregated to determine an “average” amount, the BP is the single lowest price at which the manufacturer sells the product to a single customer. Thus, it is inappropriate to require a manufacturer to “stack” discounts offered at one level of the pharmaceutical delivery system (e.g., to a wholesaler) on top of discounts offered at a completely different level of that system (e.g., to a retailer or health plan). This clarification is consistent with CMS’s preamble discussion of the BP definition as well.

B. Patient Assistance Programs

The Proposed Rule exempts from BP those “prices negotiated under a manufacturer’s sponsored Drug Discount Card Program,” and “goods provided free of charge under a manufacturer’s patient assistance programs.” The Proposed Rule does not define any key terms or discuss CMS’s interpretation of these exemptions.

CMS should clarify the scope of its exemptions related to patient assistance programs. CMS should define the term “patient assistance program” and, to the extent applicable, distinguish patient assistance programs from manufacturer’s Drug Discount Card and coupon programs. In making such distinctions, CMS should specify that patient assistance programs may include programs where products are furnished through a coupon that may or may not be redeemed directly to the manufacturer. For example, some patient assistance programs provide for the redemption of product through retail channels.

Further, CMS should clarify what is meant by the requirement that goods must be provided “free of charge” under a manufacturer’s patient assistance program. For example, it is not uncommon for patient assistance programs to require enrollees to pay a modest co-payment, enrollment fee, and/or handling fee for products provided thereunder. This could result in such products not being considered to be “free of charge.” Such amounts are consistent with maintaining patient responsibility in health care decision-making, however, and indeed, the Office of Inspector General (“OIG”) has approved patient assistance programs involving some patient cost sharing amounts for precisely this reason. These products legitimately are provided through patient assistance programs, and requiring patients to pay a modest amount for products should not materially affect the nature of the arrangement or whether the goods may be excluded from BP. Therefore, further guidance is needed to prevent manufacturers from placing additional restrictions on patient assistance programs because they do not technically meet the “free of charge” requirement.

IV. Authorized Generics – Section 447.506

Consistent with the requirements of the Deficit Reduction Act of 2005 (“DRA”), the Proposed Rule sets forth special treatment for so-called “authorized generics.” In general, proposed 42 C.F.R. § 447.506 provides that the original new drug application (“NDA”) holder (hereinafter the “brand manufacturer”) must include both its own sales of the product, as well as the sales of the product by the “authorized generic manufacturer” in the brand manufacturer’s calculations of AMP and BP. This basic approach appears to be consistent with the statute. Nevertheless, CMS should clarify the applicability of the rule to several common types of transactions. A specific discussion of transaction types is particularly important in light of the variety of such arrangements in the market.

First, manufacturers often enter into simple co-marketing or co-promotion arrangements under which two manufacturers promote the same drug (*i.e.*, a single NDC). Under such arrangements, the original manufacturer continues to own the NDA and NDC of the product, and is responsible for rebate program participation. However, a second manufacturer may be responsible for promoting the product within certain physician specialties, or within certain territories, or for certain market segments such as managed care. The second manufacturer receives a fee for its promotional services. In any event, regardless of which manufacturer “controls” the pricing policy with respect to the drug, the ultimate sales prices are taken into account by the NDA holder. CMS should confirm that this arrangement would not qualify as an authorized generic arrangement, because there is only a single product and all of the sales associated with that single product originate with the original manufacturer and must be appropriately considered when calculating AMP and determining BP.

Second, under a common type of authorized generic arrangement, the “brand manufacturer” grants a license to the “authorized generic manufacturer” to sell a generic version of the product, in return for a license fee. The generic manufacturer, in turn, manufactures its own product at its own facilities pursuant to the license, and sells the product under its own NDC number. Under this model, the authorized generic

manufacturer's sales to end-user customers would need to be taken into account by the brand manufacturer in its pricing calculations under the Proposed Rule, along with the brand manufacturer's sales data for sales of product bearing its own NDC. CMS should clarify, however, that the license fee under this transaction would not need to be taken into account in pricing calculations. Such fees are not transaction sales prices, but instead are payments for general, intangible rights to market the product under the authority of the brand manufacturer's NDA.

The third transaction type is similar to the second in that it involves a grant of authorization, but instead of (or perhaps in addition to) a license fee, the brand manufacturer also enters into a contract manufacturing and supply agreement under which it produces the product for the authorized generic manufacturer for a specified fee or price. With respect to this scenario, the Proposed Rule is somewhat ambiguous in that it could be read to require the brand manufacturer to take into account for BP purposes the contract manufacturing fee or the "transfer price" at which the fabricated product was "sold" to the authorized generic manufacturer. Our client does not believe that such contract manufacturing prices should be taken into account in the BP determination. Such prices are not commercially determined prices, but rather represent contract manufacturing arrangements. Moreover, if contract manufacturing "prices" were taken into account, the brand manufacturer could be subject to a BP on the same unit of product in two different quarters (e.g., in quarter one based on the contract manufacturing price, and in quarter two based on the authorized generic manufacturer's sale price to a customer). Accordingly, CMS should clarify that contract manufacturing prices need not be taken into account in authorized generic arrangements, and instead only the authorized generic manufacturer's prices for the sale of product in the market must be considered.

In addition to these traditional authorized generic models, CMS should clarify that the authorized generic rules simply do not apply to situations in which a product is sold to a second manufacturer for purposes of incorporating the product into a "kit" consisting of multiple products. Under these circumstances, the "kit" itself constitutes a separate product for regulatory purposes, and is marketed under the labeler code of the second manufacturer. Thus, the arrangement is not an authorized generic arrangement at all, because the original manufacturer is not authorizing the second manufacturer to market a "generic" version of the product. Rather, it is simply a supply agreement for a component of a completely separate product.

We also urge CMS to confirm that a true "divestiture" of a product, under which a brand manufacturer sells all rights to the product to another company and ceases to sell the product itself, does not constitute an authorized generic arrangement. Under this scenario, as of the transaction date, it is common for the brand manufacturer to have existing unsold inventory. This inventory typically transfers to the new owner as part of the arrangement, but the new owner may not relabel it under its own NDC. Under the current program, the original manufacturer continues to report the AMP and BP for product bearing its labeler code, and we would expect this practice to continue taking into account the sales of that specific inventory by the new owner. However, our client does not believe that it is appropriate in these circumstances for the "new" manufacturer's sales of product bearing the new owner's labeler code to be attributed to the "original"

manufacturer for reporting purposes. The original manufacturer has ceased selling the product, has no control of the prices charged by the second manufacturer, and does not benefit from any revenue realized from these sales. In sum, true divestiture should not qualify as an authorized generic arrangement because the product in question is not a generic product, but rather is the original product.

Finally, CMS should clarify the exclusion from the definition of “authorized generic drug” for drugs that are repackaged for use in institutions. For example, CMS should confirm that private label arrangements involving the branded product sold with its 9 digit NDC, but with distinct packaging and a different package code, do not constitute “authorized generic drugs” where the private label product is used in an institution. In addition, CMS should also confirm that private label arrangements involving distinct packaging due to variations in package size from the branded product do not constitute “authorized generic drugs” where the private label product is used in an institution.

In addition to these policy concerns, our client has significant operational concerns and questions associated with the reporting for authorized generic arrangements. First, under the Proposed Rule, brand and authorized generic manufacturers will have to share pricing data to facilitate appropriate reporting. CMS should confirm that it will allow manufacturers some measure of flexibility in reporting in order to address the information systems issues that will undoubtedly arise. Similarly, CMS should confirm that brand manufacturers may rely on AMP and BP data furnished to them by authorized generic manufacturers without having to review the underlying data and methodologies for accuracy. Second, and related to the first, because the reporting will necessarily require sharing of sales data, CMS should consult with antitrust and trade regulation enforcement agencies such as the Federal Trade Commission about the new requirements of the DRA, and urge those agencies to consider issuing guidance concerning these mandatory data-sharing activities. Finally, CMS should provide guidance concerning situations where, after the authorized generic product has been launched, the brand manufacturer discontinues the product. Ordinarily in such circumstances, the brand manufacturer’s AMP from its final quarter of sales would be used to determine rebate liability through the program termination date for the product. CMS should clarify that this treatment would continue, and that the brand manufacturer would not have to take into account authorized generic sales data after the date it ceases marketing the brand product. Otherwise, the brand product might effectively “never” be terminated for purposes of the program even though the brand manufacturer no longer sells it.

V. Requirements for Manufacturers – Section 447.510

A. Application of the Regulations

The Proposed Rule implements the provisions of the DRA pertaining to prescription drugs under the Medicaid rebate program and the DRA’s requirement that the Secretary of the Department of Health and Human Services publish a final regulation no later than July 1, 2007. The Proposed Rule also clarifies certain aspects of the

Medicaid rebate calculation not addressed in the DRA such as bundles, coupons and refinements to the retail class of trade definition and puts into regulation other guidance that CMS has issued since the Medicaid rebate program was implemented. In some cases, the Proposed Rule changes CMS's historic interpretations of the rebate program.

CMS should clarify in its Final Rule that, other than those provisions with implementation dates specified under the DRA, the regulations will apply on a prospective basis only, starting at least two quarters after CMS releases the Final Rule and, as detailed below, in the case of baseline AMP recalculations, following a longer period. The prospective application of the Final Rule is necessary because, historically, the calculation of AMP has been ambiguous and, as reported by the OIG, manufacturers currently do not calculate AMP in a consistent manner. Accordingly, if the provisions of the Final Rule apply on a retrospective basis, this could necessitate many manufacturers having to recalculate and resubmit AMPs and BPs for prior quarters. This could create an unanticipated administrative burden for CMS as it reviews the changes and also could distract manufacturers from the important task of implementing the Final Rule changes on a going-forward basis. Moreover, there are a number of provisions of the Proposed Rule that reflect changes in the agency's approach in areas not addressed by the DRA itself.

CMS also should give manufacturers a reasonable timeframe before it implements any changes specified in the Final Rule. Again, because manufacturers currently may not be calculating AMP in a consistent manner or in a way that wholly meets the requirements of the Proposed or Final Rule, it may take time for manufacturers to make the necessary systems changes required to implement all of the provisions of the Final Rule. Our client believes that allowing at least two quarters to comply with the Final Rule guidance following its release will be necessary to minimize inaccuracies and potential errors that could result from manufacturers rushing to implement the changes.

