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DEC 21 2007

December 20, 2007

Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-FC
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-8012

Re: CMS-2238-FC (Medicaid Program; Prescription Drugs)

Dear Acting Administrator Weems:

TAP Pharmaceutical Products Inc. ("TAP") appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") final rule implementing provisions under the Deficit Reduction Act of 2005 ("DRA") as published in the *Federal Register* on July 17, 2007 ("Final Rule").[1] TAP is one of the nation's leading pharmaceutical companies and is committed to delivering high quality pharmaceutical products for patients. We provide innovative and effective products in diversified treatment areas, including oncology, gastroenterology and gynecology.

TAP appreciates CMS' consideration of comments submitted under the proposed rule which provided additional guidance to manufacturers in calculating average manufacturer price ("AMP") and Best Price,[2] including, among other things, CMS allowing manufacturers the ability to restate AMP and including physician sales in the AMP calculation. While we agree with many of the elements under the Final Rule, there are certain provisions that require further clarification to ensure that AMP and Best Price calculations are consistent among manufacturers. These elements are described below.

I. Bundled Sales Definition

Based on our review, the definition of a "bundled sale" under the Final Rule differs significantly from the definition CMS has provided in the Medicaid Drug Rebate Agreement (the "Rebate Agreement") and in its prior guidance on the Medicaid drug rebate program. The Final Rule defines a "bundled sale" as:

[1] Medicaid Program; Prescription Drugs, Final Rule, 72 Fed. Reg. 39142 (Jul. 17, 2007).
[2] Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

through its owned mail order pharmacy fall within the retail class of trade and will be accounted for under the purchase agreement between the manufacturer and the PBM.

While TAP appreciates CMS' efforts to provide further guidance by posting to its website responses to specific questions, in this case it has generated greater confusion. The confusion appears to be a result of the multiple forms of price concessions manufacturers may provide to PBMs. One form of price concession is the rebates paid to the PBM based on utilization of the manufacturer's drugs by health plan members. These rebates are paid to the PBM with the intent that they will, in whole or in part, be passed on to the health plan clients of the PBM, effectively reducing the price of drugs to the health plan. Another form of price concession is a discount off the price of drugs purchased by the PBM directly from the manufacturer (rather than purchasing through a wholesaler). This price concession reduces the cost of drugs to the PBM for drugs that it dispenses through its owned mail order pharmacy. Both of these types of price concessions could constitute "mail order purchases" under the Final Rule.

TAP requests clarification that CMS intends the term "mail order purchases" to apply to both (i) price concessions provided by manufacturers to a PBM under an arrangement where the PBM purchases drugs directly from the manufacturer for dispensing by the PBM's owned mail order pharmacy *and* (ii) rebates provided by the manufacturer to a PBM based on prescription claims that are processed through the PBM's mail order pharmacy.

III. GPO Administrative Fees

TAP believes that the administrative fees paid to Group Purchasing Organizations (GPO) are bona fide service fees paid to the GPO for facilitating the contracting function of its members and, therefore, do not constitute price concessions to the GPO's members. Such fees should not be treated as price concessions unless the fees, or a portion of the fees, are passed on to the members or customers of the GPO. TAP requests that CMS clarify that administrative fees paid to GPOs by manufacturers are not price concessions unless the GPO is contractually obligated to pass such fees through to its members or customers.

IV. Aggregation of Discounts Under Best Price

TAP requests clarification regarding statements made by CMS in the Final Rule in connection with aggregation of discounts for purposes of calculating Best Price. As one example, CMS' response to the following comment requires clarification:

> "...when best price is determined, customary prompt pay discounts extended to wholesalers should not be aggregated with price concessions available to an end-customer under a contract administered through a wholesaler chargeback arrangement, regardless of whether the manufacturer negotiated the contract directly with the end-customer or with a third party."[15]

CMS responded that it does not agree which implies that CMS believes that customary prompt pay discounts *should be* aggregated with price concessions available to the end-customer and, further, that the aggregate discount must be included in the Best Price calculation. Such a position is inconsistent with the definition of Best Price which relates to "the lowest price available from the manufacturer...to any entity."[16] In addition, if CMS required manufacturers to aggregate discounts offered to different entities, this would result in an artificial Best Price that is not actually available to any purchaser.

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[15] *Id.* at 39199.
[16] 42 C.F.R. § 447.505(a).

Please clarify that CMS does not intend to require manufacturers to aggregate discounts to different entities when determining Best Price except where one customer (e.g., wholesaler) is obligated by contract to pass the prompt pay or other discount on to the end-customer.

* * * * *

TAP appreciates the opportunity to comment on these important issues, and we look forward to working with CMS to ensure that beneficiaries have continued access to vital medications. We sincerely hope that CMS will consider our comments and will incorporate our suggestions into the final rule. Please do not hesitate to contact me with any questions regarding our comments or if you need additional information.

Respectfully submitted,

Laura Cline

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December 20, 2007

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BY HAND DELIVERY

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Washington, DC 20201

Re: Final Rule with Comment Period, Medicaid Program; Prescription Drugs [CMS-2238-FC]

Dear Sirs:

The following comments to the Centers for Medicare and Medicaid Services (CMS) are submitted in response to CMS' final rule with comment implementing those provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program, which was published in the Federal Register on July 17, 2007 (71 Fed. Reg. 77174-77200). We represent manufactures of covered outpatient drugs that participate in the Medicaid drug rebate program and we regularly counsel them concerning compliance with their obligations under their Medicaid drug rebate agreements. We appreciate this opportunity to address implementation of specific aspects of the final rule affecting the methodology by which the Average Manufacturer Price (AMP) and best price are calculated and reported to CMS.

