The Specialty & Biotech Distributors Association
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Hand Delivery

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

Re: Comments on CMS-2238-P: Medicaid Program; Prescription Drugs; Proposed Rule

Dear Ms. Norwalk:

The Specialty and Biotech Distributors Association ("SBDA") submits the following comments to the Centers for Medicare and Medicaid Services ("CMS" or "the Agency") on the Proposed Rule: "CMS-2238-P: Medicaid Program; Prescription Drugs." We appreciate the opportunity to discuss a number of important issues unique to specialty distributors. In our comments, we focus on issues related to bona fide service fees, the importance of excluding customary prompt pay discounts from both the definition of Average Manufacturer Price ("AMP") and Best Price, and the need for further clarification regarding the definition of "retail class of trade" as it pertains to drugs administered within the physician office setting. While SBDA believes that drugs administered within a physician office setting should be excluded from the retail class of trade for reporting and reimbursement purposes, the Proposed Rule does not specifically denote this fact. Accordingly, we respectfully request that the Agency confirm our interpretation in the Final Rulemaking.

As CMS finalizes this rulemaking, we urge the Agency – to the extent feasible and permissible under the statute – to define the myriad of definitions impacting the Medicaid Program in a manner consistent with other federal health care programs. Following such an approach will increase compliance with all federal laws, and equally important, will minimize regulatory burdens and program complexities that may unintentionally establish an uneven playing field between competitors' pharmaceutical products.

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. Much of our regulatory efforts have focused on obtaining clarifications to the Average Sales Price ("ASP") system, but ensuring that AMP and Best Price are defined appropriately is also critical given the increasing number of physician-administered specialty drugs and biologics that are reimbursed under Medicaid.

Our members include AmerisourceBergen Specialty Group, Cardinal Health, Inc., Curascript, Health Coalition, Inc., Oncology Therapeutics Network, and U.S. Oncology. Together, we represent over eighty percent of the physician office specialty distribution volume 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. Our specialty distributors typically do not sell drugs within the "retail class of trade," so our comments focus on core issues that arise in this rulemaking regarding physician-administered drugs.

II. CMS's Proposal to Exclude Bona Fide Service Fees from AMP Will Establish a Uniform and Consistent Treatment of these Fees Across the Medicare and Medicaid Programs

In the Proposed Rule, CMS clarifies that bona fide service fees should be excluded from the calculation of AMP. SBDA applauds the Agency for its position on this matter. The Proposed Rule defines a bona fide service fee as "a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, that is 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." This language replicates the definition CMS recently finalized in the context of the ASP methodology for Medicare Part B Drugs in the CY 2007 Physician Fee Schedule Final Rule. 71 Fed. Reg. 69,624, 69,787 (Dec. 1, 2006).

SBDA strongly supports CMS's proposed definition of bona fide service fees and believes the Agency's decision to adopt the same definition of these fees for both ASP and AMP will enhance uniformity in reporting across the Medicare and Medicaid Programs. For distributors and manufacturers, establishing one consistent definition of bona fide service fees is essential to improving compliance and reducing administrative burden and complexity. As such, in finalizing this rulemaking, we encourage CMS to confirm several points by replicating portions of the narrative of the Physician Fee Schedule Final Rulemaking and deleting the specific reference to "distribution fees" in the Proposed Rule's definitions of AMP and Best Price.

SBDA's request to reiterate the narrative of the Physician Fee Schedule Rulemaking is important, yet easy to implement. Specifically, we ask CMS to confirm that the terms "bona fide," "itemized," and "actually performed on behalf of the manufacturer or otherwise performed" include "any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69,668. The Agency developed this definition after receiving significant commentary regarding ASP from SBDA and many other interested parties. In that context, CMS recognized that the definition of bona fide service fees should not be restrictive as it might impede the development and innovation of specialty distribution services and practices. So long as a service provides "value" to a manufacturer, and meets the other prongs of the service fee test, the ASP Final Rulemaking permits exclusion of the related fee from the calculation of ASP.

For ease of reference, the Agency should simply repeat in the Final Rule the ASP narrative cited above pertaining to "value to the manufacturer that are associated with the efficient distribution of drugs." Further, CMS should reiterate that AMP will incorporate the ASP definition's reference to services that are performed "on behalf of" a manufacturer as including both those services that a manufacturer possesses the capacity to perform and those that only another entity can perform. *Id.*

In the Proposed Rule, the second prong of the bona fide service fee definition provides that an excluded fee must equal fair market value. CMS specifically requested comments on this issue of fair market value. In response to this request, we ask CMS to utilize the same approach it took in the ASP context. Under that interpretation, CMS defined these fees as "expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities." 71 Fed. Reg. at 69,669. Under an identical interpretation for AMP purposes, CMS should continue to permit manufacturers, depending on the circumstances and the nature of the services involved, to calculate the fair market value for a *set* of itemized bona fide services, rather than for each service individually. Moreover, as the method for determining fair market value may vary based on the terms of the contract at issue, CMS should refrain from requiring manufacturers to follow a particular method for evaluating whether a fee equals fair market value. *Id.* These positions are articulated at great length in the Final Physician Fee Schedule Rulemaking. *Id.*

The last prong of the bona fide service fee definition requires these fees to "not be passed on, in whole or in part, to a client or customer of an entity." We again urge CMS to replicate its interpretation of this clause in the ASP context for AMP. CMS indicated for ASP purposes that if a manufacturer has ascertained that a fee paid satisfies the requirements of the bona fide service fee definition, "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 an entity." *Id.*

Finally, SBDA believes CMS should apply the definition of bona fide service fees to the term "distribution services." Incorporating the term "distribution services" into the definition of AMP does not reflect the fact that many core distribution services – such as packaging, shipping and handling – may meet the test of a bona fide service fee and may be appropriately excluded from AMP. We believe the ASP Final Rulemaking already has clearly articulated a standard for exclusion. As such, the AMP Final Rulemaking need not reference distribution services as *necessarily* distinct from bona fide services. While distribution services may not always meet

the three prong bona fide service fee test established under ASP, they certainly *may* meet the definition. Thus, categorically including these terms in AMP is inherently contradictory and may confuse manufacturers and distributors regarding the scope of the recently implemented ASP definition.

III. CMS Should Finalize Its Proposed Definition of Customary Prompt Pay Discounts in the Definition of AMP

In the Deficit Reduction Act of 2005 ("DRA"), Congress statutorily excluded from AMP "customary prompt pay discounts" provided to wholesalers, yet did not define this term. To implement the requirements of the DRA, CMS proposes to define the term "customary prompt pay discount" to mean "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date." We support this proposed definition and encourage CMS to finalize it exactly as written in the Proposed Rule.

Manufacturers offer prompt pay discounts to specialty distributors in most contracting arrangements to recognize the "time value" of money and to reflect the credit risks associated with the management and delivery of drugs and biologics to physician offices. These contracting terms substantially lower the cost of distribution to the manufacturer and the physician and provide an incentive to distributors to make timely payments, which enhances the efficiencies within the supply chain to the benefit of patients, physicians, and the Medicaid Program.

The language of the Proposed Rule reflects Congress' intent to exclude a broad and varied array of prompt pay dating terms. In fact, during the legislative debate, efforts were made to cap or limit the scope of these terms, but Congress rejected these initiatives. Congress wished to provide contracting flexibility to manufacturers and distributors because it was concerned about impairing the integrity of the supply chain or adding cost inefficiencies to the Medicaid Program. We urge CMS to reject similar efforts to limit these terms in the Final Rulemaking.