In the case of resetting baseline AMP, CMS should consider a longer implementation timeframe than two quarters following release of the Final Rule. Specifically, CMS should set a date certain deadline in which manufacturers must submit recalculated baseline AMPs (e.g., January 1, 2009) but require that all manufacturers who choose to recalculate must refile their AMPs back to the effective date of the Final Rule. Such additional latitude is necessary because it is unlikely that all manufacturers that choose to reset their baseline AMPs will have ready access to the historical information needed to make this calculation. Further, given the importance of the baseline AMP in determining a manufacturer's rebate liability, any recalculation should not be undertaken lightly or in a manner that does not allow adequate time for thorough review and analysis.

B. Certification Requirement

The Proposed Rule requires manufacturers to certify their quarterly and monthly AMP reports and adopts the certification requirements established by Medicare Part B for ASP figures. The ASP certification reads, in part, as follows: "I certify that the reported Average Sales Prices were calculated accurately and that all information and statements

made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith.”

Our client believes that, if the ASP certification language is to be used in connection with AMP and BP data for the purpose of the Medicaid program, it should be revised. Specifically, given that the Medicaid AMP reporting requirements and calculation standards are new, and given the inevitable uncertainties associated with any newly-implemented standards, the certification language should contain a knowledge qualifier until the standards are no longer in a state of flux and manufacturers can become more comfortable with the exact standards to be imposed. Further, a qualifier seems necessary in order to recognize the “knowledge” element of the Medicaid civil monetary penalty standard. Stated otherwise, although the civil monetary penalty provision applicable to Medicare and ASP submissions imposes liability for misrepresentations in reporting regardless of intent or knowledge, the Medicaid statute’s civil monetary penalty provision only imposes liability for “knowingly” providing false information to CMS. Accordingly, the appropriate certification should be expressly qualified and should read as follows: “To the best of my knowledge and belief, the reported Average Manufacturer and Best Prices were calculated accurately and all information and statements made in this submission are true, complete, and current.”

VI. Further AMP Clarifications

A. Reporting of Multiple AMPs

CMS should coordinate with the Office of Public Affairs within the Healthcare Systems Bureau of the Health Resources and Services Administration (“OPA”) to ensure that manufacturers are required to calculate and report only a single AMP, and to offer covered entities discounts based on the AMP methodology specified in the Final Rule. In a January 30, 2007 letter, the OPA indicated that, notwithstanding the DRA changes to the AMP calculation for purposes of the rebate program, manufacturers that have signed pharmaceutical pricing agreements must continue to calculate 340B ceiling prices in accordance with the provision of the Social Security Act “as in effect on the date of enactment of this section.” OPA letter (quoting 42 U.S.C. § 256B(c)). The OPA letter interprets this to mean that 340B ceiling prices must continue to reflect a reduction for prompt pay discounts.

Our client strongly opposes any putative requirement that it would need to calculate two separate AMPs. This would pose significant burdens on manufacturers and would likely inhibit their ability to implement the DRA. Further, it would pose significant operational challenges for both CMS and manufacturers in light of the more frequent reporting requirements under the DRA.

Moreover, if OPA’s basic statutory construction were actually followed to the letter, the administrative burden would be both significant and could result in little practical change to the prices available to covered entities. Section 340B of the Public Health Services Act was enacted as part of the 1992 Veterans Health Care Act. Therefore, references to the Social Security Act should be based on the statutory

provisions in effect at that time (i.e., those provisions in effect under the Omnibus Budget Reconciliation Act of 1990 (“OBRA 1990”). Section 1927(k) of the Social Security Act then defined AMP to mean the average price paid to the manufacturer for drugs distributed to the retail pharmacy class of trade. A deduction for customary prompt pay discounts was not added until this provision was subsequently amended under the Omnibus Budget Reconciliation Act of 1993 (“OBRA 1993”). Accordingly, following OPA’s interpretation literally, the calculation of AMP for purposes of the 340B program should not (and should never have) included a reduction for customary prompt pay discounts. This treatment is wholly consistent with the post-DRA treatment of AMP whereby customary prompt pay discounts are not deducted from AMP. Moreover, following the OPA’s interpretation literally would require that manufacturers determine 340B prices using pre-OBRA 1993 Base AMP data.

Notwithstanding OPA’s misstatement of the 340B AMP calculation requirements as continuing to require a reduction for customary prompt pay discounts, our client is concerned about the significant administrative and computational burden that may result if OPA requires a different AMP calculation than CMS. For example, the 1992 provisions of the Social Security Act did not address the treatment of authorized generic arrangements and presumably must be excluded from AMP for 340B purposes. Accordingly, given the post-DRA importance of AMP and CMS’s responsibility in defining key aspects of the calculation through its issuance of the Proposed and Final Rules, CMS should coordinate with OPA and require, on a going forward basis, that manufacturers calculate only a single AMP that is consistent with the DRA.

B. Physician-Administered Drugs

The DRA amended how physician-administered drugs should be treated for purposes of the Medicaid rebate and allows states to collect a rebate for physician-administered drugs only to the extent that Medicaid covers the cost of such drugs. Because Medicaid generally only covers a portion of the costs of physician-administered drugs provided to beneficiaries dually eligible for both Medicare and Medicaid (“dual eligibles”), while Medicare covers the rest, CMS should limit the states’ ability to collect rebates for the entire cost of such drugs. The Proposed Rule, however, fails to address this issue. Moreover, in a response letter to Senator Grassley dated December 15, 2006, CMS stated that its position on this issue – to allow states to receive the full rebate amount for drugs administered by physicians to dual eligibles, regardless of the fact that Medicare pays a portion of that cost – would continue.

As stated by Senator Grassley, the DRA requires that Medicaid rebates only be paid for the Medicaid portion of the cost of physician-administered drugs provided to dual eligibles. To the extent that Medicare, as primary payor, covers the majority of that cost, states are not authorized to collect the full amount. He writes: “There should be no question that [the] language [allowing states to collect rebates] refers only to rebates collected pursuant to the Medicaid rebate authority in Section 1927 and, therefore, only for the Medicaid payments made for such drugs. It is also clear that this language certainly does not grant states the authority to collect rebates for prescription drug expenses covered by the Medicare program.” Letter from Charles E. Grassley,

Chairman, United States Senate Committee on Finance, to Mark B. McClellan,
Administrator, CMS (Aug. 14, 2006).

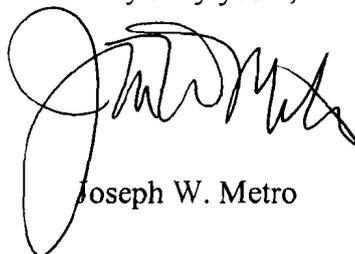
CMS has acknowledged in its response to Senator Grassley that section 1927(a)(7)(A), as amended by the DRA, requires physician-administered single source drugs to be identified in order to secure Medicaid rebates for which Medicaid payments are made. CMS nevertheless concludes that rebates for which Medicare payments are made are also collectible under the Medicaid rebate program. There is no basis for this position which both contradicts the legislative intent of the DRA provision as outlined by Senator Grassley and manipulates the purpose of the Medicaid rebate statute – to ensure that Medicaid did not have to pay more for drugs than manufacturers charged other purchasers – by perpetuating a windfall for the states.

Accordingly, CMS, in accordance with the DRA amendments to the Social Security Act, should expressly retract in the Final Rule its current policy allowing states to collect the entire cost of physician administered drugs for dual eligibles if Medicare is the primary payor for that unit. Our client proposes that CMS establish a method for states to pro-rate the rebate amounts by applying an appropriate ratio to each unit of physician-administered product.

* * * *

We appreciate the opportunity to comment on these issues. Please do not hesitate to contact us if you have any questions.

Very truly yours,

A handwritten signature in black ink, appearing to read "Joe Metro", written in a cursive style. The signature is positioned above the printed name "Joseph W. Metro".

Joseph W. Metro

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February 20, 2007

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BY COURIER

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS-2238-P

Dear Acting Administrator Norwalk:

The law firm of Covington & Burling LLP submits these comments in response to regulations proposed on December 22, 2006, by the Centers for Medicare & Medicaid Services (CMS) to implement the provisions of the Deficit Reduction Act of 2005 pertaining to prescription drugs under the Medicaid program and to clarify other issues relating to the determination of Average Manufacturer Price (AMP) and best price. Covington & Burling provides regulatory advice to a wide variety of pharmaceutical clients, including many prescription drug manufacturers whose drug products are reimbursable under the Medicaid program. In the course of our representation of these clients, they have alerted us to a number of concerns regarding the proposed rule. As discussed below, we believe that portions of the proposal require further clarification or would be unduly burdensome for both manufacturers and CMS. Along with our clients, we are very grateful to CMS for its efforts to clarify various long-standing issues and for the opportunity to comment on the implications of CMS's proposals.

I. **Manufacturer Coupons**

The proposed rule would exclude from AMP and best price 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 would seem to require that coupons redeemed by a consumer to an intermediary, such as a pharmacy (which then seeks reimbursement from the manufacturer), be included in AMP and best price.

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Such an interpretation of the rule could result in fewer patients receiving assistance in paying for their drugs because manufacturers would be less likely to enter into arrangements whereby consumers could redeem manufacturer coupons at the point of sale. Instead, it is more likely that manufacturers would require consumers to send their coupons and proof of purchase directly to the manufacturer, which would then issue a rebate check to the consumer. The point-of-sale process is very easy for the consumer and results in the consumer not having to make an initial outlay of the coupon amount. By contrast, the paperwork involved in redeeming the coupon after purchase may discourage many consumers from taking advantage of the coupon offer. And those who do complete the redemption process will have to wait weeks or months to receive the benefit of the coupon. Thus, CMS's proposed treatment of coupons not redeemed directly to the manufacturer would be disadvantageous to consumers.

In addition, CMS has in the past taken the position that the discounts provided through a drug discount card redeemed by the pharmacy, rather than directly by the patient, to the manufacturer would not be included in the determination of best price.¹ In coming to this conclusion, CMS noted the following elements of the program at issue:

- The benefit provided to the patient was set by the manufacturer without any negotiation between the manufacturer and a third party;
- The entire amount of the benefit was made available to an individual patient, without any opportunity for the retail pharmacy other third party (such as an insurer or pharmacy benefit manager (PBM)) to reduce that benefit or take a portion of it for its own purposes; and
- The pharmacy collected no additional payment, other than the benefit amount, from the drug discount program. (We assume that a fee that merely reimbursed the cost incurred by the pharmacy in processing the coupon would not be considered an "additional payment.")