These comments address the following areas covered by the final rule with comment: 1) definition of "bona fide service fee"; 2) rebates and administrative fees paid to a PBM on purchases through its mail order pharmacy; 3) PBM rebates designed to adjust provider prices; 4) prices to contract customers purchasing indirectly through wholesalers; 5) Patient Assistance Programs; 6) smoothing indirect sales; 7) reporting customary prompt pay; 8) sales of authorized generics; 9) bundled discounts; and 10) definition of "single source drug."

1. Definition of Bona Fide Service Fee

Sections 447.504(h)(19) and 447.505(d),(12) of the final rule exclude from AMP and best price administrative fees and services fees associated with sales to enumerated entities if they qualify as "bona fide service fees." Conversely, the final rule seems to require that a fee which does not qualify as a bona fide service fee must be treated as a price concession, whether or not the entity receiving the fee actually purchased product from the manufacturer, unless the purchase to which the fee relates is expressly excluded from AMP and best price. The definition of bona fide service fee requires the fee be for fair market value, related to the efficient distribution of drugs, and not passed through to a customer of the recipient.

When applied in practice, this rule is causing difficulty. In particular, it raises questions as to how a fee paid to a non-purchaser that negotiates prices and administers a contract should be treated if the fee fails to meet the definition of bona fide service fee. It makes little sense to treat such fees as adjustments to the price paid by a customer of the service provider if the fees are intended to be retained as compensation rather than to be passed through as an adjustment to the purchase price paid by the service provider's client or customer.

With respect to the requirement that the fee relate to the efficient distribution of drugs, the preamble suggests that a bona fide service fee is not limited to wholesaler distribution services. For example, in discussing the exemption for manufacturer coupons, the preamble to the final rule recognizes that a modest fee paid to a pharmacy to service a coupon redemption program would not be considered a price concession to the pharmacy and would be excluded as a bona fide service fee. See 72 Fed. Reg. at 39187. Therefore, we assume CMS considers such a service to be one related to the efficient distribution of drugs at the retail level. On the other hand, CMS indicated in the preamble that agreements to manage rebate agreements covering retail transactions are not associated with the efficient distribution of drugs. *Id.* at 39182.

We believe that fees paid to entities for the purpose of negotiating prices on behalf of purchasers, and are not intended to be passed through to purchasers, should be considered bona fide service fees, as it is far more efficient for manufacturers to negotiate the terms of a single contract with a group purchasing organization applicable to many purchasing customers than it is to deal directly with those purchasers. Moreover, even if the fees do not relate to the efficient distribution of drugs, it would be unfair to reduce AMP and best price by fees which compensate the service provider and do not adjust prices paid by a pharmacy or other provider that might be reimbursed by Medicaid. For the same reason, we believe reasonable administrative fees paid to PBMs should be exempt from AMP and best price if they are intended to compensate the PBM for services and are not intended to adjust the purchase price paid by the PBM's mail order pharmacy or its client plans. Likewise, fees paid to a non-purchaser for marketing or promotional services should not be considered a discount associated

with sales to the service provider's customers if they do not share in the fee. Accordingly, we request that CMS clarify that administrative or service fees paid to a non-purchaser are included in AMP and best price only if those fees are intended to be passed through to a purchaser.

Another problem associated with implementation of this rule is how to deal with a rolled up fee for itemized services if only some of the services are for fair market value or relate to the efficient distribution of drugs. We request that CMS clarify whether companies may apportion a fee between bona fide service fee and price concession or whether the entire amount must be included as a price concession.

2. Inclusion of PBM Rebates on Mail Order Purchases in AMP

Section 447.504(g)(6) and (9) of the final rule include in the AMP calculation sales to mail order pharmacies and separately include rebates provided to PBMs for their mail order pharmacy purchases. Likewise, section 447.504(h)(22) exempts from AMP rebates to PBMs except for their mail order pharmacy purchases. We understood the intent of the final rule was that AMP should reflect manufacturer price concessions available to a mail order pharmacy owned by a PBM, whether those price concessions are provided in the form of discounts to the pharmacy at the point of sale, rebates paid to the pharmacy directly, or rebates paid to the PBM on prescriptions filled by its mail order pharmacy. The problem with this rule in practice is that manufacturers do not necessarily know whether rebates paid to a PBM are for its mail order purchases, or whether payments to a PBM on prescriptions dispensed by its mail order pharmacy are passed through in whole or in part to the mail order business

The majority of PBMs that own a mail order pharmacy negotiate rebates on prescription units purchased by their plans from the PBM's own pharmacy, along with rebates on participating retail pharmacy utilization. Some also negotiate administrative fees on all rebate transactions regardless of whether they are with the PBM's mail order pharmacy. Others retain a portion of the rebate to cover their service. For that reason, many PBMs have not separated out their own pharmacy utilization from that of the other pharmacies. As discussed above, we urge CMS to consider administrative fees paid to a PBM to be excluded from AMP and best price, whether or not the fee is paid on a mail order or retail pharmacy prescription. However, for purposes of this comment, we assume CMS still considers fees paid to manage rebate agreements to be price concessions and thus the same as a rebate. In order to include in AMP rebates and fees paid to the owner of the mail order pharmacy, manufacturers must first obtain the mail order prescription utilization data. Additionally, because manufacturers do not know whether and to what extent the PBM passes through the rebate and fee to its mail order pharmacy and client health plans, or uses the payments to reduce the mail order pharmacy's acquisition cost, they must make certain assumptions. These issues have proven difficult in implementation of the final rule.