SBDA notes that the Proposed Rule specifically includes cash discounts in the calculation of AMP. While we believe CMS's intent to exclude customary prompt pay discounts is clear, cash discounts in the pharmaceutical industry are sometimes expressed as "prompt pay discounts." As such, when the Agency finalizes this rulemaking, we ask that it refrain from defining "cash discounts" in a manner that is inconsistent with the definition of customary prompt pay discounts in the Proposed Rule. Clarity and consistency of pricing terms is essential for the accurate submission of AMP data.

In these comments, we also wish to point out a potential inconsistency within the Department of Health and Human Services ("HHS") regarding the new definition of AMP. Currently, the Health Resources and Services Administration ("HRSA") is proposing to disregard the DRA-mandated prompt pay discount change to AMP for purposes of calculating 340B prices. As you know, the 340B statute uses the definition of AMP in the Medicaid statute as the foundation for 340B prices. In a January 30, 2007 letter to manufacturers, HRSA stated that for 340B price calculation purposes, manufacturers should continue to reduce AMP by the prompt pay discount despite the statutory mandate from the DRA. In effect, HRSA is requiring

manufacturers to produce two separate AMPs – one for use in the Medicaid program and one for use in the 340B program.

We fundamentally disagree with HRSA's regulatory authority to issue such a mandate and raise it to your attention. HRSA's suggestion to report a 340B-specific AMP is inconsistent with HRSA's past interpretation of the 340B statute and arguably constitutes an arbitrary and capricious exercise of regulatory authority because it will be at odds with the express terms of the DRA.

As supporting evidence for dual AMPs, HRSA cites a clause in the 340B statute (which exists within the Public Health Service Act) that indicates references in the statute to the Social Security Act should be read as those references existed when the 340B statute was created on November 4, 1992. The 340B statute contains ten references to the Social Security Act, the definition of AMP among them. The substance of many of these references has changed significantly since November 4, 1992, and, up until now, HRSA has readily incorporated these changes into the functioning of the 340B program. To now require the definition of AMP for 340B purposes to be the same as the definition in effect on November 4, 1992 would not only be unduly burdensome for manufacturers, but would set a dangerous and ill-advised precedent for future changes.

Given that the statutory underpinnings of the 340B program are so closely intertwined with the Medicaid program, we believe coordination and consistency between CMS and HRSA is vital to the success of both programs. To the extent manufacturers, covered entities, and others in the supply distribution chain must manage both programs using common definitions and interlocking policies, HHS should encourage consistency between the agencies. Accordingly, HHS should require HRSA and CMS to utilize the same definition of AMP for Medicaid and 340B purposes. Prompt payment terms should be excluded from both programs.

IV. CMS's Proposal to Exclude Bona Fide Service Fees From Best Price Ensures Uniformity of Treatment of these Fees in Medicaid; a Similar Approach Should be Adopted for Prompt Pay Discounts

Unlike its proposals in the AMP context, CMS proposes to *include* customary prompt pay discounts in the calculation of Best Price, despite the fact that these terms are not intended to serve as price concessions and "do not affect the price actually realized by the manufacturer." For a number of important public policy reasons, we urge CMS to modify its position in the Final Rulemaking and to exclude customary prompt pay discounts for purposes of Best Price in a consistent manner as it does for AMP. This approach more appropriately reflects the intent of Congress to continue encouraging the use of prompt pay discounting terms in contracts between manufacturers and distributors because they serve an important role in providing a revenue stream to distributors to ensure the safe and effective distribution of drugs to patients.

In the Proposed Rule, CMS argues that no evidence exists to suggest that Congress intended to change the definition of Best Price to exclude customary prompt pay discounts. While it is true that the DRA did not directly amend this provision, characterizing Congress' intent on this position as unclear is incorrect. Congress' express purpose in excluding customary prompt discounts from AMP was to eliminate any incentives to limit the use of these terms.

Congress' objective may only be accomplished if CMS treats these terms in a consistent manner for AMP *and* Best Price.

Further, the fact that customary prompt pay discounts typically do not represent price concessions and do not "affect the price actually realized by the manufacturer" is another important reason for CMS to exclude customary prompt pay discounts from the Best Price determination.

The historic treatment of price concessions in the determination of Best Price is noted clearly throughout CMS guidance on the definition of Best Price. Significantly, the Agency's guidance documents indicate that pricing terms should be included only when they "affect the price actually realized by the manufacturer." Here, CMS may appropriately exclude customary prompt pay discounts on those grounds even though the DRA did not modify the statutory section of Best Price. No statutory change is required to reflect the Agency's long-standing policy of including in Best Price only those pricing terms that represent price concessions.

Finally, we note that the Proposed Rulemaking treats bona fide service fees in a consistent manner for AMP and Best Price. We applaud this approach because it confirms that bona fide service fees do not constitute price concessions. CMS should exclude customary prompt pay discounts from Best Price for that same reason.

V. Scope of the "Retail Class of Trade Definition" As It Applies to Physician-Administered Drugs

We commend CMS for proposing to define the "retail pharmacy class of trade" to ensure that manufacturers determine AMPs in a more consistent manner, but we are concerned with the ambiguous manner in which the Proposed Rulemaking applies the definition to the physician office class of trade. We urge CMS to explicitly state in the Final Rule that the retail class of trade does not include physician-administered drugs.

Section 1927(k)(1) of the Social Security Act, which governs the Medicaid Rebate Program, defines AMP to mean, "with respect to a covered outpatient drug of a manufacturer for a rebate period, 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, after deducting customary prompt pay discounts." Section 1927(k)(1), Social Security Act (emphasis added). Until the issuance of the Proposed Rule, the Medicaid Program has operated without a clear or consistent definition of the entities included in and excluded from the retail class of trade. As CMS explains in the preamble to the Proposed Rule, both the Government Accountability Office ("GAO") and the Office of Inspector General ("OIG") expressed concern regarding the inconsistencies in manufacturers' methods for determining AMP and, as a result, recommended that CMS define the phrase "retail pharmacy class of trade."

Ambiguities in the Preamble

To respond to the GAO's and OIG's concerns, CMS proposes in the preamble to the Proposed Rule to define the retail pharmacy class of trade to include "any entity that purchases prescription drugs from a manufacturer or wholesaler for dispensing to the general public . . .

except as otherwise specified by statute or regulation (such as, HMOs, hospitals)." (emphasis added). In reaching this definition, CMS explains in the preamble to the Proposed Rule that it considered broad definitions, which would encompass prices to nursing home facilities, and narrow definitions, which would exclude prices to pharmacy benefit managers ("PBMs") and other entities. In the end, CMS decided upon a definition that it believes is broad enough to remain consistent with past guidance and avoids resulting in a higher AMP. Moreover, CMS appears to have focused narrowly on whether an entity dispenses drugs to the general public – instead of whether it is traditionally viewed as a "retail" outfit – as a key factor in separating those entities included in the retail class of trade from those that are excluded. For example, it considered including prices of sales to nursing home pharmacies (long-term care ("LTC") pharmacies), but ultimately excluded them because they do not dispense drugs to the general public.