We request that CMS clarify the language of the proposed rule so that it is clear that coupon programs that meet the above criteria should not be taken into account for purposes of determining AMP and best price. Such a clarification is consistent with CMS's current policy, and the statutory definitions of AMP and best price and would allow consumers to continue to enjoy the benefits of coupons redeemed at point of sale.

¹ See Letter from Thomas A. Scully, Administrator, Centers for Medicare & Medicaid Services, to Thomas McKenna, Senior Vice-President/Planning and Operations, Bristol-Myers Squibb Company (Oct. 22, 2002).

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While it is not completely clear, we assume that CMS would consider coupons redeemed by a consumer through a program that requires that the consumer send the coupon to a fulfillment house that processes the redemption on behalf of the manufacturer to be “coupons redeemed directly to the manufacturer.” In such an arrangement, processing is being outsourced, but the fulfillment house is acting as the agent of the manufacturer for purposes of the redemption program. In addition, the fulfillment house has no role in the distribution or dispensing of the drug product itself. We therefore request that CMS confirm this interpretation in the final rule.

II. Authorized Generics

The proposed rule requires that AMP and best price determinations for a branded drug include the prices of authorized generics marketed by another manufacturer or subsidiary of the brand manufacturer or NDA holder. It also provides that the secondary manufacturer or subsidiary must pay the single source or innovator multiple source rebate for the authorized generic based on utilization under its own NDC number.

The proposed rule does not address the actual process by which competitors will be expected to share data in order to comply with the rule. Given the understandable reluctance on the part of drug manufacturers to disclose to their competitors information that would otherwise be deemed confidential, we believe that any such process cannot succeed without clear guidance from CMS on the matter. We therefore request that CMS include in the final rule a clear description of the process by which the required data sharing is to occur.

In addition, we request that CMS clarify in the final rule that the manufacturers of authorized generics continue to have an independent price reporting obligation based only on their own data and that the rebates to be paid on their products would be based on their reported AMP and best price.

III. Bundled Sales

The proposed rule would require AMP and best price to be adjusted for any bundled sales. 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 proposed rule would require that the aggregate value of the discounts be proportionately allocated across all of the drugs in the bundle.

The definition of a bundled sale in the proposed rule seems to broaden that concept in ways that would be problematic. As defined in the 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 National Drug Code (NDC) level) or upon some other performance requirement (e.g., the achievement of market share, inclusion or tier placement on a formulary), or where the

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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.” CMS’s current policy, as set forth in the Sample Rebate Agreement, is that a bundled sale refers to 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 current definition includes only arrangements where there is a purchase requirement for each product in the bundle, not merely a formulary placement requirement. A formulary placement requirement without a purchase requirement does not condition a discount on another product on purchase of the placed product and should not be the basis for considering a sale to be bundled.

The requirement that the value of the discounts be proportionately allocated across all of the drugs in the bundle could open the door for manipulation with regard to price reporting for bundled products. To illustrate this point, consider the following example of three bundled products, each sold at a discount:

Product	Units Sold	WAC	Sales at WAC	Percentage Discount	Unallocated Discount Amount	Allocated Discount Amount	Unallocated Net Sales	Allocated Net Sales	Potential Best Price without Allocation	Potential Best Price with Allocation per Proposal
A	20	\$100	\$2,000	10%	\$200	\$948	\$1,800	\$1,052	\$90	\$52.62
B	50	\$100	\$5,000	10%	\$500	\$2,369	\$4,500	\$2,631	\$90	\$52.62
C	1000	\$100	\$100,000	50%	\$50,000	\$47,383	\$50,000	\$52,617	\$50	\$52.62
Total	1070		\$107,000	Aggregate : 47.38%	\$50,700	\$50,700	\$56,300	\$56,300		
A	500	\$100	\$50,000	10%	\$5,000	\$5,374	\$45,000	\$44,626	\$90	\$89.25
B	550	\$100	\$55,000	10%	\$5,500	\$5,911	\$49,500	\$49,089	\$90	\$89.25
C	20	\$100	\$2,000	50%	\$1,000	\$215	\$1,000	\$1,785	\$50	\$89.25
Total	1070		\$107,000	Aggregate : 10.75%	\$11,500	\$11,500	\$95,500	\$95,500		
A	20	\$100	\$2,000	20%	\$400	\$1,166	\$1,600	\$834	\$80	\$41.68
B	50	\$100	\$5,000	40%	\$2,000	\$2,916	\$3,000	\$2,084	\$60	\$41.68
C	1000	\$100	\$100,000	60%	\$60,000	\$58,318	\$40,000	\$41,682	\$40	\$41.68
Total	1070		\$107,000	Aggregate : 58.32%	\$62,400	\$62,400	\$44,600	\$44,600		

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Product	Units Sold	WAC	Sales at WAC	Percentage Discount	Unallocated Discount Amount	Allocated Discount Amount	Unallocated Net Sales	Allocated Net Sales	Potential Best Price without Allocation	Potential Best Price with Allocation per Proposal
A	500	\$100	\$50,000	20%	\$10,000	\$15,514	\$40,000	\$34,486	\$80	\$68.97
B	550	\$100	\$55,000	40%	\$22,000	\$17,065	\$33,000	\$37,935	\$60	\$68.97
C	20	\$100	\$2,000	60%	\$1,200	\$621	\$800	\$1,379	\$40	\$68.97
Total	1070		\$107,000	Aggregate : 31.03%	\$33,200	\$33,200	\$73,800	\$73,800		

As this example shows, if CMS requires allocation of the aggregate value of the discounts across a bundle, best price for a particular product within the bundle will be affected not only by the discounts on and volume of sales of that product, but also by the discounts on and volume of sales of the other products within the bundle. Thus, a manufacturer could conceivably manipulate best price by the way it bundles products and the customers to whom it offers the bundles.

In addition, the administrative burden of requiring manufacturers to implement a system for aggregating and allocating discounts for bundled sales will be huge. Developing a system to account for lagged discounts for bundled products poses a particular challenge. Each customer's bundle will have to be evaluated separately to determine its effect on best price and AMP. Moreover, much of the volume data needed to allocate the bundled discounts will be lagged data and may require multiple recalculations in subsequent quarters.

The agency has estimated that the start-up burden for complying with the requirements of the proposed rule is \$50,000 per manufacturer and that that it will take each manufacturer 208 hours to implement the necessary systems. Based on conversations with numerous drug manufacturers, we believe that these figures greatly underestimate the costs of developing a system for allocating bundled sales, to say nothing of the costs to implement the systems changes necessary to comply with the remainder of the proposed regulation. (We have been informed that some manufacturers believe that the cost of necessary systems changes could be millions of dollars). We therefore urge CMS to reconsider both the definition of a bundled sale and how such a sale should be treated for purposes of determining AMP and best price.

IV. Definition of Best Price

"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

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payments) in the same quarter for which AMP is computed” (emphasis added). Immediately after reciting that definition in the preamble, however, CMS states that “[i]t continues to be [CMS’s] policy that best price reflects the lowest price at which the manufacturer *sells* a covered outpatient drug to any purchaser” (emphasis added). It appears that it is CMS’s intent to interpret “lowest price available” to mean “the lowest price at which the manufacturer sells” the product. Throughout the preamble, CMS appears to use the terms “available” and “sells” interchangeably. We believe that CMS’s interpretation is appropriate. If best price were defined to include the lowest price available, whether or not there was a sale at that price, manufacturers would face difficult data collection and documentation requirements in ensuring that all prices offered were taken into account. Further, manufacturers may have a disincentive to negotiate with purchasers out of concern for having to include any prices offered in their subsequent determination of best price, even if the negotiations did not lead to a sale. We therefore request that CMS confirm that best price will continue to be the lowest price at which a drug is actually sold.

V. Cumulative Discounts

The Sample Rebate Agreement specifies that best price is to reflect cumulative discounts or other arrangements that subsequently adjust the prices actually realized. The proposed rule does not address the issue of how manufacturers should cumulate discounts in determining best price. But as the General Accounting Office (GAO) described in its 2005 report, manufacturers differ in how they account for downstream discounts. Some manufacturers calculate their net sale price as their price to the wholesaler, reduced by any subsequent discounts, such as chargebacks and discounts to PBMs. Other manufacturers consider only the price charged to the wholesaler and therefore do not take subsequent discounts to other entities into account in calculating best price to the wholesaler. (A separate calculation is made to determine best price to the PBM.) This ambiguity leaves room for considerable manipulation of best price. Since the statute provides that best price is to reflect “the lowest price available . . . to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, *or* governmental entity within the United States,” Social Security Act § 1927(c)(1)(C) (emphasis added), it is not appropriate to consider discounts other than the discounts offered to one customer when determining best price, for those other discounts are never available to that customer. We therefore request that CMS clarify that discounts to a single entity should be cumulated, but discounts to different purchasers should not be cumulated, when determining best price.

VI. Smoothing

The proposed rule recognizes that if “monthly AMP were calculated simply using sales in that month, [industry] pricing practices might result in fluctuations” in the AMP from month to month. In particular, many manufacturers offer rebates or other price concessions at the end of a calendar quarter, which would result in a drop in AMP for that month. CMS therefore proposes to allow manufacturers to rely on estimates regarding end-of-quarter rebates or other price concessions and to allocate those estimates in their calculation of monthly AMP. The preamble

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also mentions several other possible methodologies for handling lagged rebates and discounts, such as the use of 12-month rolling average estimates.

While we agree that such "smoothing" would maximize the utility of AMP and minimize volatility in prices, we are concerned that CMS has greatly underestimated the efforts required by manufacturers to implement a system that would facilitate smoothing. We therefore request that CMS explicitly state that manufacturers will have the option to employ any smoothing process that CMS may adopt, but that use of such a methodology is not mandatory. If CMS were to make smoothing mandatory in any circumstances, we urge CMS to extend the period for compliance with these methodologies, for we believe that the time and resources required will be greater than CMS has anticipated. Extra time is also appropriate in light of the fact that the CMS proposal does not give manufacturers any clear idea of what smoothing methodology may be developed.

VII. Sales to Hospitals

The proposed rule provides that direct and indirect sales to hospitals for use in the inpatient setting be excluded from AMP because these prices are not available to the retail pharmacy class of trade. By extension, therefore, sales of drugs dispensed in hospital outpatient pharmacies would be included in AMP. In practice, however, hospitals do not generally purchase drugs for use solely in one setting or the other. We have been informed that manufacturers have no way of tracking how their drug products are used once they are purchased by a hospital, so they cannot separate inpatient uses from outpatient uses. Manufacturers believe that many hospitals would not be able to provide them with this information. Expecting manufacturers to implement systems to track their products in the hospital setting would be unduly burdensome, if not impossible in some cases. We therefore recommend that CMS clarify in its final rule that all sales to hospitals are be excluded from AMP.