First, some PBMs have refused to provide data on the number of mail order prescription units on which rebates and fees have been paid, because they do not believe CMS considers rebates paid on mail order prescriptions under their rebate agreements to be rebates for mail order purchases, which makes it difficult for manufacturers to compute an accurate AMP. However, as most rebates on prescriptions dispensed by a PBM-owned mail order pharmacy are paid pursuant to a rebate agreement, if they were excluded from AMP, relatively few discounts provided on mail order would ever be included in AMP, thereby increasing the basis for the Medicaid payment to mail order pharmacies for multiple source drugs. Second, some portion of the rebate amount paid on a mail order prescription may be passed through to the client plan, but in the absence of a contractual provision addressing retention of rebates and fees, which is rare, any allocation of the payments between the PBM and its client plan would be an estimate at best.

In the preamble to the final rule, CMS does not squarely address this problem. Although the preamble recognized that manufacturers may have difficulty obtaining data from PBMs, it appears that CMS assumed manufacturers would have the data pertaining to mail order sales. The preamble states that manufacturers need not obtain utilization data in order to differentiate between retail and non-retail on the "non-mail order" sales. This response suggests that CMS' concern was with differentiating between prescriptions paid by "included" and "excluded" entities (*e.g.*, retail pharmacy versus long term care pharmacy) rather than between mail order prescriptions and all other prescriptions within the retail class of trade.

We request clarification on what CMS meant by the mail order exception to the PBM rebate exclusion from AMP. Specifically, we request that CMS state whether it expects AMP to reflect rebates paid to PBMs that own mail order pharmacies on their pharmacies' prescription utilization pursuant to a rebate agreement between the manufacturer and the PBM. We further request clarification on whether manufacturers may make reasonable assumptions as to the amount of rebate or fee retained by the PBM on its mail order transactions under the rebate agreement.

3. Inclusion of PBM Rebates in Best Price

Section 447.505(13) of the final rule excludes PBM rebates from best price with two exceptions: where the rebate adjusts the price for its mail order pharmacy purchases and where it is "designed to adjust the prices at the retail or provider level." We are concerned with application of both exceptions to the exclusion of PBM rebates from best price. For purposes of determining best price, we understand the term "provider" includes plans that provide health care coverage or services. Although manufacturers have no control over what a PBM does with the rebates it receives, the majority of rebates paid to a PBM are intended to adjust the prescription price paid by its client health plans. We assume the exception to the PBM rebate exemption is intended to continue the practice of including prices available to health plans in best

price, whether discounts are available to these entities directly or through PBMs. Otherwise, all price concessions available to plans represented by PBMs would be exempt. The distinction between a PBM and its client plans, however, presents serious implementation issues because of the difficulty in obtaining information on which a rebate allocation can be based.

Many PBM agreements providing for payment of an administrative fee to the PBM describe the payment as covered by the GPO administrative fee safe harbor, and it is reasonable to assume in these situations that such a fee is not designed to adjust prices paid by the client plans. However, manufacturers have no way to ascertain whether a rebate payment intended to reduce the prescription price is shared with the PBM's plans. In addition, if the PBM owns a mail order pharmacy that dispenses drugs to a client plan's beneficiary, it is unclear whether a rebate paid on the mail order claim should be assumed to be a price concession available to the mail order pharmacy in its entirety, or a price concession to the plan, or allocated to both, and if so on what basis. Obviously, a rebate that is designed to adjust the prescription price paid by a PBM's client plan cannot be treated simultaneously as a discount to the dispensing pharmacy. This is particularly important where an administrative fee is paid to the PBM in addition to the rebate. It is reasonable to assume in that case that the PBM is functioning like a GPO, *i.e.*, the fee is provided for the administrative service and the rebate is provided as a discount on the prescription price. We request that CMS clarify how it expects these two distinct exceptions to the PBM rebate best price exemption be implemented in practice, and we urge adoption of a policy that recognizes the distinction of the entities with whom the manufacturer transacts business. For purposes of best price, a price available to a customer should not be adjusted by a fee paid to a different customer that does not share the fee.

4. Prices to Contract Customers Purchasing Indirectly

Since inception of the Medicaid rebate program, for purposes of determining the lowest price available to a customer, companies have treated prices available to wholesalers separately from contract prices available to other customers who purchase from manufacturers indirectly through wholesalers. Wholesalers are paid a service fee to distribute drugs to these end customers at the manufacturer's contract price and process a chargeback so that they are made whole. They do not share in the discount available to these end customers. The preamble, however, is very confusing with respect to aggregation of end customer discounts with customary prompt pay discounts provided to wholesalers in calculation of best price. Although we agree with CMS' comment that the DRA only excluded prompt pay discounts from AMP, Congress did so because wholesaler discounts are averaged together with retailer discounts in AMP. We are concerned that the preamble suggests a discount available to a wholesaler should be combined with a discount offered to an indirect customer serviced by the wholesaler in calculating the lowest price available to either customer.

The price realized by a manufacturer's indirect contract customer does not include any prompt pay discount offered to the direct customer. Likewise, the discount to the indirect customer is not available to the wholesaler that processes orders from the customer, passes through the manufacturer's price to the customer, and distributes drugs to the customer for a service fee. If a chargeback credit for reimbursing the wholesaler were considered a discount to the wholesaler not the contract customer, the chargeback could not be combined with any price concessions provided directly to the contract customer unless the same discount were considered in best price twice. That makes no sense. Separate discounts available to individual customers cannot be combined simply because the manufacturer realizes less profit when it offers discounts at both the wholesaler and retailer/ provider levels. Please clarify that best price is the lowest net price available to a particular purchaser, not the net profit realized by the manufacturer on a unit after it moves through the chain of distribution.