Nowhere in the preamble does CMS specifically state whether it intends to include prices to physicians in the retail class of trade. In the same way that CMS excluded sales to LTC pharmacies from the AMP calculation because they typically are closed operations that serve only residents of a specific LTC facility, a physician office is not a retail location open to the general public. Unlike a retail pharmacy, a physician office is a closed operation that does not permit patients to purchase prescriptions on a walk-in basis. No one can dispute the fact that these drugs are not available to the general public. 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 and patients may not obtain drugs under a prescription from another physician. Accordingly, CMS should adopt a "general public" test that excludes drugs administered in the physician office setting from the retail class of trade.

At the same time, however, CMS does intend to calculate AMPs for purposes of determining rebates owed under the Medicaid Program. Thus, CMS is left with an inherent inconsistency in terms of how to apply the AMP rule to physician-administered drugs. On the one hand, CMS must facilitate the collection of rebates. On the other hand, CMS must breathe meaning into the definition of retail class of trade and "general public."

SBDA would suggest that CMS resolve this tension by calculating the AMPs for purposes of determining rebates owed to the Medicaid Program, but employing a separate system for purposes of public reporting and reimbursement. Failure to take such an approach would, in some cases, artificially lower the AMP reimbursement levels substantially enough that many retail pharmacies might be unable to purchase certain drugs for an amount under the Medicaid reimbursement levels.

The Agency must reconcile the two conflicting provisions of "retail class of trade" and the terms that should be included in AMP for purposes of calculating rebates. As CMS considers this issue, we note that although Congress took action in the DRA to amend the Medicaid statute to require the submission of data on physician-administered drugs for the purpose of determining Medicaid *rebates*, it chose not to amend the statute's treatment of physician-administered drugs for *reimbursement* purposes. Moreover, the Proposed Rule even makes explicit mention of the fact that, to implement the requirements of the DRA, it must consider physician-administered

drugs to be covered outpatient drugs for the "limited purposes of determining rebates on these drugs." (emphasis added). This indication acknowledges CMS's understanding that for all purposes other than determining rebates, physician-administered drugs do not constitute covered outpatient drugs within Medicaid.

For all of these reasons, we respectfully request that the Agency modify its approach to sales that will be used for purposes of calculating reimbursement and public reporting.

VI. Conclusion

SBDA appreciates the opportunity to submit comments to CMS on significant matters affecting the integrity and financial viability of the specialty distribution system. We urge the Agency to finalize this rulemaking in a manner that recognizes the importance of consistent and uniform treatment of bona fide service fees and customary prompt pay discounts across the Medicaid Program. We further ask the Agency to confirm our interpretation of the scope of the definition of AMP. While the statutory language is potentially inconsistent, it does not envision including physician-administered drugs in the retail class of trade for reimbursement and reporting purposes.

Respectfully Submitted,

John F. Akscin /ER

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VIA HAND DELIVERY AND ELECTRONIC DELIVERY
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Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-2238-P, Proposed Rule – Medicaid Program, Prescription Drugs

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services ("**CMS**") proposed rule on Medicaid Program, Prescription Drugs, the "**Proposed Rule**".[1] Daiichi Sankyo, Inc. respectfully submits the following comments to the Proposed Rule regarding Medicaid average manufacturer price ("**AMP**") and Best Price ("**BP**") calculations. We appreciate the opportunity to submit these comments and are available to discuss them with you at your convenience.

We understand the challenges associated with providing clear guidance with respect to the highly complex issues surrounding the AMP and BP calculations. As a general matter, we are concerned that the Proposed Rule raises several questions that, if unanswered, may lead to inconsistencies in manufacturers' price reporting. We have set forth some of these issues below for your consideration. Where possible, we have attempted to organize our comments pursuant to the headings in the Proposed Rule.

I. DAIICHI SANKYO, INC. BACKGROUND

Daiichi Sankyo, Inc. is headquartered in Parsippany, New Jersey, and is the U.S. subsidiary of Daiichi Sankyo Co., Ltd., a global pharmaceutical company headquartered in Japan. The company's strategic focus is on cardiovascular diseases. Research and development of new therapies is also focused in the areas of glucose metabolic disorders, infectious diseases, cancer, immunology and bone and joint diseases. Daiichi Sankyo's portfolio of covered outpatient drugs currently includes Benicar® (olmesartan medoxomil) and BenicarHCT® (olmesartan medoxomil/hydrochlorothiazide), WelChol® (colesevelam HCl), Evoxac® (cevimeline HCl) and Floxin OTIC® (ofloxacin otic).

II. GENERAL COMMENTS

We respectfully request that CMS define what the terms "include" and "exclude" mean with respect to the dollars and units components of the AMP calculation generally. The Proposed Rule is not clear as to how to treat such terms for purposes of actually performing the AMP calculation. For example, if a discount is

[1] 71 Fed Reg. 50,428 (Dec. 22, 2006), file code CMS-2238-P.

"included" in AMP, does CMS expect manufacturers to deduct the value of the discount from the numerator (dollars) of the AMP equation but keep associated units in the denominator (units)? Similarly, for an "excluded" sale, are the dollars to be subtracted out of the numerator and not reduced by any related discounts, and the associated units to be subtracted from the denominator? If so, in cases where the purchase price associated with an "excluded" sale is not known to the manufacturer (as is often the case with indirect sales), how should a manufacturer value such units – at wholesale acquisition cost ("**WAC**")? Alternatively, should "excluded" transactions be ignored (e.g., neither sales dollars, discounts or units deducted from the AMP calculation) in light of the difficulties in valuing the sales? Is there a difference in the treatment of transactions that are "not included" versus transactions that are "excluded"? In some cases the Proposed Rule references including "sales" to certain entities, in some cases it references including "sales and associated rebates, discounts and other price concessions": does CMS intend there to be a difference in the affect on sales dollars, discounts and units based on the terminology used? In this regard, we request that CMS include both of the following in the final rule: (i) a sample AMP calculation and (ii) a chart indicating for each of the various entities that may affect the AMP and BP calculation whether sales, discounts, and/or units are deducted from the gross ex-factory dollar and unit numbers for purpose of calculating AMP.

III. SPECIFIC COMMENTS

A. Section 447.502 (Definitions)

1. Bona Fide Service Fees

   a. The Proposed Rule states that service and administrative fees are included in AMP. However, the Proposed Rule states that "bona fide" service fees are excluded from AMP, without reference to administrative fees. Can an administrative fee qualify as a "bona fide service fee" that would be excluded from AMP?

   b. If an administrative fee is paid to a group purchasing organization in accordance with the group purchasing organization statutory exception and/or safe harbor to the federal healthcare anti-kickback statute (21 C.F.R. § 1001.952(j)), does it also need to fit the definition of "bona fide service fee" to be excluded from AMP?

   c. When defining the term "bona fide service fees" for purposes of the average sales price ("**ASP**") final rule issued on December 1, 2006, CMS included extensive guidance in the preamble interpreting the various components of this term (*see* 71 Fed. Reg. 69623, 69666-70 (Dec. 1, 2006)). We respectfully request clarification as to whether CMS's guidance on this term issued in the ASP context is relevant to the analysis of service fees in the AMP and BP context. Specifically, we respectfully request CMS to clarify that, as is the case with ASP: "If 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."

   d. We respectfully request clarification that service and administrative fees, regardless of whether such fees are "bona fide" as defined by CMS, are not "included" in AMP unless paid to an entity included in AMP under Section 447.504(g) of the Proposed Rule. Also, if a service fee is determined not to be "bona fide", should manufacturers prorate the service fee to apportion it to AMP-included sales only? Because AMP-excluded sales are removed from gross sales, the discounts associated with such sales should be removed from the gross discount dollars before the discounts/rebates being included (dollars being removed) from AMP calculations. Otherwise, it would result in an artificially low AMP number and this AMP number would reflect sales to AMP-included entities and discounts for AMP-included and AMP-excluded entities.