VIII. Definition of Managed Care Organization (MCO)

In some places in the proposed rule and preamble to the proposed rule, CMS uses the terms "HMO" and "MCO" seemingly interchangeably. But in other places, it refers to "health maintenance organizations (HMOs), including managed care organizations (MCOs)," suggesting that MCOs are a class or subset of HMOs. The term "managed care organization" is usually used as an umbrella term to refer to a number of different entities, one of which is an HMO. We therefore request that CMS clarify the definition of "managed care organization" for purposes of the final rule.

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We once again thank CMS for the opportunity to comment on the proposed rule and for its efforts to produce a final rule that will meet statutory objectives and provide a clear and realistic framework for all parties.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Anna D. Kraus".

Anna D. Kraus

Christopher G. Janney
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John FEB 20 2007 *sj*

February 20, 2007

BY HAND DELIVERY

The Honorable Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-2238-P: Medicaid Program; Prescription Drugs

Dear Acting Administrator Norwalk:

On December 22, 2006, the Centers for Medicare & Medicaid Services ("CMS") published the referenced proposed rule ("Proposed Rule") in the Federal Register, 71 Fed. Reg. 77174. Among other things, the Proposed Rule addresses how pharmaceutical manufacturers should calculate the "average manufacturer price" ("AMP") and "best price" ("Best Price") of their covered outpatient drugs for purposes of the Medicaid drug rebate program ("MDRP"). On behalf of Novation, LLC ("Novation"), University HealthSystem Consortium ("UHC"), and VHA, Inc. ("VHA"), we respectfully submit comments with respect to certain aspects of the Proposed Rule.

UHC is a legal cooperative that is owned, governed and controlled by state-owned and private, non-profit academic medical centers and teaching hospitals. VHA is a legal cooperative that is owned, governed and controlled by non-profit, tax-exempt, community based hospitals. Both UHC and VHA are idea-generating and information-disseminating organizations that help their members pool resources, create economies of scale and improve clinical care and operating efficiency. Consistent with their missions, UHC and VHA offer their members (among other things) group purchasing programs. For purposes of these programs, UHC and VHA act both directly and through their jointly-owned agent, Novation.

I Administrative Fees

A. Proposed Rule

The Proposed Rule provides that any “administrative” or “service” “fee” that “reduce[s] the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade” must be included in the calculation of AMP.¹ Similarly, the Proposed Rule provides that any “administrative” or “service” “fee” that “reduce[s] the price available from the manufacturer” to certain entities must be included in the calculation of Best Price.² Specifically excluded from the calculation of AMP and Best Price, however, are “bona fide service fees,”³ which are defined 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.⁴

B. Comments

1. “Bona Fide Service Fees” and Price Concessions

As noted above, the Proposed Rule provides that if a drug manufacturer pays a “bona fide service fee,” that payment does not constitute a price concession for AMP or Best Price purposes. Given the importance of this issue, we would urge CMS to clarify that the converse is not true. That is, just because a drug manufacturer’s payment does not meet the definition of a “bona fide service fee” does not mean that the payment is, necessarily, a price concession for purposes of calculating AMP or Best Price.

¹ 42 C.F.R. § 447.504(i)(1) (proposed).

² 42 C.F.R. § 447.505(e)(1) (proposed).

³ 42 C.F.R. § 447.504(h)(11) (AMP) (proposed); 42 C.F.R. § 447.505(d)(12) (Best Price) (proposed).

⁴ 42 C.F.R. § 447.502 (proposed).

Indeed, were the case otherwise, any payment made by a drug manufacturer to any “entity” could be deemed a price concession, even if the payment plainly does not fall into that category. For example, drug manufacturers use electricity and, as such, make payments to utility companies (*i.e.*, “entities”). Such payments may not qualify as a “bona fide service fee” (for example, the amount paid by the manufacturer to the utility might be more or less than fair market value). Plainly, however, the fact that the manufacturer’s payment to the utility does not qualify as a “bona fide service fee” does not mean that the payment constitutes a price concession for AMP or Best Price purposes.

In order to avoid any confusion or misinterpretation of the Proposed Rule, and given the importance of having AMP and Best Price calculated in a uniform and consistent manner, we respectfully suggest that CMS clarify that while payments that qualify as “bona fide service fees” are “safe harbored” — that is, such payments do not, as a matter of law, constitute price concessions for AMP or Best Price purposes — payments that do not qualify as “bona fide service fees” may or may not constitute price concessions.

2. GPO Fees

In the preamble to its recent “average sales price” (“ASP”) final rule (“ASP Rule”), CMS states that it is “continuing to develop [its] understanding of the variety of agreements” made with entities such as group purchasing organizations (“GPOs”).⁵

For this reason, at this time we believe it is premature for us to provide specific guidance with respect to treatment of fees paid by manufacturers to . . . GPOs in the ASP calculation . . . Instead, we will continue to consider the comments received and to study the matter further . . . In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Act, Federal regulations, and its customary business practices. These assumptions should be submitted along with the ASP data.⁶

⁵ 71 Fed. Reg. 69624, 69669 (December 1, 2006).

⁶ 71 Fed. Reg. at 69669.

We believe that the most reasonable interpretation of this statement is that until CMS provides specific guidance with respect to the treatment of GPO fees, if a manufacturer's customary business practice is (for example) to exclude such fees from the calculation of ASP — on the assumption that fees paid to a third party do not constitute price concessions offered to a purchaser — the manufacturer may continue this practice, provided it informs CMS in writing of this assumption.

We believe that CMS should adopt this same approach with respect to the determination of AMP and Best Price. In order to avoid uncertainty and confusion among manufacturers, GPOs and other third parties — and in an effort to ensure uniformity in AMP and Best Price reporting to the greatest extent possible — we would urge CMS to make this clarification when it finalizes the Proposed Regulations. Among other things, it would not make sense for a manufacturer to exclude bona fide GPO fees from its determination of ASP (based on CMS' statements in the ASP Rule preamble), but to include such fees in calculating its AMP and Best Price (based on CMS' silence with respect to this issue in the Proposed Regulations).

3. Payments Not Controlled by Manufacturer

For the reasons set forth below, we believe that there are certain fees that plainly are not "price concessions" offered "by" a "manufacturer" "to" a "purchaser" and, as such, should not be included in the calculation of AMP or Best Price. Depending on the meaning of "passed on" in the definition of "bona fide service fee," however, these fees may not fall into the "bona fide service fee" category. A hypothetical helps demonstrate the point. Assume the following:

- January 1, 2007: Manufacturer enters into a personal services agreement with Organization.
- January 15, 2007: Pursuant to this agreement, Organization furnishes services to Manufacturer. Manufacturer pays Organization a \$90 fee for these services.
- February 1, 2007: Organization enters into a personal services agreement with (retail) Pharmacy (one of Organization's customers). Manufacturer is not involved in the negotiation of, and is not a party to, this Organization-Pharmacy agreement.

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- February 15, 2007: Pursuant to this agreement, Pharmacy furnishes services to Organization. Organization makes a \$90 payment to Pharmacy for these services.
- March 1, 2007: In discussions with Organization, Manufacturer learns of Organization's agreement with (and \$90 payment to) Pharmacy.
- During the first quarter of 2007, Manufacturer sells 20 units of Drug A for \$100 per unit. One of these units is sold to Pharmacy.

Under these circumstances, it might be contended that the \$90 fee paid by Manufacturer to Organization (on January 15) does not qualify as a "bona fide service fee" on the ground that it was "passed on" by Organization to Pharmacy (on February 15). (Although we do not believe that this would be a fair or reasonable interpretation of "passed on," the term is not defined in the Proposed Rule, and this issue is not discussed in the Proposed Rule's preamble.) Even were CMS to concur with this interpretation, however — and, as such, conclude that the fee does not qualify as a "bona fide service fee" — CMS presumably would not take the position that the \$90 fee at issue constitutes a price concession "by" or "from" Manufacturer "to" Pharmacy for AMP or Best Price purposes.

It is true that the funds for the payment from Organization to Pharmacy came from Manufacturer — at least in the macro sense that \$90 flowed from Manufacturer to Organization on January 15, \$90 flowed from Organization to Pharmacy on February 15, and money is fungible. It also is true that Manufacturer had knowledge of Organization's payment to Pharmacy. These two facts, however, are not sufficient to establish that Manufacturer made a \$90 price concession to Pharmacy.

The reason for this is straightforward: although (1) the funds may have originated (again, in a macro sense) with Manufacturer, and (2) Manufacturer had knowledge of the payment by Organization to Pharmacy, Manufacturer did not control this payment. That is, the payment by Organization to Pharmacy was not made at the request of, or pursuant to a contractual (or other legal) obligation that Organization owed to, Manufacturer. Rather it was made pursuant to a separate, independent agreement between Organization and Pharmacy, an agreement that Manufacturer did not negotiate and was not a party to. Under these circumstances, we do not believe that it can be said that the \$90 payment by Organization to Pharmacy reasonably can or should be deemed a price concession "by" or "from" Manufacturer to Pharmacy.

Indeed, were the case otherwise, third parties would be permitted effectively — and unilaterally — to lower a manufacturer's Best Price (for example) and, in the process, create substantial Medicaid drug rebate liability for the manufacturer. In the above hypothetical, for example, if Manufacturer is not required to take the \$90 payment by Organization to Pharmacy into account for purposes of calculating Best Price, then the Best Price of Drug A for the quarter at issue would be \$100. If Manufacturer is required to take the \$90 payment into account — notwithstanding the fact that Manufacturer had no control over the payment, which was not made pursuant to any request by Organization or any obligation that Organization owed to Manufacturer — then the Best Price of Drug A arguably would be \$10 for the quarter at issue. (A difference of this magnitude, of course, could have a multi-million dollar impact on a manufacturer's Medicaid drug rebate liability.)

In order to ensure that manufacturers (and others) can be confident that payments under circumstances such as these will not be deemed price concessions for AMP or Best Price purposes, we urge CMS to consider making two amendments to the Proposed Regulations. First, under Section 504(i) — “Further clarification of AMP calculation” — CMS should add a new Section 504(i)(4), providing as follows:

where an entity (other than the manufacturer) makes a payment to one of its clients or customers, this payment will not constitute a price concession by the manufacturer, and will not have to be taken into account in calculating AMP, if the payment was not made at the request of, or pursuant to a contractual or other legal obligation owed by the entity to, the manufacturer.