5. Patient Assistance Programs

Section 447.505(9) of the final rule provides that the calculation of best price excludes goods provided free of charge under a manufacturer's patient assistance program (PAP). Similarly 447.505(7) and (8) exempt prices negotiated under a manufacturer-sponsored drug discount program and manufacturer coupons to the extent the full value of the coupon is passed on to the consumer and the entity redeeming the coupon does not receive any price concession. The best price rules thus mirror the AMP exemption rules except there is no separate exemption for vouchers as there is under 447.504(h)(16). The preamble indicates that the beneficiary of a PAP must receive the full value of the free drugs and the pharmacy dispensing them must receive no price concession or payment from the manufacturer other than the "benefit amount," although it may receive a bona fide service fee for administering the program. 72 Fed. Reg. at 39189. We understand the purpose of these provisions is to ensure that the pharmacy does not share in the price concession available to the PAP beneficiary, not that the pharmacy must forego any profit when it sells a prescription to a PAP beneficiary.

Under some PAPs, pharmacies are provided replacement drugs, but often pharmacies will only participate in these assistance programs if they are compensated for the prescription dispensed to the beneficiary at a retail price. In these cases, manufacturers, acting as insurers, reimburse the pharmacies at a rate comparable to what the pharmacy would receive from other plans or assistance programs in order to compensate the pharmacy for the retail value of the prescription, which is the benefit provided to the beneficiary. Thus the "benefit amount" paid to the pharmacy is the normal retail price paid on behalf of the beneficiary. The only difference between reimbursement under a PAP and reimbursement under a discount card program is that, with the former, the benefit amount is the entire retail cost, and with the latter, the patient and the manufacturer share the retail cost. In our view, when a PAP is the sole payer and reimburses the pharmacy at a normal managed care rate, the full value of the

dispensed units at the retail level is passed through to the patient, the pharmacy is paid the benefit amount, and the pharmacy's acquisition cost is unaffected.

This rule, however, has created confusion over treatment of the reimbursement, specifically, whether the amount of reimbursement on behalf of a PAP beneficiary in excess of the pharmacy acquisition cost should be considered a discount available to the pharmacy. We do not believe this is a fair reading of the preamble as the benefit amount paid the pharmacy includes a reasonable retail mark-up, and the pharmacy's acquisition cost of the dispensed drugs is the same regardless of whether the drugs are sold to the PAP beneficiary or another consumer for the same retail price. However, we agree if the manufacturer paid the pharmacy more than the typical managed care reimbursement rate, the increased margin could be considered a price concession. As a policy matter, we believe pharmacies should be encouraged to participate in assistance programs financed by manufacturers. We are concerned that a rule that treats pharmacy reimbursement at a normal benefit rate as a price concession to the pharmacy will add needless administrative complexity to an already complicated system. Further, if only replacement drug programs are exempt from best price, we believe this will discourage pharmacy participation.

We request that CMS clarify that reimbursement of a pharmacy on behalf of a patient under a manufacturer PAP is not a price concession to the pharmacy if the pharmacy is reimbursed at a typical managed care rate.

6. <u>Smoothing Lagged Indirect Excluded Sales</u>

In the final rule, CMS required manufacturers to use a specified "smoothing" formula for reducing gross sales by lagged discounts on non-exempt sales. The final rule did not address smoothing indirect sales to excluded classes of trade where the transaction lags behind the original wholesaler sale. Recently, CMS was asked whether a company could smooth these excluded sales. However, CMS' response posted on its website addressed a different question - whether the excluded sales should be included in the smoothing formula applied to non-exempt sales. Normally, excluded indirect sales are removed from the AMP calculation at WAC in the quarter in which the chargebacks are processed, but following this methodology can skew AMP if a large number of lagged excluded sales are realized in a quarter in which there are few remaining sales to absorb discounts to the retail pharmacy class of trade. Therefore, discretionary smoothing of the excluded units and removal of a corresponding value from gross sales dollars is appropriate. Smoothing the exclusions could easily be accomplished by determining the ratio of indirect excluded units to wholesaler units over a 12 month period, and then removing from gross sales the number of units resulting from application of that percentage to the current period. Such a methodology would prevent volatility and yield a truer AMP. Please clarify that a manufacturer may, if it chooses, determine the lagged indirect sales to be excluded in a period by applying a smoothing formula.

7. Reporting Customary Prompt Pay

The final rule requires manufacturers to report customary prompt pay discounts provided on each of its drugs during the quarter as aggregate sales dollars, and to use documented actual amounts not estimates. However, the rule does not specify whether manufacturers may use the actual amount offered at the point of sale as reflected on the invoice, or whether they must determine if the full amount of the offered discount was later taken as a credit. If the latter is required, it will be a much more difficult process for manufacturers, as this data does not reside in the sales data used by price reporting systems. Since the CPP reported to CMS is not used to calculate reimbursement rates or rebates, we urge CMS to clarify that manufacturers may use the CPP amounts offered at the point of sale in computing quarterly CPP.