2. Bundled Sale

   a. "Bundling" is defined under the Proposed Rule to include an arrangement where an "other price concession is conditioned upon the purchase of the same drug or drugs of different types..." Does CMS mean to state that a bundle is where the discount on one drug is contingent upon the purchase of another drug (i.e., discount of drug X is contingent upon the purchase of drug Y)? While we do not believe it is the intention of CMS to consider different strengths of the same drug (e.g., same NDA, different NDCs) being offered to a customer as being a bundle, we believe that the definition requires clarification.

B. Section 447.504 (Determination of AMP)

1. (a) AMP means...

   a. As a general comment, while some wholesalers may send a manufacturer detailed reporting as to each entity to which they have sold the manufacturer's product, this is not necessarily a standard for all wholesalers and all manufacturers. As such, manufacturers in many cases rely on chargeback data to identify the retail pharmacy class of trade for AMP calculations. To the extent there is no chargeback associated with a sale, a manufacturer may have no way of knowing whether the end purchaser was "retail". We are seeking confirmation from CMS that this is acceptable.

2. (c) Customary Prompt Pay Discount means...

   a. We respectfully request clarification of the meaning of the word "routinely" when defining customary prompt pay discounts. If a manufacturer offers special or extended terms on a limited basis (e.g., during product launch) would such discounts be considered "routine" and, if, so, how should a manufacturer account for them with respect to AMP and Prompt Pay Discount reporting?

3. (e) Retail Pharmacy Class of Trade means...

   a. The Proposed Rule defines the "Retail Pharmacy Class of Trade" to include a pharmacy benefit manager (or "**PBM**"). We interpret the Proposed Rule to treat both PBM mail order business as well as other PBM business as retail pharmacy class of trade. If this interpretation is correct, it is logical that CMS should also treat non-staff model managed care organizations and employer group health plans as retail pharmacy class of trade. When a PBM is acting in a mail-order capacity as the rebate contracting agent of a plan, the financial incentives are analogous in many ways to a plan performing its own rebate contracting, and it seems incongruous to treat these two arrangements differently. We seek clarification in this regard.

4. (f) Wholesaler means...

   a. The definition of "wholesaler" appears to be inconsistent with CMS's list of sales included in the AMP calculation under the Proposed Rule. Because the AMP is to reflect the average price "from wholesalers for drugs distributed to the retail pharmacy class of trade" (emphasis added), CMS may need to adjust the definition of "wholesaler" to incorporate some of the entities listed under Proposed Rule § 447.504(g) such as individual patients (see §447.504(g)(7)). Alternatively, we respectfully suggest that CMS reconsider whether all of the sales enumerated under §447.504(g) are appropriately "included" in AMP based on the proposed definition of "wholesaler".

5. Sales, Rebates, Discounts, or other Price Concessions included in AMP

   a. We note that Proposed Rule § 447.504(4) states that nominal price sales to a "covered entity described in section 340B(a)(4) of the Public Health Service Act" are not included in AMP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children's hospitals in the definition of "covered entity" for purposes of the Best Price exclusion. However, the definition of "covered entity" under Public Health Service Act was not amended accordingly. Will prices to such children's hospitals (defined in 42 U.S.C. § 1396r-8(a)(5)(B) be eligible for the AMP exclusion?

   b. We respectfully request clarification as to CMS's position on PBM price concessions. In the preamble, CMS states: "We propose to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized the manufacturer for drugs provided to entities in the retail pharmacy class of trade." Is it CMS's intent, based on its inclusion of PBMs in the definition of "retail pharmacy class of trade", that all rebates, discounts or other price adjustments to PBMs be included in (deducted from) AMP, unless specifically excluded? Alternatively, does the language "that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade" place a burden on manufacturers to trace any non-mail order PBM discounts to the ultimate seller to identify whether such seller is an entity in the retail pharmacy class of trade? In the mail order context, chargeback data will generally allow manufacturers to attribute PBM discounts to the ultimate seller of the product. However, in non-mail order arrangements, where the PBM is not a purchaser, there can be difficulties in tracing and classifying such end sales. In many cases, such classification will be impossible. We respectfully request clarification as to CMS's expectations in this regard.

   c. We request that CMS add the wording "where identifiable and to the extent the data is available" when giving guidance on what items to include or exclude from AMP calculations (e.g., discounts given to an excluded class of trade that cannot be identified in a rebate submission from a PBM).

   d. Section 447.504(7) of the Proposed Rule "includes" direct sales to patients. See the discussion above under regarding the definition of "wholesaler." We note that "including" these sales and presumably, discounts, in the AMP calculation may potentially serve as a disincentive for manufacturers to offer patients assistance programs or other subsidies to patients. If the intent of the AMP calculations is to determine the net price by wholesalers to the retail class of trade, including sales and discounts directly to patients may improperly lower the AMP.

   e. Section 447.504(10) of the Proposed Rule "includes": "rebates, discounts, or other price concessions (other than rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade." We respectfully request that CMS clarify the meaning of the term: "associated with".

   f. The Proposed Rule states that only manufacturer coupons redeemed directly by the patient can be excluded from AMP and BP:

      i. We note that manufacturer coupons and vouchers, directly or indirectly redeemed by the patient, serve to provide financial assistance to patients rather than the "retail pharmacy class of trade." We note that as an administrative matter, manufacturers do not always process patient coupons and vouchers directly. Two scenarios are common: (i) a patient will pay a co-pay for the

product at the pharmacy and then redeem a coupon to a third-party vendor under contract with the manufacturer, and the vendor (not the consumer) will then invoice the manufacturer for the value of the coupon; (ii) a patient will present with a coupon or voucher at the pharmacy, and the pharmacy will supply the drug to the patient out of its inventory, at a reduced cost to the patient according to the terms of the coupon, and the vendor (not the consumer) will then invoice the manufacturer for the reimbursement paid to the pharmacy (which may include a negotiated rate and a dispense fee). Is it CMS's intent that the value of coupons or vouchers redeemed by third party vendors are to be "included" in AMP and BP calculations? We respectfully request that they should not be, in light of the negligible impact such arrangements have at the "retail" pharmacy level versus the tremendous benefit to patients.

ii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance on how to value such transactions for purposes of the respective calculations. For privacy reasons, manufacturers often do not have full transparency into the dispensing of a coupon or voucher prescription (e.g., how many tablets are dispensed with a particular coupon). Similarly, even if the manufacturer were to have such transparency, other valuation issues should be addressed (e.g., if a single coupon were redeemed for an order of product that has to be filled over two prescriptions due to a pharmacy not having the full amount of medication to dispense at once – how should such coupon be allocated?).

iii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance regarding how a manufacturer may properly structure a Patient Assistance Program utilizing coupons (if the coupons are redeemed either at the pharmacy or through an agent of the manufacturer) and still keep its patient assistance program BP and AMP exempt.

iv. We respectfully request that CMS define "coupon" and clarify its position with respect to vouchers including the characteristics of a voucher program versus a coupon program.

g. Section 447.504(12) of the Proposed Rule "includes": "sales and associated rebates, discounts, or other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program (MA-PD), State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), and Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations)." We respectfully request that CMS clarify the meaning of the term: "associated with sales of drugs provided to the retail pharmacy class of trade". If a manufacturer were to provide discount to a PBM in connection with its Medicare Part D mail order business, would that discount be "included" in AMP? We further request that CMS clarify the handling of a qualified retiree prescription drug plans for purposes of AMP.

h. We respectfully request that CMS clarify the meaning of the following statement in the preamble of the Proposed Rule: "Therefore, we would clarify that rebates paid to the States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that the price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included." This will also effect SCHIP XIX. How are rebates paid to states Medicaid agencies under either the CMS Rebate Agreement or a CMS-approved supplemental rebate agreement (and the associated units) to be

treated for purposes of AMP? Are manufacturers expected to perform some level of diligence to "trace" Medicaid sales to the retail pharmacy class of trade.