Second, and similarly, under Section 505(e) — “Further clarification of best price” — CMS should add a new Section 505(e)(4), providing as follows:

where an entity (other than the manufacturer) makes a payment to one of its clients or customers, this payment will not constitute a price concession by the manufacturer, and will not have to be taken into account in calculating best price, if the payment was not made at the request of, or pursuant to a contractual or other legal obligation owed by the entity to, the manufacturer.

It should be emphasized that these amendments would not protect payments that are, in effect, rebates or other price concessions offered by a manufacturer, but that simply flow through a third party. For example, assume the following:

- January 1, 2007: Manufacturer and Organization enter into an agreement, pursuant to which (1) Manufacturer agrees to sell Drug A to Pharmacy for \$100 per unit, (2) Manufacturer agrees to pay Organization a fee equal to two percent of Pharmacy's purchases of Drug A, and (3) Organization agrees that for each \$2 in fees that it receives from Manufacturer, it will pass \$1 of this \$2 back to Pharmacy.
- January 2, 2007: Pharmacy purchases one unit of Drug A from Manufacturer for \$100.
- January 15, 2007: Pursuant to the Manufacturer-Organization agreement, Manufacturer pays Organization \$2.
- February 1, 2007: Pursuant to the Manufacturer-Organization agreement, Organization passes \$1 of this \$2 back to Pharmacy.

Under these circumstances, the \$1 payment by Organization to Pharmacy could — quite reasonably — be considered a price concession “by” or “from” Manufacturer to Pharmacy (and would not be protected by the “safe harbors” proposed above). Although the payment at issue was made by Organization to Pharmacy, it was made pursuant to a preexisting contractual obligation owed by Organization to Manufacturer. Indeed, as a practical matter, the Manufacturer-Organization agreement effectively provides (1) for Manufacturer to pay a one percent fee to Organization and (2) for Manufacturer to pay a one percent rebate to Pharmacy, which rebate simply was administered by Organization.

* * *

As an alternative to the amendments discussed above, CMS could amend the “bona fide service fee” definition as follows:

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. *For purposes of this definition, a payment by an entity to one of its clients or customers will not be considered "passed on" if the payment is not made pursuant to the request of, or a contractual or other legal obligation owed by the entity to, the manufacturer.*

4. Payments Not Passed On

Under the Proposed Rule, any "fee" that is paid by a manufacturer to any "entity" will not qualify as a "bona fide service fee" — and, therefore, could potentially constitute a "price concession" for AMP or Best Price purposes — if the fee does not represent "fair market value," even if the fee is not "passed on," in whole or in part, to a purchaser. For the reasons set forth below, we believe that there are certain payments that could potentially fall into this (non-"bona fide service fee") category but plainly should not be considered price concessions offered by a manufacturer to a purchaser. Again, a hypothetical helps demonstrate the point. Assume the following:

- Manufacturer has a personal services agreement with Organization. Pursuant to this agreement, Organization furnishes services to Manufacturer on January 1, 2007, and Manufacturer pays Organization a \$2,000 fee for these services on January 15.
- The "fair market value" of the services furnished by Organization to Manufacturer is \$1,800.
- During the first quarter of 2007, Manufacturer sells 20 units of Drug A for \$100 per unit.
- Organization does not make any payments to any of the purchasers of Drug A.

Under these circumstances, the \$2,000 payment from Manufacturer to Organization would not qualify as a "bona fide service fee" because it is greater than "fair market value." By the same token, we assume that CMS would not deem the payment a "price concession" by Manufacturer to a purchaser because no portion of the \$2,000 paid by Manufacturer to Organization was ever paid, passed on or otherwise transferred to any purchaser.

In order to ensure that manufacturers (and others) can be confident that payments under circumstances such as these will not be deemed price concessions, we urge CMS to consider making two amendments to the Proposed Regulations. First, under Section 504(i) — “Further clarification of AMP calculation” — CMS should add a new Section 504(i)(5), providing as follows:

Where a manufacturer makes a payment to an entity other than a purchaser, and this payment is not passed on in whole or in part by the entity to a purchaser of the manufacturer’s drugs, this payment will not constitute a price concession by the manufacturer, and will not have to be taken into account in calculating AMP.

Second, and similarly, under Section 505(e) — “Further clarification of best price” — CMS should add a new Section 505(e)(5), which would provide as follows:

Where a manufacturer makes a payment to an entity other than a purchaser, and this payment is not passed on in whole or in part by the entity to a purchaser of the manufacturer’s drugs, this payment will not constitute a price concession by the manufacturer, and will not have to be taken into account in calculating best price.

Once again, as an alternative to the amendments discussed above, CMS could simply amend the “bona fide service fee” definition as follows:

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.
Where a manufacturer makes a payment to an entity other than a purchaser, and this payment is not passed on in whole or in part by the entity to a purchaser of the manufacturer’s drugs, this payment need not represent fair market value in order to qualify as a bona fide services fee.

5. Fair Market Value

As noted above, one of the elements of the “bona fide service fees” definition is that the fee represents “fair market value.” In the preamble to the ASP Rule, CMS correctly notes that the “appropriate method or methods for determining whether a fee represents fair market value may depend upon the specifics of the contracting terms,” and that “manufacturers are well-equipped to determine the most appropriate, industry-accepted method” for determining fair market value.⁷ “Therefore,” CMS concludes, “we are not mandating the specific method manufacturers must use to determine whether a fee represents fair market value for purposes of excluding bona fide service fees from the calculation of ASP.”⁸

In the preamble to the Proposed Rule, CMS states that it is “not proposing to define fair market value,” but the agency does invite comments from the public regarding “an appropriate definition for fair market value.”⁹ We would recommend that CMS adopt for purposes of the Proposed Rule the position that it has taken for purposes of the ASP Rule; that is, CMS should not mandate the specific method manufacturers must use to determine whether a fee represents fair market value.

However, we would urge CMS to consider developing one or more “deeming” provisions that would enable manufacturers to rely upon the protections of the “bona fide service fee” safe harbor (or any other safe harbors that include a “fair market value” element) without having to engage in potentially costly and time consuming valuations. Toward that end, we respectfully submit that it would be appropriate to develop and implement such a deeming provision with respect to fees (1) paid by manufacturers to a “group purchasing organization,” as that term is defined at 42 C.F.R. § 1001.952(j), (2) pursuant to arm’s length, bona fide negotiations between the manufacturer and the GPO. Such fees have long been recognized by Congress and the U.S. Department of Health & Human Services as an integral part of the hospital supply chain and, indeed, have been afforded statutory and regulatory exemption from the prohibitions of the federal health care program anti-kickback law.

In sum, we urge CMS to consider amending the Proposed Rule to further clarify — by adding a new definition to the regulations, amending the definition of “bona fide

⁷ 71 Fed. Reg. at 69669.

⁸ 71 Fed. Reg. at 69669.

⁹ 71 Fed. Reg. at 77180.

service fee,” or otherwise — that a fee paid by a manufacturer to a group purchasing organization, as that term is defined in 42 C.F.R. § 1001.952(j), represents “fair market value” if the fee results from arm’s length, bona fide bargaining between the manufacturer and the GPO.

II Nominal Price Exclusion

A. Proposed Rule

The Deficit Reduction Act of 2005 (“DRA”) provides that the “nominal price” exclusion (“NPE”) to the determination of Best Price applies to drugs offered at nominal prices to (1) a “covered entity described in section 340B(a)(4) of the Public Health Service Act,” (2) an “intermediate care facility for the mentally retarded,” and (3) a “State-owned or operated nursing facility.”¹⁰ In addition, the NPE applies to “[a]ny other facility or entity that the Secretary determines is a safety net provider to which sales of drugs at a nominal price would be appropriate” based on a consideration of certain factors.¹¹

In the preamble to the Proposed Rule, CMS states that it considered — but decided against — using its authority under the DRA to expand the universe of entities covered by the NPE. Specifically, CMS

considered proposing that we use the broader definition of safety net provider used by the Institute of Medicine (IOM). In its report, “America’s Health Care Safety Net, Intact but Endangered,” the IOM defines 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 patients.” We also considered proposing how the Secretary might use the four factors to allow the nominal price

¹⁰ DRA § 6001(d)(2).

¹¹ DRA § 6001(d)(2). These factors are (1) the “type of facility or entity,” (2) the “services provided by the facility or entity,” (3) the “patient population served by the facility or entity,” and (4) the “number of other facilities or entities eligible to purchase at nominal prices in the same service area.” DRA § 6001(d)(2).

exclusion to best price to apply to other safety net providers.¹²

B. Comment

In a letter to CMS dated January 31, 2007, U.S. Senators Max Baucus and Charles E. Grassley discussed in some detail the NPE and the work of the U.S. Senate Committee on Finance (“Committee”) relating to the NPE. According to the letter, Congress established the NPE in an effort to protect discounts offered to “charitable organizations and clinics.” The letter further provides that based on a survey conducted by the Committee, not-for-profit, acute care teaching, and other hospitals “appeared to be the primary recipients of nominal prices” that were offered by manufacturers in a manner that was “consistent with Congressional intent” (emphasis added).

Under these circumstances, we respectfully request that CMS exercise its authority under the DRA and amend the Proposed Rule by expanding the NPE to include sales to hospitals and other health care providers that (1) qualify as tax exempt charitable organizations under Section 501(c)(3) of the Internal Revenue Code or (2) are owned or operated by a federal, state or local governmental authority.

In the absence of this amendment, manufacturers will eliminate substantial discounts previously made available to such providers, whose costs will increase accordingly. Given the dramatic increase in drug prices over the past 15 years — according to the Kaiser Foundation, spending on prescription drugs grew from \$40.3 billion in 1990 to \$188.5 billion in 2004¹³ — eliminating these discounts will serve only to further exacerbate the financial burden of safety net providers.¹⁴

¹² 71 Fed. Reg. at 77184-77185.

¹³ Kaiser Family Foundation, “Prescription Drug Trends” (June 2006).

¹⁴ In the preamble to the Proposed Rule, CMS states that manufacturers may use the NPE as a “marketing tool” in a manner that is inconsistent with “the spirit and letter of the law.” 71 Fed. Reg. at 77185. With respect to this concern, which we believe is valid, we would simply note that it applies to any and all manufacturer-buyer arrangements and, as such, should not (in and of itself) serve as a justification for excluding tax exempt charitable organizations, or government owned/operated providers, from the NPE.