8. Authorized Generics

The preamble to the final rule has created considerable confusion with respect to the treatment of sales of authorized generics. In the proposed rule, CMS proposed that the owner of the drug's NDA combine the average price of the drug sold by the authorized seller to the retail pharmacy class of trade with the AMP for the brand. That is consistent with the statutory requirement that the AMP for a drug approved under an NDA include all sales of the drug to the retail pharmacy class of trade. In the final rule, CMS exempted from this statutory requirement sales other than those made by the owner of the NDA because of concerns with difficulties in obtaining sales data from the authorized seller. Section 447.506(b) provides: "A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler." (Emphasis added.) This language does not preclude a company from complying with the statute if the data is available. For companies that sell generic versions of brand products through a wholly owned subsidiary, and that calculate the AMP and best price for both the brand and generic version, there is no issue as to availability of the transactional data. Please confirm that when authorized generic sales data for a drug is available to the manufacturer holding title to the NDA because, for example, it owns or controls the generic drug manufacturer, it may include all sales of the drug to the retail pharmacy class of trade in its reported AMP.

With respect to best price, section 447.506(c) of the final rule similarly provides that "a manufacturer holding title to the original NDA must include best price of an authorized generic drug in its computation of best price ...to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or government entity in the United States only when such drugs are being sold by the manufacturer holding title to the original NDA." Thus, there must be a sales transaction by the holder of the NDA. The preamble to the final rule is confusing because it refers to the "transfer price" between the owner of the NDA and the authorized seller, including a subsidiary. We understand a sales price to be the result of an arms length transaction. Although a company

holding title to an NDA may bargain to sell its product to another manufacturer for an initial price that is subsequently adjusted upward, an agreement to provide a manufacturing service is the sale of a service not a product. Further, in the case of a wholly-owned subsidiary, a generic version of drug may be manufactured within the corporate organization at cost, not sold to the subsidiary in an arms length transaction. Please confirm that an intra-company transfer of manufacturing cost is not a sale of the product, and that for purposes of best price, in such a situation, where the owner of the NDA has access to the generic manufacturer's sales data because it owns or controls the generic business, the sale by the generic manufacturer to any manufacturer, wholesaler, retailer, provider, etc. should be considered in the best price of the drug reported by the owner of the NDA.

9. Bundled Sales

Section 447.502 of the final rule defines "bundled sale" ...However, there remains some confusion as to what is meant by discounts on drugs within the bundled arrangement. It is not uncommon for a drug to be part of a bundled deal and also be discounted separately based on sales criteria for that drug alone. For example, a discount could be offered on Drug A based on purchases of undiscounted Drug B, and a separate discount on Drug A based on market share of just Drug A. Clearly, for best price purposes, the allocated share of a bundled discount must be aggregated with any other discount applicable to the same drug that is not contingent on the purchase of another drug. However, that does not mean a non-contingent discount must be apportioned as if it were also within the bundled arrangement. If that were the case, allocating the non-contingent discount to other drugs would improperly increase the true best price of the drug on which the non-contingent discount was given. We request that CMS clarify that discounts offered on a drug independent of the terms of a bundled deal should not be included in the allocation of the bundled discounts.

10. Definition of Single Source Drug

The definition of covered outpatient drug in section 1927(k)(2) of the Social Security Act distinguishes between drugs approved under section 505 of the Federal Food Drug and Cosmetic Act and biological products licensed under section 351 of the Public Health Service Act. Section 1927(k)(7)(A)(iv) of the Social Security Act defines "single source drug" to mean "a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration..." The preamble to the final rule makes it clear that a covered drug is approved under a "new drug application" if it follows the Food and Drug Administration process specified in Section 505 of the Federal Food Drug and Cosmetic Act. Accordingly, drugs, biological products and insulin approved under an NDA are within the statutory definition of single source drug. The final rule recognizes that certain categories of outpatient drugs that were originally sold as patented drugs are not single

source drugs or innovator multiple source drugs because they were not approved under the NDA procedures of section 505. These drugs are properly categorized as "other than single source drugs or innovator multiple source drugs." At the same time, the final rule defines single source drug to include biological products that are approved and sold under a different regulatory scheme than the NDA procedures. Unless and until Congress changes the statutory definition of single source drug to include covered outpatient drugs approved under the biological licensing procedures of section 351 of the Public Health Service, only biological products approved under an NDA may be included in the definition of single source drug. The final rule is inconsistent with the statute and arbitrarily expands the definition of "single source drug" to include certain covered outpatient drug products that are categorized as "other drugs" under the statute.

We hope the information provided in this letter is useful to you and that you will consider it in clarifying remaining issues in implementing the DRA.

Sincerely,

Donna Lee Yesner

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December 14, 2007

BY ELECTRONIC DELIVERY

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Washington, D.C. 20201

SUBJECT: CMS-2238-FC (Medicaid Program; Prescription Drugs)

Dear Acting Administrator Weems,

Baxter Healthcare Corporation (Baxter) appreciates the opportunity to comment on the above-mentioned final rule published in the Federal Register on July 17, 2007 (the Final Rule).[1] For 75 years, Baxter has assisted healthcare professionals and their patients with the treatment of complex medical conditions, including hemophilia, immune disorders, cancer, infectious diseases, kidney disease, and trauma. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

The Centers for Medicare and Medicaid Services (CMS) published the Final Rule in order to implement the mandate of the Deficit Reduction Act of 2005 (DRA) to promulgate a regulation that "clarifies the requirements for, and manner in which, average manufacturer prices are determined." Baxter would like to thank CMS and the Secretary for working with patients, providers, manufacturers, and suppliers of health care providers to clarify the Medicaid rebate program, and commends the agency for further working with affected parties by accepting public feedback on the Final Rule.

Our comments address a number of topics included in the Final Rule, but those of primary importance to Baxter are as follows:

- Bundled Sales: CMS should clarify the discount reallocation methodology for bundled sales.
- Best Price: CMS should clarify that discounts should only be aggregated when realized by a single purchaser.
- PAPs and AMP: CMS should confirm that patient assistance programs may provide free goods so long as they are not contingent on a future purchase.