6. (h) Sales, Rebates, Discounts, or other Price Concessions excluded from AMP

   a. We respectfully request confirmation that clearly identifiable indirect sales to "excluded" entities should be excluded from AMP calculations (e.g., sales identified through chargeback data). Similarly, please confirm that indirect sales to excluded entities, if not identifiable as such by the data available to a manufacturer, are not required to be "excluded".

   b. We respectfully request that CMS clarify whether the references to health maintenance organizations ("**HMOs**") and managed care organizations ("**MCOs**") under section 447.504(h)(5) of the Proposed Rule are limited to so-called "staff-model" HMOs and MCOs that purchase pharmaceuticals for dispensing to their members, or whether they include so-called "IPA-model" HMOs and MCOs that arrange for pharmacy discounts but do not actually purchase drugs.

   c. We respectfully request clarification as to the appropriate AMP treatment of direct and clearly identifiable indirect sales and discounts to entities that dispense to only their own patients (e.g., to physicians, home health care, clinics, long term care, prisons, ambulatory care centers, surgi-centers, and other outpatient health care centers).

   d. We respectfully request clarification as to the appropriate AMP treatment of discounts and administrative fees paid to group purchasing organizations.

   e. We support CMS's determination to exclude returned goods from the AMP calculation. However, we respectfully request additional clarification regarding what it means that goods were "returned in good faith." Assuming that a manufacturer has no evidence to the contrary, may a manufacturer assume that goods are returned in good faith? Alternatively, we request that CMS delete the "good faith" requirement, as this issue is in the purview of the returners and not the manufacturer.

   f. We request clarification on whether a manufacturer may treat all chargeback reversals as returns if data is not available to the manufacturer to indicate otherwise.

7. (i) Further Clarification of AMP Calculation

   a. We understand that the requirement that a manufacturer must adjust the AMP if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized is not new. However, we suggest that CMS consider implementing a tolerance level for quarterly AMP variation, within which an AMP restatement (positive or negative) would not be permitted, in order to reduce the burden on states, CMS and manufacturers.

   b. When calculating quarterly AMP, would CMS consider allowing manufacturers the option of calculating a weighted quarterly AMP based upon the monthly AMPs that were submitted for the quarter? In this regard, we would respectfully request that manufacturers choosing this option not be required to restate AMPs. This would eliminate restating of quarterly AMPs as monthly AMPs are generally not allowed to be restated. This would also reduce the administrative burden on the states, CMS and manufacturers in connection with the restatement of quarterly AMPs.

C. 447.505 (Determination of Best Price)

1. CMS states for Best Price reporting "that the best price includes the lowest price available to any entity..." We respectfully request that CMS clarify that the intent of this provision is that the BP represents the best price *achieved* and consider conforming the proposed regulation to this intent.

2. When referencing "Tricare" after depot throughout the Proposed Rule is CMS stating that all Tricare discounts (mail and retail) are to be excluded from AMP and best price? Further, if CMS is asserting that Tricare's retail discount program (TrXX) is viewed as a depot, we respectfully request that CMS clarify that CMS is interpreting only the Medicaid Drug Rebate Statute and not the Veterans Health Care Act.

3. With regard to a manufacturer's patient assistance program ("**PAP**"), would reduced charges to recipients be included in best price? The Proposed Rule indicates that only "goods provided free of charge under a manufacturers' patient assistance program" would be exempt. We respectfully request that CMS exclude all prices under manufacturer PAPs from BP determinations.

4. The determination of what constitutes a "state pharmaceutical assistance program" ("**SPAP**") has been subject to varying guidance from CMS over the years. We are familiar with the several CMS Manufacturer Releases in this regard. We respectfully request that this issue be resolved through the regulatory process. One suggestion would be that manufacturers be allowed to rely on the most current SPAP list published by CMS, and that any deletions from that list apply only prospectively from the first date a manufacturer is able to terminate its contract with that program.

5. See also comments above under AMP discussion.

D. Section 447.506 (Authorized Generic Drugs)

1. The Proposed Rule indicates that, with respect to authorized generics, the original manufacturer must include the authorized generics' manufacturer's data in the calculation of AMP and Best Price. In light of the potentially anticompetitive ramifications of such data sharing, we respectfully request that CMS address an appropriate mechanism to exchange such information within applicable regulatory parameters, including those of the Federal Trade Commission.

2. We request that CMS clarify how manufacturers should handle situations where pricing data is not available from the secondary manufacturer.

3. We request that CMS clarify how manufacturers should account for any transfer pricing of the product when sold from the NDA-holder to the authorized generic manufacturer.

4. We request that CMS clarify that "authorized generic drugs" do not include situations where a drug product is purchased from a branded manufacturer and being marketed under two labeler codes solely during the term while the original product holder sells out its inventory.

E. Section 447.508 (Exclusion from Best Price of Certain Sales at Nominal Price)

1. We note that Proposed Rule § 447.508(a) states that nominal price sales to a "covered entity described in section 340B(a)(4) of the PHSA" are excluded from BP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children's hospitals in the definition of "covered

entity" for purposes of the Best Price exclusion. However, the definition of "covered entity" under Public Health Service Act was not amended accordingly.

2. Separately, 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I) (and Section 447.505(d)(1) of the Proposed Rule) excludes any price to a "covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title)."

3. Will nominal prices to children's hospitals defined in 42 U.S.C. § 1396r-8(a)(5)(B) be eligible for the BP exclusion? Will such prices be separately reportable under Section 447.510(4) of the proposed rule?

F. Section 447.510 (Requirements for Manufacturers)

1. (a) Quarterly Reports

   a. Can CMS clarify how manufacturers will be required to report the Customary Prompt Payment discount to the agency from an operational perspective? For example:

      - When reporting customary prompt payment discounts, should manufacturers recognize these at the time of the sale of the product to the customer?

      - Do manufacturers report customary prompt payment discounts at the 9 digit NDC, the 11 digit NDC or at the labeler code level?

2. (c) Base Date AMP Report

   a. Due to the intense amount of resources that may be required to restate Base Date AMPs, we respectfully request that CMS offer additional time to complete this process beyond the first full quarter after the final rule has been published. We recommend that manufacturers be given 12 months to accomplish this. It may be difficult and, in some cases impossible, for manufacturers to recalculate Base Date AMPs, due to factors such as the passage of time and product sales and acquisitions. As an alternative to recalculating Base Date AMP, we respectfully request that CMS consider allowing manufacturers to calculate AMP under their current (pre-final AMP rule) methodology, then calculate AMP under the methodology established in compliance with the final AMP rule, when issued. The manufacturer could then use the ratio from that difference and apply it to their original Baseline AMP.