III Retail Pharmacy Class of Trade

A. Proposed Rule

Section 504(e) of the Proposed Rule defines “retail pharmacy class of trade” as “any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public.” Section 504(g)(3) of the Proposed Rule, in turn, provides that the AMP for “covered outpatient drugs shall include . . . [s]ales (direct and indirect) to hospitals, where the drug is used in the outpatient pharmacy.”

B. Comment

As a threshold matter, unlike chain, independent and mail order pharmacies, hospital outpatient pharmacies arguably do not provides drugs to the “general public.” Rather, hospital outpatient pharmacies generally provide drugs to hospital outpatients (just as nursing home pharmacies, sales to which are excluded from the calculation of AMP,¹⁵ generally provide drugs to nursing home residents). As such, it is not clear that including sales to hospitals in Section 504(g)(3) is consistent with the retail pharmacy class of trade definition in Section 504(e).

In all events, we are concerned that if the retail pharmacy class of trade is interpreted to include hospital outpatient pharmacies, this may result in increased drug costs and/or lower drug reimbursement for hospitals (including, of course, hospitals that are tax exempt charitable organizations). For this reason, we would request that CMS consider adopting a more narrow definition of “retail pharmacy class of trade” that excludes sales to hospitals where the drug is used in the outpatient pharmacy.

* * *

¹⁵ 42 C.F.R. § 447.504(h)(6) (proposed).

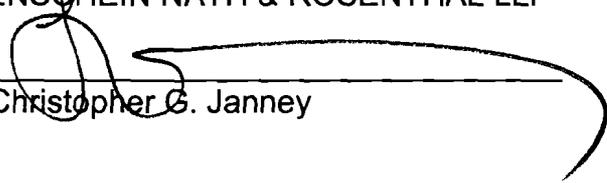
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In closing, we would like to thank CMS for providing us with this opportunity to comment on, and make recommendations concerning, the Proposed Rule. Please do not hesitate to contact us if you have any questions concerning these comments or require further information.

Respectfully,

SONNENSCHNEIN NATH & ROSENTHAL LLP

By:



Christopher G. Janney



February 20, 2007

FEB 20 2007

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Re: Comments on Proposed Rule implementing the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. 42 CFR Part 447

Dear Ms. Norwalk:

Caremark Rx, Inc. is a leading pharmaceutical services company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark processes over 550 million prescription drug claims annually, operates 7 mail pharmacies and 21 specialty pharmacies, and has network pharmacy contracts with over 62,000 participating retail pharmacies.

Caremark appreciates the opportunity to comment on the proposed rule for the calculation of AMP and best price. We believe these issues are of fundamental importance to all sectors of the prescription drug industry, and that the calculation of AMP in particular will have ramifications that extend well beyond the impact on manufacturer rebate payments under the Medicaid program. Given the many entities that will be affected by the manner in which AMP is calculated, as well as the new dual role for AMP as both a reimbursement and rebate metric, we believe that CMS should consider the following general principles as it finalizes the proposed rule:

- **Fairness and Fidelity to Congressional Intent.** In accordance with Congressional intent, CMS should try to faithfully capture the drug price paid by retail pharmacies, and should exclude those drug sales that are not reflective of the prices paid by retail pharmacies, and those price discounts that are not provided to retail pharmacies.

- **Consistency.** The rule should be consistent with “established Medicaid rebate policies”, definitions and terms set forth in current CMS guidance, such as Medicaid Program Releases and the National Rebate Agreement created under the Omnibus Budget Reconciliation Act of 1990 (“OBRA 1990”). It should also be consistent in treating similarly-situated entities similarly, while recognizing entities that are not similarly-situated.
- **Operational Simplicity.** CMS should avoid including in the calculation of AMP data that is not readily available to manufacturers, or that would significantly increase the number of calculations and assumptions to be made.
- **Impact on Competition.** CMS should avoid requiring the disclosure of sensitive competitive pricing and financial information that is not currently known by manufacturers in order for manufacturers to calculate AMP.
- **Clarity.** CMS should provide clear and objective standards and rules, relying on existing safe harbors where available.
- **Impact on Government Programs.** CMS should consider that changes in the calculation of AMP will affect public programs. Changes that result in an increase in drug costs for government programs such as Medicare Part D and Medicaid, are contrary to the clear intent of Congress in OBRA '90 and the Deficit Reduction Act of 2005.

With these general principles in mind, we offer the following specific comments.

A. Definitions

These comments on the proposed definitions in 42 CFR 447.500 apply for purposes of the determination of both AMP and best price.

1. Administrative Fees

We support the exclusion of legitimate service fees from AMP and best price since, by definition, these fees are paid for services, not the “drug” itself, and so do not fall within the statutory definition of AMP or best price. However, this exclusion only recognizes one of the two standard methods by which manufacturers have paid, and legally protected, service fees. Manufacturers traditionally pay administrative fees to entities that assist them in negotiating and contracting with multiple plan sponsors for participation in the manufacturer’s rebate program. Absent this assistance, a manufacturer would otherwise be required to negotiate and contract with thousands of plans for rebates, and in turn implement and administer separate rebate programs for a daunting array of plan benefit designs and formularies. In addition to this centralized administrative role, these entities will usually undertake to calculate the amount of rebates applicable to the products for each plan sponsor and invoice the manufacturer for rebates, provide the manufacturer with detailed reports on product utilization and rebate

calculations, allocate and distribute rebates to plan sponsors, utilize internal control measures to protect against payment of unearned rebates, and provide other related services that the manufacturer may require.

For purposes of complying with the Federal anti-kickback statute, manufacturers have generally sought to structure these service arrangements to meet either one of two safe harbors created by the Office of Inspector General (OIG), namely, the Personal Services and Management Contracts safe harbor at 42 CFR 1001.952(d) or the Group Purchasing Organization (GPO) safe harbor at 42 CFR 1001.952(j).¹ Both of these safe harbors serve the same purpose as the exclusion for bona fide service fees in this proposed rule, in that they are intended to distinguish legitimate service payments from payments that are really disguised discounts or potentially illegal payments.

However, despite the alignment in purpose, an arrangement structured under the GPO safe harbor may not be compatible with elements of the bona fide service fee exclusion. Therefore we recommend that, in addition to the exclusion for bona fide service fees, CMS create an additional explicit exclusion for administrative fee arrangements that meet the GPO safe harbor. This will ensure consistency between the two regulatory frameworks and continued equal treatment of the two types of service fee arrangements. It will allow parties that have specifically structured their fee arrangements to meet the GPO safe harbor to avoid having to attempt to restructure their contracts and business arrangements down the line, which could otherwise potentially impact thousands of contracts or, even more problematic, potentially put the parties in the untenable position of having to choose which regulatory structure to meet, even though both are intended to protect legitimate administrative service fee arrangements that are not disguised payments for referrals or rebates.

Recommendation: Provide an explicit exclusion from AMP and best price for administrative fee arrangements that meet the GPO safe harbor under the anti-kickback statute.

2. Bona Fide Service Fee

We understand that CMS wishes to ensure that only legitimate service fees are carved-out, and not discounts disguised as service fees. However, we are concerned that the additional condition requiring that the manufacturer would have incurred the fee in the absence of the service arrangement will in fact exclude legitimate service fees paid for real services provided in connection with the service arrangement. For example, a rebate agreement might include, in addition to rebates and price concessions, a service fee payable for services related to administering this rebate agreement with respect to all the plan sponsor clients of the service provider. The services include calculating the rebates applicable to each plan sponsors' products, invoicing the manufacturer, preparing detailed reports on product utilization and rebate calculations for the manufacturer, allocating and distributing rebates to plan sponsors, and utilizing internal control measures to protect against payment of unearned rebates.

¹ See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736.

individuals who have serious chronic illnesses that often require additional ancillary services. In many cases the medications are injectables, for which patients may require the assistance of a physician or other health care provider. In addition, specialty pharmacy patients usually have more serious or complex medical conditions, and require a far higher level of service, often over an extended period of months or even years. In light of this, specialty pharmacies deliver a very different, and specialized, set of products and services as compared to retail pharmacies. Specialty pharmacy patients are frequently located hundreds of miles from the pharmacy, and drugs are shipped to the patient, and consultations between patients and health care professionals are via telephone. There are no “walk-in” specialty pharmacy patients.

As the above description demonstrates, specialty pharmacies are not only a completely different distribution channel for drugs, but a completely different type of business, providing complex drugs to an identifiable patient population in a different way than a retail pharmacy. As such, specialty pharmacies should be specifically excluded from the definition of “retail class of trade”. As currently written, the definition of “retail pharmacy class of trade” depends solely on whether the pharmacy serves the general public, irrespective of whether the pharmacies differ in virtually every other meaningful respect. While this is certainly one factor that should be considered, given the greater complexity and diversity in the prescription drug market than even a decade ago, this alone should not be definitive, and other factors that distinguish between the well-recognized and markedly different types of pharmacies serving patients today should also be considered. If AMP is to be meaningful as a reimbursement benchmark, it should seek to capture the price of drugs to as similarly-situated a group of pharmacies as possible, with respect not only to the class of patients served, but also the types of drugs sold, the nature of the pharmacy facilities and activities, the method of drug storage and delivery, inventory policies, the method of drug administration, the level of patient education, other clinical and administrative services provided, and the location and nature of the pharmacies, to name only a few. All these factors affect the costs and operations of the pharmacy, including its drug costs which, after all, are what AMP is intended to capture.

Retail pharmacies generally maintain inventories of a greater variety of drugs with a lower per unit cost than specialty pharmacies, home infusion, or long-term care pharmacies. This is a function not only of the types of drugs retail pharmacies purchase (retail pharmacies purchase mainly oral medications and comparatively few that require special storage and handling) but also the retail pharmacy business model, since most retail pharmacies are located on prime real estate to attract the walk-in customer who not only fills prescriptions, but purchases other health care items and sundries. Conversely, most specialty and home infusion pharmacies are located in industrial areas, where there is little, if any, general consumer traffic, and where storage is far less costly, so they are able to maintain large refrigeration units, sterile and non-sterile preparation and packaging areas, and appropriate storage for administration devices. Specialized storage, preparation, handling, and precisely-timed and controlled shipping are key components of the specialty pharmacy business model – quite different than the limited prescription drug storage and over-the-counter sales that are part of the retail pharmacy model. Specialty pharmacies also coordinate care with outside professional agencies such as home nursing

All of these are legitimate services performed for the manufacturer that it would otherwise need to perform itself or contract for another party to perform, but they are also all related to the service agreement in the sense that the services would not be necessary if there were no agreement to provide rebates in the first instance. While CMS may not have intended to exclude these types of services by adding the condition that the services would otherwise have to be performed “in the absence of the service arrangement”, we believe this is how it will be construed by most manufacturers. Therefore, we recommend that CMS eliminate this condition, since it does not relate to the issue of whether the fees are legitimate service fees, and the definition already contains the essential requirements, namely, that the payment be (i) for legitimate services (ii) that the manufacturer would otherwise have to perform or have others perform for it, and (iii) represent fair market value.