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[1] 72 Fed. Reg. 39,142 (July 17, 2007).

- Authorized Generics: CMS should continue to exclude the sales by secondary manufacturers of authorized generics from the AMP calculation of branded drugs.
- Certification: CMS should include a clear knowledge standard in the certification language in the Medicaid context.

1. CMS Should Clarify the Treatment of Drugs and Non-Drug Products in a Bundled Arrangement for Purposes of Reallocating Discounts.

The Final Rule introduces significant changes with regard to the definition of bundled sales and the discount reallocation methodology associated with such arrangements. In order to assist manufacturers in implementing these changes, Baxter urges that CMS clarify the reallocation methodology

The Final Rule specifies a reallocation methodology for discounts on bundled sales. Specifically, 42 C.F.R. § 447.502 provides that:

> For bundled sales, the discounts are allocated proportionally to the total dollar value of the units of all drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement shall be proportionally allocated across all the drugs in the bundle.[2]

Baxter would like CMS to clarify the treatment of non-drug products in this reallocation methodology. Under the new bundled sale definition, a bundled sale involves a price concession "conditioned upon the purchase of the same drug, drugs of different types [...] or another product."[3] While the definition of bundled sale clearly states that a bundle may include non-drug products, the ensuing reallocation methodology does not address whether the discounts in the bundled arrangement should be proportionally allocated across both drug and non-drug products as well. Baxter requests that CMS issue guidance clarifying the treatment of drug and non-drug products in the reallocation methodology.

2. CMS Should Clarify that Only Discounts Realized by a Single Purchaser Need to Be Aggregated When Calculating Best Price

In order to be consistent with the applicable statutory provisions, CMS should clarify that discounts are only to be aggregated for purposes of calculating Best Price when they are realized by a single purchaser, not when they are provided to separate customers. The Medicaid statute defines Best Price as follows:

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2 72 Fed. Reg. at 39,240 (42 C.F.R. § 447.502) (emphasis added).

3 *Id.* (emphasis added).

> The term best price means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug and Cosmetic Act) the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.[4]

This definition clearly emphasizes that it is the price given to a particular entity, as reinforced by the statute's use of the term "any" before the list of entities. Similarly, the Medicaid Drug Rebate Agreement and the Final Rule define Best Price as the lowest price provided to a single entity.[5] Given the focus of all three definitions on the price realized by a single purchaser or provider, it seems logical to conclude that discounts should only be aggregated when received by the same purchaser or provider.

The different approach taken in defining AMP supports this conclusion as well. In the definition of AMP, CMS emphasizes the price received by the manufacturer, rather than that paid by a particular entity.[6] Consistent with that emphasis on the manufacturer, discounts across all retail purchasers are included when calculating AMP. This clearly contrasts with the focus in the Best Price definition and therefore necessitates different treatment of discounts in the context of the two price calculations.

Baxter believes that guidance in the preamble to the Final Rule on this issue is unclear. In particular, on pages 39,198 to 39,199 of the Federal Register, CMS responds to several comments in a way that suggests the agency may expect aggregation of discounts across purchasers in the calculation of Best Price. We ask CMS to clarify that manufacturers should only aggregate discounts where the discount impacts the price realized by a single purchaser. Thus, where a manufacturer provides a discount to one entity, it need not be aggregated with another discount provided by the manufacturer to a second entity, unless the discount to the first entity is passed on to the second at the manufacturer's direction or otherwise designed to affect the price of the second entity. This clarification is consistent with the existing statutory, regulatory, and Agreement definitions of Best Price and Baxter urges CMS to issue this guidance.

3. CMS Should Confirm that Patient Assistance Programs Involve Provision of Free Goods that are Not Contingent on Future Purchase Requirement.

The Final Rule specifies that financial assistance and free goods provided by manufacturers through patient assistance programs (PAPs) are excluded from the calculation of AMP and BP.[7] The preamble to the Final Rule sets out four criteria that

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4 42 U.S.C. §1396r-8(c)(1)(C)(i)(2007).

5 Agreement at § I(d); 42 C.F.R. § 447.505(a).

6 42 C.F.R. § 447.504(a).

7 72 Fed. Reg. at 39,241-42 (42 CFR §§ 447.504(h)(12) & 447.505(d)(9)). The definition of AMP states that "sales to" PAPs are excluded from AMP, and the definition of BP states that "goods provided free of charge" under a PAP are excluded from BP.

PAPs must satisfy in order to qualify for these exclusions.[8] One of the four criteria that a PAP sale must meet in order to be excluded from AMP and BP is:[9]

> The program is focused on extending free products not contingent upon any purchase requirement or extending financial assistance to low-income individuals and families, as determined by CMS.

The preamble discussion further specifies that "patient assistance programs and manufacturer coupons that provide free goods which are not contingent upon future purchases to patients" are among the types of programs that should be excluded from AMP.[10] As this commentary does not address the impact of a PAP providing free goods conditioned on a prior or past purchase, Baxter requests confirmation from CMS that a patient assistance program may still qualify as a PAP if it extends free products contingent upon a past purchase requirement.

4. CMS Should Maintain its Approach to Authorized Generics.

The Final Rule interprets AMP to exclude manufacturer-to-manufacturer sales of authorized generics from the calculation of the AMP for a branded drug. The rule defines AMP as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."[11] In the authorized generic context, "A manufacturer holding title to the original NDA of the authorized generic drug must include the sales of this drug in its AMP only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler."[12] As CMS indicates in the preamble to the Final Rule, this interpretation "eliminates the need for manufacturers to share information on sales to other entities and potential competitors."[13] Baxter supports CMS' approach to authorized generics. We agree with CMS that, by directing that the AMP calculation for the branded drug is to remain unblended, the Final Rule eliminates significant antitrust and anti-competitive concerns, and avoids unduly burdening secondary manufacturers with additional price reporting responsibilities.