3. (d) Monthly AMP

   a. With respect to price concessions to the retail class of trade, is it acceptable for manufacturers to run monthly reports, and include these sales and discounts in the AMP calculations, based upon the "post" date of chargebacks, which indicates when a chargeback has been "paid"? This would be using the "cash" methodology.

   b. We respectfully request that CMS clarify how a manufacturer may "estimate" their monthly AMP. With respect to using an "estimation" or "smoothing" methodology, we recommend that manufacturers should be permitted to use a four-quarter rolling average of rebates to sales, and apply that percentage to monthly sales. Using a four quarter rolling average for smoothing is operationally more feasible than a 12-month rolling average because rebates and other price concessions are typically invoiced by customers and paid by manufacturer on a quarterly basis. We also request that CMS clarify that manufacturers should be allowed to estimate excluded sales for the month, using a four-quarter rolling average based upon gross

sales units divided by excludable AMP units for determining the ratio of non-eligible AMP sales.

c. The Proposed Rule requests comment on the issue of estimating the lagged discounts associated with quarterly AMPs in addition to monthly AMPs. We note that in some cases, it may be appropriate for a manufacturer to use the estimation methodology for the monthly calculations and the cash methodology for the quarterly submissions, as, on a quarterly basis, the lagged concessions may be significantly reduced. We note that this may vary from manufacturer to manufacturer, and thus it would make sense for CMS to permit manufacturers to use either cash or estimation for quarterly AMPs, provided the determination as to which method is to be used is consistent.

d. Regardless of CMS's determination as to timeframe for estimation, we request that CMS clarify whether the current reporting period is included in the estimation (e.g., does the current month data count as one of the twelve months in a twelve-month rolling average?).

e. We respectfully request that CMS clarify how a manufacturer should treat a negative monthly AMP.

f. We respectfully request that CMS clarify what it considers to be "lagged price concessions".

g. CMS Manufacturer Release # 76 (Dec. 15, 2006) states: "Adjustments, such as those resulting from sales data, received after the reporting period ends, should be reflected in the next monthly AMP submission." We respectfully request that CMS confirm whether this is CMS's position under the Proposed Rule as well. If so, we note that the addition of data attributable to a previous month's transactions into a later month's AMP could artificially inflate or deflate the later month's AMP.

4. (e) Certification of Pricing Reports

a. The requirement in the Proposed Rule that the CEO, CFO or delegated direct report of CEO or CFO certify the AMP and BP submissions seems unnecessary and burdensome to manufacturers. We note that there are already a number of significant legal disincentives to a manufacturer in connection with reporting inaccurate numbers, including civil monetary penalties and various state and federal prohibitions against false claims. As a practical matter, in may be difficult to obtain a signature from such senior executives on a routine basis every month, due to travel schedules. Moreover, such individuals are not necessarily in the best position organizationally to verify the accuracy of the reporting to CMS. Therefore, we respectfully request that CMS reconsider requiring such certification.

b. In the event that CMS keeps the certification requirement, we note that the references in the Proposed Rule to the CEO, CFO or delegated direct report of CEO or CFO may not fit the organizational structure of all manufacturers. The titles "CEO" and "CFO" are organization-specific, and we note that Daiichi Sankyo, Inc. has neither (rather, we have a President and a Vice President of Finance). We recommend that CMS clarify that the certification may come from an individual with within the organization with authority and accountability equivalent to an individual holding such a title.

G. Other Comments

1. We note that there is a strong potential for duplicate discounting by manufacturers in connection with physician-administered drugs that are paid as primary under Medicare and secondary under Medicaid. In some cases, this could result in a manufacturer being required to rebate more than

100% of the WAC of a product on a single claim. We respectfully request that CMS use this rulemaking as an opportunity to clarify that when a state Medicaid program pays on a drug claim in the capacity of a secondary payor, such Medicaid program should not be entitled to a full rebate on the associated unit. We do not believe that it was the intent of the Medicaid Drug Rebate Statute to permit states to claim rebates that are disproportionate to the reimbursement payments made by the states on the drugs.

2. How should manufacturers handle the Health Resources and Services Administration Office of Pharmacy Affairs' ("**OPA's**") request for a separate AMP calculation (reduced by prompt pay discounts)? How would the OPA AMP number be reported to CMS (if OPA's request stands) so that CMS can use this AMP for their reporting obligations to OPA? This requirement may be burdensome for both manufacturers and for CMS.

3. What is the process for manufactures to dispute a monthly AMP published on the CMS website if they believe it to be incorrect?

4. Will manufacturers be permitted or required to restate their AMP back through 1Q2007 after the AMP rules become final? We respectfully request that CMS clarify that any final rule applies prospectively only. In this regard, we further request that CMS permit manufacturers at least six months from the publication of the final rule to be in compliance with any requirements that are not statutory requirements under the Deficit Reduction Act of 2005.

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Please feel free to contact us if you have any questions or require further information in this regard.

Sincerely,

Daiichi Sankyo, Inc.

By: Edward J. McAdam Sr.

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BY HAND DELIVERY

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Re: Comments of Allergan, Inc., Forest Laboratories, Inc., Otsuka America Pharmaceutical, Inc., and Reliant Pharmaceuticals, Inc. on Proposed Rule CMS-2238-P, Medicaid Program Prescription Drugs

Dear Sirs:

The following comments to the Centers for Medicare and Medicaid Services (CMS) are submitted on behalf of Allergan, Inc. of Irvine, California, Forest Laboratories, Inc. of New York, New York, Otsuka America Pharmaceutical, Inc. of Rockville, Maryland, and Reliant Pharmaceuticals, Inc. of Liberty Corner, New Jersey, in response to CMS' proposed rule to implement 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 December 22, 2006 (71 Fed. Reg. 77174-77200). Allergan, Forest, Otsuka, and Reliant are manufacturers of single source and innovator multiple source drugs, as defined in section 1927(k) of the Social Security Act, and all participate in the Medicaid rebate program. We welcome this opportunity to address the specific proposals in the proposed rule affecting the methodology by which the Average Manufacturer Price (AMP) and best price are calculated and reported to CMS.

The following comments are organized by topics addressed in the proposed rule. In the first section, the subject of the comment is limited to the calculation and reporting of AMP. In the second section, the subject pertains to the treatment of particular transactions as price concessions in both AMP and best price. The third section concerns the calculation and reporting of best price and other pricing data submitted to CMS.

As a preliminary matter, CMS must reassess the small business impact of the proposed rule. CMS estimates that the majority of the 550 manufacturers affected by the rule are small businesses, yet its limited assessment of the cost impact of the proposed rule on small businesses and manufacturers generally is inadequate. At this stage, it is difficult to determine whether rebate liability will be increased due to changes to the calculation of AMP and best price; however, such an increase is likely should the final rule alter the statutory definition of best price to require aggregation of separate discounts to distinct and unrelated entities if the discounts are "associated with" the same unit of a product. In addition, the preamble to the proposed rule grossly underestimates its impact in terms of the strain it will place on manufacturers' available resources and the administrative cost of implementation. The preamble estimates each of the manufacturers will spend $50,000 on start-up costs and nothing additional for operations. In reality, companies must spend hundreds of thousands of dollars modifying their drug price reporting systems and hire additional personnel in order to meet the requirements of the proposed rule. The proposed rule must adopt reasonable policies that will be the least burdensome for manufacturers to implement. Specific operational issues and the impact from changes to best price are discussed below.