Recommendation: Eliminate the condition that the services would be required “in the absence of the service arrangement” or otherwise clarify that fees paid for bona fide administrative services related to the administration of a rebate contract will qualify as “bona fide service fees” as long as they are: (i) for legitimate services (ii) that the manufacturer would otherwise have to perform or have others perform for it, and (iii) represent fair market value.

3. Wholesaler

The definition of “wholesaler” is critical to the calculation of AMP, since AMP is defined by statute as “the average unit price paid to the manufacturer... by wholesalers”² for drugs distributed to retail pharmacies. Thus, the price must be for a drug (i) purchased, (ii) by a wholesaler, and (iii) distributed to retail pharmacies. If any one of these elements is not present, the transaction is not relevant for purposes of calculating AMP. Therefore, transactions between a manufacturer and a party that is not a wholesaler cannot, by definition be included in the calculation of AMP. In Manufacturer Release 28, CMS explicitly stated (emphasis added) “Drug prices to PBMs have no effect on the AMP calculations *unless the PBM is acting as a wholesaler* as defined in the rebate agreement”. (Emphasis added) Similarly, in Manufacturer Release 29, CMS reiterated that “We generally consider drug prices to PBMs as having no effect on the AMP calculations *unless the PBM is acting as a wholesaler* as defined in the rebate agreement”. (Emphasis added)

In the proposed rule, CMS proposes to expand the statutory definition of AMP by defining “wholesaler” to mean “any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, covered outpatient drugs, but that does not relabel or repackage the covered outpatient drugs.” This definition differs from that in the national rebate agreement in that it specifically refers to PBMs and includes in the definition not only those who purchase the drugs, but also those who “arrange” for the purchase of drugs. Conversely, the national rebate agreement defines “wholesaler” as “any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.”

² Section 1927(k)(1) of the Social Security Act

The national rebate agreement definition of “wholesaler” is consistent with the plain meaning and traditional understanding of the term. For example, “wholesaler” is defined in the dictionary as a “merchant middleman who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users mainly for resale or business use”³, and the term “wholesale” as “the sale of goods in quantity, as to retailers.”⁴ Although each of these definitions is slightly different, they include one fundamental aspect, namely, that in order to be a wholesaler, the entity must buy and sell the product, and not simply “arrange for” its sale. If and when an entity buys drugs from a manufacturer for resale, then with respect to those transactions only, the entity is indeed a wholesaler. But if an entity does not purchase any drugs from the manufacturer, but simply “arranges” or negotiates rebates from manufacturers on behalf of the ultimate payers, then this does not meet the definition of “wholesaler,” nor does it in any way resemble the role wholesalers are generally understood to perform.

PBMs do not act as wholesalers when performing the core PBM functions of administering drug benefits or “arranging” for the provision of related drug benefit services. It is not appropriate for CMS to distort the well-understood, plain meaning of the term “wholesaler,” or the longstanding definition of the term in the national rebate agreement in order to pull in transactions that AMP was never intended to capture, nor traditionally has captured. CMS should retain the definition of “wholesaler” that was previously used in the national rebate agreement or understood generally, to mean an entity that purchases drugs from the manufacturer for resale. Failure to recognize a difference between wholesalers and PBMs would result in an AMP that is artificially low. This would be especially problematic now that AMP is being used as a reimbursement benchmark as well, since it would not accurately reflect the drug prices available to the very retail pharmacies it would be used to reimburse.

Recommendation: Define the term “wholesaler” consistent with its traditional meaning and the definition in the national rebate agreement to mean any entity that purchases drugs from a manufacturer for purposes of resale.

B. Definition of Retail Pharmacy Class of Trade and Determination of AMP

1. Mail Pharmacy Sales

CMS proposes to include all mail pharmacies in the definition of “retail pharmacy class of trade” for purposes of calculating AMP. According to CMS, mail pharmacies “are simply another form of how drugs enter the retail class of trade.” This is in contrast to sales to nursing home pharmacies, which CMS proposes to exclude from AMP because “nursing home pharmacies do not dispense to the general public.”

Even accepting CMS’ proposed definition of “retail pharmacy class of trade” as turning solely on whether the pharmacy sells or provides drugs to the general public, CMS’ assumption that all mail pharmacies serve the general public is not correct. Most mail

³ Merriam-Webster Online Dictionary.

⁴ Random House Webster’s College Dictionary.

pharmacies are like nursing home pharmacies in that they *do not* dispense to the general public. Their distinguishing feature is that services are limited strictly to members, either of the payer clients with whom they have contracted or of any private “discount” card program members. Thus, while the members of the general public could walk into any retail pharmacy with a prescription and seek to get it filled there and then or home-delivered, that same person could not send that prescription in to most mail pharmacies and expect it to be processed. Only if that person is a member of a group for which the mail pharmacy has contracted to provide mail pharmacy services, and for which the mail pharmacy can confirm eligibility, will the prescription be processed.

There are other distinguishing features upon which we believe the definition of “retail pharmacy class of trade” should depend – features that are equally, if not more, important than the population served by the pharmacy. For example, retail pharmacies are not able to shift market share for drugs as effectively as are other types of pharmacies, such as long-term care or mail pharmacies. In general, it is not part of normal business practice for retail pharmacies to independently contact the patient’s prescriber to change a prescription to a therapeutically equivalent, but more cost-effective drug, for the patient. In contrast, mail pharmacies and long-term care pharmacies customarily do just that, based on formularies developed by the Pharmacy and Therapeutics Committee (P&T Committee) and adopted by the payer. As a result, retail pharmacies generally do not obtain the same market share rebates as mail service and long-term care pharmacies, even when they contract directly with the manufacturer. It stands to reason, therefore, that the OIG has consistently discussed sales to nursing home and mail-order pharmacies together, assuming that whatever rule applied to one would apply to the other, and indeed, recommending that sales to both be excluded from the calculation of AMP.⁵

Mail pharmacies differ from retail pharmacies not only in their identifiable patient population and degree of intervention, but also in the mix of drugs they sell, the average days’ supply per prescription, and the volumes they purchase. All of these factors allow mail pharmacies to negotiate prices with manufacturers that are significantly lower than those received by retail pharmacies.

2. Specialty Pharmacy Sales

The proposed rule does not discuss specialty pharmacy sales at all, or indicate how CMS believes they should be treated for AMP calculation purposes. Specialty drugs represent a distinct and growing segment of the prescription drug market, and we believe it is important for the final rule to recognize specialty pharmacies as a distinct type of pharmacy. Like mail and LTC pharmacies, specialty pharmacies operate quite differently from retail pharmacies, are not open and accessible to the walk-in public and should clearly be excluded from the “retail class of trade”.

Specialty drugs differ from traditional prescription drugs in that they are typically very high cost drugs, often biopharmaceuticals, that require special storage and handling (e.g. refrigeration, reconstitution, use of an administration device), and are provided to

⁵ See General Accountability Office (GAO), “Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States”, February 2005, p.14, footnote 27.

visits, and routinely conduct extensive prescriber and patient outreach, and benefit verification, as well as certain disease management and education functions.

In almost every respect, the business of traditional “walk-in” retail pharmacies differs from that of specialty pharmacies. For this reason, CMS has recognized in Medicare Part D that retail pharmacies are distinct from not only long-term care pharmacies, but also from home infusion pharmacies, specialty pharmacies, and mail order pharmacies. Indeed, these types of pharmacies are all referred to by CMS as “non-retail” pharmacies, within Part D. Different rules apply to them with respect to access and reimbursable services, and CMS expects that Part D plans will have a different set of standard terms and conditions for each of these pharmacy types in the Part D plan’s network. Similarly, in its merger review analysis of these very separate classes of trade, the Federal Trade Commission has repeatedly distinguished the provision of PBM services and specialty pharmacy services from retail pharmacy services, and defined each as noncompetitive and as operating in wholly separate relevant competitive markets.⁶

We believe that “retail pharmacy class of trade” should be defined consistently with the common use of the term “retail pharmacy” as a walk-in pharmacy, and within the meaning of Medicare Part D, and should exclude not only nursing home and other long-term care pharmacies, but also, at the very least, should exclude mail pharmacies, home infusion pharmacies and specialty pharmacies. If the term “retail pharmacy class of trade” is to have any meaning or purpose as capturing a distinct pharmacy type for purposes of drug purchasing, then it cannot simply lump together all these diverse types of pharmacies operating in clearly different market segments, and must go beyond the inchoate definition provided in the proposed rule.

Recommendation: “Retail pharmacy class of trade” should be defined consistently with the meaning of the term “retail pharmacy” for purposes of Medicare Part D, and should exclude all “non-retail” pharmacies, such as mail and specialty pharmacies, since these types of pharmacies not only serve different populations than those served by retail pharmacies, but also operate under very different business models, with different operating structures and different drug costs.

C. PBM Discounts, Rebates or Other Price Concessions

CMS proposes to include in the calculation of AMP the rebates and price concessions received by PBMs from manufacturers for drugs distributed to the retail class of trade. The apparent rationale for this decision is that the exclusion of these price concessions could result in “artificial inflation of AMP.” While we agree that the exclusion of PBM rebates and other price concessions will cause AMP to be higher than it would be if these discounts were included, we disagree with the characterization of this higher amount as “artificial inflation.” Instead, we believe the exclusion of these amounts results in a more accurate reflection of AMP, and that their inclusion artificially depresses AMP because

⁶ See, for example, Federal Trade Commission Statement, “In the Matter of Caremark Rx, Inc./AdvancePCS,” <http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf>, and “In the Matter of CVS Corporation, and Revco D.S., Inc.,” <http://www.ftc.gov/os/caselist/c3762.htm>.

PBMs are not wholesalers, nor are PBM rebates reflected in the prices paid by retail pharmacies.