5. CMS Should Include a Knowledge Requirement in the AMP and Best Price Certification Language.

In the Final Rule, CMS requires manufacturers to certify their monthly and quarterly AMP and Best Price data. CMS has now issued the certification language through the DDR system, and Baxter encourages CMS to modify that language to further acknowledge the intent requirement contained in the Medicaid statute's civil monetary penalty provision.

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8 72 Fed. Reg. at 39,188-89.

9 *Id.*

10 *Id.* at 39,189.

11 72 Fed. Reg. at 39,241 (42 C.F.R. § 447.504(a)) emphasis added).

12 *Id.* at 39,243 (42 C.F.R. § 447.506(b)) (emphasis added).

13 *Id.* at 39,199-200.

The Medicaid statute subjects manufacturers to civil monetary penalties for "knowingly" providing false information to CMS.[14] In response to that language, CMS has issued the following certification language through its DDR system:

> **I hereby certify, to the best of my knowledge, the data being sent to CMS with this submission is complete and accurate at the time of this submission, and was prepared in accordance with the manufacturer's good faith, reasonable efforts based on existing guidance from CMS and the manufacturer's reasonable assumptions regarding the provisions of section 1927 of the Social Security Act, the National Medicaid Drug Rebate Agreement, and applicable federal regulations. I understand that the information contained in this submission may be used for Medicaid rebate and payment purposes and that civil monetary penalties and/or termination from the Medicaid Rebate Program may be enforced if the information provided is found to be misrepresented. I further certify that I am authorized to submit this information in accordance with 42 CFR 447.510(e).**

Baxter supports CMS's inclusion of the explicit statement in the first sentence that all representations included in that first sentence are made "to the best of [the certifier's] knowledge," as such a requirement is supported by the language of the Medicaid statute itself. However, and for this same reason, Baxter believes a similar limitation must be added to the second sentence, to provide that civil monetary penalties may be enforced if the submitted pricing data are "**knowingly** misrepresented." This language is appropriate because it captures the fact that the Medicaid civil monetary penalty provision only applies to the knowing submission of false information. Baxter urges CMS to make this change to the certification language as soon as possible.

6. Conclusion.

Baxter appreciates the opportunity to comment on this Final Rule. We commend CMS on the additional clarity the rule provides to the Medicaid drug rebate program, and we believe adopting additional changes will help ensure that patients have access to the medicines that they need. Please feel free to contact me by phone at 202-508-8200 or email at sarah_creviston@baxter.com if you have any questions or would like additional information.

Sincerely,

Sarah Creviston
Vice President, Government Affairs, U.S.
Baxter Healthcare Corporation

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[14] Social Security Act § 1927(b)(3)(C).

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The Specialty Biotech Distributors Association
1501 K Street, NW
Washington, DC 20005

December 21, 2007

Hand Delivery

The Honorable Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-FC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on CMS-2238-FC: Medicaid Program; Prescription Drugs; Final Rule with Comment Period (AMP Provisions)

Dear Administrator Weems:

The Specialty Biotech Distributors Association ("SBDA") submits the following comments to the Centers for Medicare and Medicaid Services ("CMS" or "the Agency") on the Final Rule with Comment Period ("Final Rule"): "CMS-2238-FC: Medicaid Program; Prescription Drugs." We are grateful for the opportunity to provide additional comments on several of the average manufacturer price ("AMP") provisions that are critically important to our industry, including the Final Rule's definitions and guidance for bona fide service fees, customary prompt pay discounts, and the retail pharmacy class of trade.

We commend the Agency for establishing a regulatory definition of bona fide service fees for AMP purposes that mirrors the definition under the average sales price ("ASP") methodology for Medicare Part B drugs. Within the bona fide service fee context, we urge CMS to allow manufacturers to use the bona fide service fee test to determine whether fees for administrative services relating to rebate contract administration may properly be excluded from the AMP calculation, rather than instituting a blanket rule under which these fees may never qualify as bona fide service fees.

SBDA also is pleased with the Final Rule's regulatory definition of customary prompt pay discounts, although we request that CMS refrain from further limiting or capping these terms. Finally, we reiterate our belief that physician offices do not provide drugs to the general public and, as such, should be excluded from the retail pharmacy class of trade.

I. BACKGROUND ON SBDA

SBDA is comprised of companies dedicated to maintaining the integrity and efficiency of the specialty distribution system in physician offices and other settings. Our member companies include AmerisourceBergen Specialty Group; Cardinal Health, Inc.; Curascript; Health Coalition, Inc.; OTN, a McKesson Specialty company; and U.S. Oncology. Together, we represent over eighty percent of the volume of drugs delivered to physician offices in the United States.

Specialty distributors provide tremendous value and efficiency to federal health care programs. While often not visible to the public, specialty distributors manage the increasingly complex handling and delivery requirements of drugs and costly new biologics for virtually all physician offices in the country. These distributors perform important services, such as warehousing products, providing specialty handling and shipping services (such as packaging, refrigeration, or customized dosing), and ensuring the timely delivery of drugs and biologics to physicians and providers.