I. AMP – §447.504

Section 447.504(a) of the proposed rule would alter the statutory definition of AMP, which is "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," to the average price "received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade." We believe this change, coupled with the very broad definition of wholesaler, is intended to capture transactions with entities who do not pay manufacturers, directly or through distributors, a price established by the manufacturer. As discussed below, when combined with the proposed inclusions and exclusions from the calculation of AMP, this definition creates confusion as applied to pharmacy benefit managers that do not purchase or take delivery of product, and their client health plans that pay pharmacies for prescriptions dispensed to the plan members. It also creates confusion with respect to fees paid to group purchasing organizations which arrange for purchase prices paid by other entities but are not themselves purchasers and are not listed in the itemized transactions included in AMP.

A. Definition of Wholesaler – §447.504(f)

Section 447.504(f) of the proposed rule would define "wholesaler" as any entity that does not relabel or repackage the covered outpatient drug. No reference is made to whether the exclusion is limited to situations in which the entity relabels or repackages under the purchaser's NDC. Section 447.504(g)(2) would include in AMP sales to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC. We interpret the definition of wholesaler to mean it is exclusive of any entity that purchases a covered outpatient drug and repackages or relabels using the purchaser's own NDC. Please confirm or provide guidance on what is meant for an entity to relabel or repackage under 337.504(f).

B. Retail Pharmacy Class of Trade – §447.504(e); Specific Inclusions and Exclusions §447.504(g),(h)

1. **Definition/Entities Not Specified in the Rule:** Section 447.504(e) of the proposed rule defines the "retail pharmacy class of trade" as any "outlet that purchases or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sell or provides the drugs to the general public." As defined, this definition could apply to any health care provider that pays for drugs or uses them to treat a patient. In the preamble, the reason given for excluding institutional pharmacies in nursing homes and long term care facilities is that these pharmacies dispense drugs only to residents of the facilities, not the general public. Likewise, it appears that sales to HMOs and managed care organizations (MCOs) are excluded because they make prescription drugs available only to their members. Guidance is required as to what is meant by the "general public" in order to determine whether entities not specified in the rule fall within the "retail pharmacy class of trade."

Sections 447.504(g) and (h) of the proposed rule list categories of customers and transactions that should be included or excluded from the calculation. However, the list is incomplete. Clarification is needed as to the treatment of private physician offices, surgical centers, ambulatory care centers, prisons, and mental health centers. Unlike walk-in pharmacies, these providers generally provide drugs incident to providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home. We also note the proposed rule includes sales to "outpatient clinics" in AMP, but it is unclear if this reference is intended to capture pharmacies in physician clinics that dispense prescriptions (like hospital pharmacies) or drugs used by such clinics in the treatment of their patients. In addition, neither the list of included nor the list of excluded transactions references sales to home health care companies that deliver product to patients. Please clarify whether prices paid by home health care organizations for drugs delivered to home bound patients are included in AMP. Also, please explain how drugs distributed directly to patients fall within the definition of drugs distributed to the

retail pharmacy class of trade when patients do not resell or provide drugs to the general public

2. **Hospital Pharmacies**. Section 447.504(g) of the proposed rule includes sales to hospitals "where the drug is used in the outpatient pharmacy. Section 447.504(h) excludes sales to hospitals "where the drug is used in the inpatient setting." As a policy matter, we have no objection to including in the retail pharmacy class of trade walk-in pharmacies located in hospitals. However, as an administrative matter, compliance with this rule will be very difficult. Most hospitals currently buy for their inpatient and outpatient requirements from their regular wholesaler or distributor under agreements negotiated by group purchasing organizations. These agreements do not specify how the drugs will be used by the member hospital and chargeback data from wholesalers indicates only eligibility to purchase under the GPO contract. Although 340B hospitals maintain separate accounts for inpatient and outpatient use, and purchases under the 340B program are identified separately from purchases under a GPO agreement, there is no feasible way at present to determine how a drug is used by a regular non-340B hospital under a GPO agreement and thus whether it should be classified retail or non-retail. We suggest that manufacturers be permitted to assume hospital purchases are for their inpatient inventory and excluded from AMP unless sales to hospital pharmacies are identifiable.

It is also unclear whether the term "outpatient clinic" is intended to capture hospital surgical centers, ambulatory care centers and outpatient departments in which a patient is admitted to the hospital and released the same day. Even if a hospital has a separate pharmacy account, drugs purchased under a GPO agreement for use by the outpatient department in treating patients are typically included in inpatient inventory and cannot be identified at the point of sale as purchased for inpatient use or use by an outpatient department. Moreover, this distinction is an artificial one, as a drug provided to a patient of the hospital during an outpatient procedure is not provided to the general public any more than if provided during inpatient care. To avoid compliance problems and administrative burden, the final rule should make it clear that hospital purchases of drugs administered to their patients, whether on an inpatient or outpatient basis, should be treated the same.

3. **Veterinary Offices**: Sales to veterinary offices are not addressed in Section 447.504(g) of the proposed rule. Please clarify whether drugs approved for human use that are sold to veterinary offices for treatment of animals are considered sales to an entity that provides drugs to the general public, and thus fall within the definition of the retail pharmacy class of trade. In our view, veterinary offices are not licensed to provide drugs to people and thus could not provide them to the general public.

4. **HMOs, MCOs, PBMs:** Section 447.504(h) of the proposed rule excludes sales to health maintenance organizations (HMOs) including managed care organizations (MCOs), but defines neither. At the same time, Section 447.504(g) includes pharmacy

benefit managers (PBMs). In the pharmaceutical industry, an MCO is considered any organized health plan that provides a pharmacy benefit and manages the benefit cost through use of a prescription drug formulary. HMOs are a type of MCO. Some purchase and dispense drugs and provide mail order coverage, while others cover prescriptions filled by network pharmacies and mail order. MCOs use either captive or independent PBMs to manage the pharmacy benefit, including the negotiation of rebates that offset the prescription prices paid by the MCO. It is unclear whether the HMO/MCO exclusion from AMP applies only to purchases by MCOs that have their own facilities, or whether it excludes rebate transactions with health plans that reimburse network providers.

If rebates to HMOs/MCOs are to be excluded, it would be very difficult for a manufacturer to distinguish between a PBM transaction and a sale to an MCO, particularly when the PBM owns the mail order pharmacy filling the prescription purchased by the MCO. An independent PBM may include ERISA plans and other clients in addition to MCO clients, and the utilization data provided to manufacturers is not broken down by the type of entity. In addition, agreements with PBMs vary. Some agree to pass through rebates to their client plans and some do not, so that the amount of the rebate passed through to the plans depends on the arrangement between the PBM and its clients. In calculating monthly and quarterly AMP based on thousands of transactions, it is vital that companies be able to automate their systems. Automation requires bright lines and categorical treatment of transactions. Currently, companies treat PBMs and MCOs (other than staff model HMOs with their own facilities) as the same class of trade. A rule that would require monthly analysis of PBM agreements to assess their relationship with MCOs in order to determine whether a rebate is in or out of AMP, and then recode the transactions, would consume enormous resources and overly burden smaller manufacturers. It is imperative that manufacturers be able to comply with AMP in the least burdensome manner consistent with the availability of data and capabilities of drug price reporting systems. Accordingly, only transactions with clearly identifiable HMOs and health plans should be treated as excluded from AMP. Manufacturers must be able to treat rebates paid to PBMs that manage benefits for MCOs (as well as other clients) as "PBM rebates," whether or not passed through to MCOs.