1. PBMs are not wholesalers, and therefore transactions with them do not fall within the definition of AMP.

This issue is discussed in greater detail in Section A.3 above.

2. PBM rebates are earned for moving market share by performing formulary management activities pursuant to plan formularies developed by a clinically-driven P&T Committee. These rebates are not passed through to retail pharmacies.

Given that AMP is intended to function not only as a basis for calculating manufacturer rebate payments, but also as basis for calculating reimbursements to retail pharmacies, it is critical that AMP also properly and fairly reflect the prices paid by retail pharmacies. PBM rebates are determined by the drug utilization of a defined group of covered lives served by the PBM, unlike retail pharmacies, that purchase drugs and thus earn rebates solely on the volume of drugs purchased in response to the needs of the general public patronizing the pharmacy. Guiding the PBM rebate negotiations and purchases is the drug formulary implemented by the PBM and payers, under the guidance and oversight of the P&T Committee. Formularies are one of the most important tools used by PBMs and payers to manage the cost and quality of the drug benefit provided - a tool that is not available to or used by retail pharmacies in the same way, since they do not limit their services to plan members or have the incentive to manage drug utilization. Within a formulary, the PBM can recommend a list of preferred drugs that will offer payers the greatest savings. By creating a preferred drug list that covers the needs of most beneficiaries and a formulary that includes other recommended drugs - based on clinical efficacy, safety, and pharmacoeconomics - PBMs have additional negotiating leverage with drug manufacturers.

PBMs are able to negotiate rebate payments from manufacturers on behalf of their payer clients based on their unique ability to shift market share by directing their payer populations toward clinically appropriate, more cost effective drugs. Retail pharmacies do not have the means, resources or incentive to perform these services. As such, the rebates negotiated by PBMs are for all practical purposes unavailable to retail pharmacies.

While PBM rebates may be passed on, they are passed on to the PBM's payer clients, and not to retail pharmacies. As such, even when PBM rebates are shared, it is usually with payers, the sales to which are explicitly excluded from AMP (namely HMOs and managed care organizations), but in no event with retail pharmacies. Given that this unique role played by PBMs is wholly outside any function that could conceivably be viewed as analogous to a wholesaler or to what a retail pharmacy could do, and the fact that PBM rebates, if passed through at all, are not passed through to retail pharmacies, there is no reasonable basis to include PBM rebates in the calculation of AMP.

3. Collecting and reporting PBM rebates raises operational and competitive concerns.

CMS requested comment on the operational difficulties of including PBM rebates and other payments in the calculation of AMP. We believe that these difficulties will be significant. Even more problematic is that efforts to make the reporting less complicated will have the counterproductive effect of undermining competition among the drug manufacturers and PBMs themselves, and thus increasing drug prices. As the FTC has noted, the percentage of rebates passed through by a PBM to a client cannot be viewed in isolation, because of the complex relationship and different transactions that may be occurring simultaneously between the parties.⁷ Thus, in order to include PBM rebates and other payments in the calculation of AMP, it would be necessary for manufacturers to essentially require disclosure by PBMs of their internal pricing structures and financial arrangements with manufacturers, payers and pharmacies. This is highly sensitive proprietary competitive information that PBMs will not willingly, and should not have to, disclose. The Federal Trade Commission staff has repeatedly opined that requiring such disclosures would undermine the ability of PBMs to negotiate lower drug prices from manufacturers and pharmacies, resulting in an overall increase in drug prices in this sector.⁸

4. Inclusion of PBM rebates in AMP will likely increase drug costs for Medicare Part D and decrease Medicaid rebates contrary to Congressional intent.

We are concerned that the inclusion of PBM rebates and discounts in the calculation of AMP will have the unintended consequence of making some manufacturers less inclined to offer them, mainly out of a concern that they will unduly depress AMP, resulting in lower reimbursement to pharmacies and, ultimately, lower sales by the manufacturer. While it is true that a lower AMP should generally result in lower Medicaid rebate payments by manufacturers, this will not always be the case, and in any event, manufacturers are extremely sensitive to the potential negative effect of a lower AMP on drug sales generally as a result of lowering pharmacy reimbursements. This has already been seen with respect to ASP, where manufacturers have become less inclined to offer rebates and price concessions that will lower ASP, and will become more acute if and when, as is anticipated, AMP is adopted more broadly as a reimbursement benchmark for other purposes.

To the extent that a manufacturer believes it will lose sales if retail pharmacies choose to dispense alternate drugs with a higher AMP, they will be less willing to offer rebates and price concessions to PBMs and their payer clients, and drug prices will increase. This is of particular concern with respect to Part D sales, where it will work against the explicit intent of Congress to encourage manufacturers to offer deeper discounts by having these discounts excluded from best price. The inclusion in AMP of PBM rebates generally, but particularly with respect to Part D drug sales, will likely have the negative effect of increasing drug prices generally, and to the Part D program in particular.

Similarly, the inclusion of PBM rebates in the calculation of AMP will potentially harm the Medicaid program, lowering Medicaid rebate payments from manufacturers as a

⁷ Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies", August 2005 (FTC Report) at 60.

⁸ See, for example, FTC Staff Letter to The Honorable Terry G. Kilgore, October 2, 2006, pp.12-14.

result of relying on an artificially lower AMP. This is contrary to Congressional intent in enacting the Medicaid rebate program in OBRA 1990, when Congress stated that Medicaid “should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy.”⁹ It also states that the program was designed to achieve significant Medicaid savings with a minimum amount of disruption to the program. Under the proposed rule, if rebates paid by manufacturers to PBMs are included in the definition of AMP, AMP will not reflect the payment made to manufacturers by wholesalers for the drugs distributed to the retail class of trade, but rather, in many cases will reflect the ultimate cost of the drug paid by the health plan or MCOs, sales to whom are explicitly excluded from AMP. We do not believe that it was Congress' intent to use this lower, already discounted, number as the base for calculating the minimum Medicaid discount. If the AMP is intended to reflect the price on which commercial discounts will be calculated, it does not seem reasonable to net out all of the price concessions that commercial insurers may receive, since it is these very price concessions that the Medicaid Program is attempting to approximate in calculating AMP in the first instance. Based on Congress' stated intent, we do not believe it is a reasonable or proper interpretation to include PBM rebates in AMP, particularly when one of the effects will be to reduce the rebates paid under the Medicaid program to below those to which Congress believed the program was entitled.

Recommendation: Exclude rebate payments to PBMs from the calculation of AMP because (i) PBMs are not wholesalers (ii) PBM rebates are typically not passed on to retail pharmacies or otherwise reflected in the drug prices paid by the “retail pharmacy class of trade”, (iii) reporting of PBM rebates will cause operational difficulties and competitive concerns, and (iv) inclusion of PBM rebates in AMP will likely increase drug costs for Medicare Part D and lower Medicaid rebate payments in violation of Congressional intent.

D. AMP Reporting

The proposed rule implements the requirements of the DRA by requiring monthly reporting of AMP by manufacturers. Specifically, manufacturers must report AMP not later than 30 days after each month, including an estimate of rebates or other price concessions. In calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary. While we understand that AMP will not be utilized directly as a reimbursement rate on its own, and that even for purposes of calculating the federal upper payment limit for multiple source drugs under Medicaid it is part of a formula, nevertheless we are concerned about the inherent delay in reporting AMP when it is used as a reimbursement benchmark. Currently, changes in AWP – the existing reimbursement benchmark – are typically passed through from the manufacturer to the ultimate payer within 24 hours, as a result of electronic feeds that re-adjust all pricing when a manufacturer price increase occurs. Under the proposed rule, the AMP reported to CMS is already 30 days old, and this AMP must then still be reported by CMS to States and posted on a public web site, and may be revised for up to 30 days. Thus, by the time AMP is posted publicly and available to be used for reimbursement purposes, it will be

⁹ USCCAN, 1990, p. 2108,

aged (by at least 60-90 days). This does not even take into account the added complications and delays if AMP were determined to include PBM rebates, since the determination of the amount of these rebate payments can occur up to 6 months or longer after the date the drug is dispensed.

This is of particular concern in light of the fact that manufacturer price changes are announced and implemented immediately to the drug purchaser. While there may be various ways to try to mitigate this impact, such as building in a cushion for price increases and inflation generally, on a drug-by-drug basis the impact could be significant, especially since it is not always obvious whether the impact should be upward or downward. We are concerned that this timing issue has not yet been addressed or even sufficiently recognized and appreciated, and believe that CMS should address it directly and in detail before states and others are encouraged to use AMP as a reimbursement benchmark.

Recommendation: Before AMP may be used as a reimbursement benchmark, CMS should address the timing issues associated with reporting AMP, and in particular, that manufacturer price changes will not be reflected in reported AMP for 60 days or longer.

E. Anticipated Effects

CMS concludes that the anticipated effect of the proposed rule on retail pharmacies will be less than one percent of revenue, on average, and that this impact is potentially even smaller when non-drug sales are considered. We believe this analysis seriously understates the potential financial impact on retail pharmacies for two reasons. First, as CMS points out, this analysis does not take into account decreases in state payments for drugs that are not on the FUL list, if and when States start to use AMP as a reimbursement mechanism generally. Since this is clearly the intent by making AMP available to states on a monthly basis and posting it on a public web site, the analysis leaves out what is likely to be the far more significant and profound financial impact on pharmacies, rendering the Impact Analysis misleading at best.

Second, although CMS refers to a loss of pharmacy revenue, the actual impact will fall directly to the bottom line, so that the \$800 million decrease in 2007 and \$2 billion decrease annually by 2011, will actually be decreases in profits, not revenue. Thus, while this may represent a 1% decrease in revenue, it actually represents a many times larger decrease in profits, depending on a pharmacy's profit margin. This is by no means insignificant. We are concerned that these inaccuracies have led CMS to the erroneous conclusion that the impact of pharmacies will be insignificant. As a result, we believe that CMS is insufficiently concerned about prospects that its "catch-all" method for calculating AMP will result in an AMP that is far lower than what most retail pharmacies can achieve.

Recommendation: Revise the Impact Analysis to reflect (i) the projected impact of the use of AMP, rather than AWP, as a reimbursement benchmark for drugs other

than those subject to the FUL, and (ii) the distinction between the impact on pharmacy profits versus pharmacy revenue.

Thank you again for the opportunity to comment on this important proposal. Please feel free to contact me at (202) 772-3501 with any questions or concerns.

Sincerely,

Russell C. Ring
SVP, Government Relations