II. COMMENTS ON AMP PROVISIONS

A. *Bona Fide Service Fees*

SBDA commends CMS for finalizing its proposal to exclude bona fide service fees from the AMP determination. We are pleased that the Final Rule adopts for AMP purposes the guidance CMS issued in the preamble to the Physician Fee Schedule Final Rule for CY 2007 on the definition and treatment of bona fide service fees in the context of the ASP methodology. 71 Fed. Reg. 69,624, 69,668-69, 69,787 (Dec. 1, 2006). We believe the Agency's decision to adopt the same bona fide service fee definition for both the ASP and AMP methodologies will enhance uniformity in reporting across the Medicare and Medicaid Programs. For distributors and manufacturers, establishing a consistent definition of bona fide service fees is essential for improving compliance and reducing administrative burden and complexity.

SBDA also strongly supports the Agency's decision to refrain from establishing a list of qualifying bona fide services and from requiring manufacturers to follow a particular method for evaluating whether a fee equals fair market value. We are particularly pleased that CMS has agreed to permit manufacturers to apply the bona fide service fee test to distribution services to determine whether these fees may properly be excluded from the AMP methodology.

We note, however, that the Agency has not refrained from identifying specific services that *do not* qualify as bona fide services. Specifically, CMS states in the Final Rule preamble that fees for administrative services related to the administration of a rebate contract do not qualify as bona fide service fees because, in the Agency's view, these services are not related to the efficient distribution of drugs or its bona fide service fee guidance interpretation. We ask for clarification as to the reasons why the administration of a rebate contract cannot be considered a bona fide service if the fee provided meets all facets of the bona fide service fee test. Clearly, if

properly structured, an entity may handle such a function for (1) a fair market value price; and (2) without passing the fee down to an end customer. The administration of rebate contracts is a bona fide, legitimate service that would otherwise have been performed by a manufacturer in the absence of a service agreement. How would this service, on its face, fail to meet the test?

Instead of creating a blanket rule under which rebate contract administration may never qualify as a bona fide service, we urge the Agency to permit manufacturers to treat fees for these services as bona fide service fees where they satisfy that definition. We also request that CMS refrain from identifying other services that it believes do not qualify as bona fide services; creating a list of non-qualifying services will render meaningless the bona fide service fee test.

B. ***Customary Prompt Pay Discounts***

Although SBDA supports the Final Rule's definition of customary prompt pay discounts, we are concerned that the preamble adds restrictions on the use of these terms that may hinder contracting flexibility. We urge CMS to refrain from implementing future guidance or clarification that further limits or caps customary prompt pay discounts.

SBDA was pleased with the customary prompt pay discount language included in the Medicaid Program Proposed Rule because it reflected Congress' intent in the Deficit Reduction Act of 2005 to exclude a broad and varied array of prompt pay discounting terms from the AMP calculation. As you may recall, Congress specifically rejected initiatives to restrict the scope of these terms during the legislative debate. Congress sought to provide contracting flexibility to manufacturers and distributors to avoid impairing the integrity of the supply chain or adding cost inefficiencies to the Medicaid Program.

In the preamble to the Final Rule, however, CMS establishes reporting and treatment guidelines that limit the types of terms that satisfy the finalized definition of customary prompt pay discounts. For example, the preamble prohibits manufacturers from assuming a blanket percentage for these terms or applying the available percentage to total direct sales. Further, CMS explains that a discount must be offered to all purchasers for payment within a specified timeframe to qualify as a prompt pay discount. CMS should grant some discretion to manufacturers in determining whether a discount is routine and consistent with customary business practice rather than dictating that these discounts must be made available to all purchasers within a set time period. To avoid further limiting contracting flexibility for manufacturers and distributors, we urge CMS to refrain from placing additional limitations or caps on these terms.

The plain language of the statute excludes "customary prompt pay discounts." It does not allow the Agency to place additional regulatory requirements on manufacturers as a condition of the exclusion of these terms.

C. ***Retail Pharmacy Class of Trade***

SBDA further requests CMS to modify the definition of "retail pharmacy class of trade." A clear definition will assist manufacturers in determining AMPs in a more consistent manner.

We are particularly concerned by CMS' statement in the preamble to the Final Rule that the retail pharmacy class of trade includes physician offices to the extent that they purchase drugs from manufacturers and provide them to the general public. We request that CMS wholly exclude physician offices from the retail pharmacy class of trade because these offices are not retail locations open to the general public.

Unlike a retail pharmacy, a physician office is a closed operation that does not permit patients to purchase prescription drugs on a walk-in basis or to fill prescriptions written by another physician. Individuals are permitted to purchase drugs from a physician's office only if they are patients of that physician. Further, the range of drugs that may be purchased in a physician's office are restricted to those drugs that the physician administers or dispenses.

If CMS disagrees with our recommendation to exclude physician offices from the retail pharmacy class of trade, then SBDA requests that CMS explain the circumstances under which it believes physician offices provide drugs to the general public so as to fall within the scope of the retail pharmacy class of trade.

III. Conclusion

SBDA appreciates the opportunity to submit comments on the AMP provisions that affect the integrity and financial viability of the specialty distribution system. Although we commend the Agency for promulgating a definition of bona fide service fees in the AMP context that is consistent with the definition for ASP purposes, we urge CMS to permit manufacturers to employ the bona fide service fee test in determining whether fees for administrative services relating to rebate contract administration may be properly excluded from the AMP calculation. We also request that the Agency refrain from implementing guidance that limits or caps the scope of customary prompt pay discounts. Finally, we respectfully ask CMS to wholly exclude physician offices from the retail pharmacy class of trade because drugs administered in that setting are not provided to the general public.

Thank you for your careful consideration of these comments.

Respectfully Submitted,

John F. Akscin
President
Specialty Biotech Distributors Association