5. Depot Prices (including Tricare) The proposed rule would exclude from AMP and best price depot prices to the federal government, including Tricare. The Tricare program purchases drugs through depot arrangements and also reimburses private sector retail pharmacies for prescriptions dispensed to Tricare beneficiaries. In its calculation of Non-Federal Average Manufacturer Price, the VA distinguishes between rebates paid on "depot" transactions, which it believes are mandated by statute, and which are currently not available to the Tricare program, and voluntary rebates paid on Tricare retail utilization which are not mandated by statute. The final rule needs to clarify whether this exclusion for depot prices applies both to mandatory rebates and voluntary rebates paid to DoD. If voluntary rebates paid to DoD are to be excluded, the

final rule must specify whether the units are to be left in the calculation, as with Medicaid rebates, or, if the units are to be excluded, the value at which the excluded units should be removed from the AMP calculation.

6. **Medicaid Purchases**. Section 447.504(g)(10) of the proposed rule would include rebates except rebates paid to Medicaid under section 1927 of the Social Security Act. Likewise, Section 447.504(g)(12) would include sales and associated rebates under Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade except rebates paid under section 1927 of the Act. The preamble to the proposed rule indicates this exclusion applies to supplemental rebates paid to the states as well. Please confirm and provide guidance as to whether this exclusion also applies when rebates are paid to Medicaid as a secondary payer under this title and the rebate agreement on outpatient prescription drugs covered by Medicare. Also, please explain what sales and associated rebates are paid under the Medicaid program other than those paid under section 1927 of the Act.

B. Restated Base Date AMP – §447.510

Section 447.510 of the proposed rule would require manufacturers to submit a Base Date AMP for the first full quarter following publication of the final rule. It would also permit manufacturers to submit a recalculated Base Date AMP. As proposed, however, the rule is inadequate. First, there is insufficient time to implement a recalculated Base Date AMP, particularly if manufacturers must use historical transactional data. Second, it must clearly account for statutory changes to AMP.

In their Medicaid rebate agreement, manufacturers agreed to pay the states a unit rebate amount on a covered drug comprised of a base rebate and an additional rebate penalty. The additional rebate is determined by the increase in current period AMP over the CPIU rate from the Base Date AMP. Prior to the DRA, Base Date AMP had to include Customary Prompt Pay (CPP) discounts routinely granted wholesalers, typically 2% of gross sales. The DRA specified that manufacturers must exclude CPP from AMP and report it separately. In discussions with industry prior to publication of the proposed rule, CMS acknowledged the need to provide an opportunity to adjust the Base Date AMP to reflect this and other statutory changes mandated by the DRA which could unfairly create the appearance of a price increase in excess of CPIU. In the product data reporting form sent to manufacturers and the instructions to industry, CMS provided a simple solution to the automatic – and artificial – increase created by the post-DRA exclusion of CPP from reported AMP: recalculate Base Date AMP to remove CPP and report a new DRA Base Date AMP that would be used to determine the additional rebate penalty after the DRA effective date. However, CMS subsequently reversed itself and prohibited manufacturers from reporting a restated Base Date AMP at this time.

The preamble to the proposed rule explains the intent is to allow manufacturers an opportunity to restate Base Date AMP so that the additional rebate penalty would not increase due to changes in the definition of AMP." However, the proposed rule appears to permit recalculation based on changes occurring only as a result of Section 447.504(e), the regulation defining the retail pharmacy class of trade. As written, it does not seem to permit manufacturers to restate the Base Date to account for all the changes to the definition of AMP, including the new requirement to exclude CPP and certain nominal prices. Changes resulting from reclassification of transactions as retail or non-retail may have no impact or may be impossible to apply to the baseline period, and in any event, do not adjust for the exclusion of CPP. Accordingly, a manufacturer must be able to restate the Base Date AMP, effective January 1, 2007, if it so chooses, to reflect statutory changes to the definition of AMP, whether or not it can recalculate transactions with customers based on changes to their categorization as retail or non-retail, in order to prevent wrongful application of the inflation penalty in the absence of an actual price increase. Moreover, manufacturers must have the discretion to calculate the adjustment for CPP based on the method used to include it (*e.g.*, 2% of direct sales). We urge CMS to permit recalculation of the Base Date AMP due to statutory changes in the definition of AMP under Section 447.504(a). Failure to permit such an adjustment followed by application of the inflation penalty could be considered a breach of the rebate agreement.

C. Smoothing Lagged Discounts and Indirect Sales

1. **Lagged Discounts**. In its final rule on the calculation of ASP, CMS required manufacturers to use a specified "smoothing" formula for reducing gross sales by discounts on non-exempt sales based on actual historic data where the discounts lagged behind the sale to which the discount applied.. CMS' formula applies a percentage of gross sales over the prior four quarters against current quarter sales net of exempt sales. Similarly, the VA has, since inception of its program under the Veterans Health Care Act, permitted use of a formula to smooth chargebacks in calculating the Non-Federal Average Manufacturer Price (NFAMP) in order to reduce volatility in quarterly pricing. Currently, AMP can fluctuate considerably quarter to quarter. As AMP is used prospectively to calculate ceiling prices under the 340B program, those prices can also be volatile, creating budgeting problems for entities purchasing under the program.

We believe smoothing lagged discounts is beneficial when an average price is used for pricing purposes, because it is not feasible to adjust the basis for payment retroactively when lagged discounts applicable to sales in the quarter become known. Thus, the final rule should provide that a manufacturer opting to use a smoothing methodology for lagged discounts should be accompanied by a rule that the manufacturer need not retroactively adjust quarterly prices. However, we believe manufacturers should have a choice in using a smoothing technique or an estimation method based on accruals and sales experience, particularly with respect to monthly

AMP. In addition, even if a manufacturer opts to use estimates in the calculation of monthly AMP, it is too burdensome to require prior period adjustments to those calculations. We support the proposed rule prohibition against restatement of monthly AMP. Finally, smoothing should not be required for the first partial year of sales for new products because the Base Date AMP can be skewed by non-recurring post-launch start-up payments.

2. **Lagged Indirect Exempt Sales**: The proposed rule would neither require nor permit manufacturers to smooth units of indirect sales known in a period after the initial sale, as did the rule for calculating ASP. In our view, application of a smoothing process to indirect exempt units may be beneficial when there are variations in the volume of rebates paid to exempt entities. However, under the proposed rule, prescription units that are reimbursed by Medicaid or state supplemental Medicaid units would not to be removed from AMP and rebates to all other state and federal plans, such as Medicare Part D, would be included in the calculation. Therefore, we see no need at this time to address this issue. In the event CMS changes the proposed treatment of these transactions, discretionary smoothing of the units and removal of a corresponding value from gross sales dollars might be appropriate.

II. Treatment of Specific Transactions

A. Administrative Fees and Service Fees – §§447.504(h)(11); 447.505(d)(12)

Unlike the "safe harbor" regulations of the Department of Health and Human Services, the proposed rule does not differentiate between administrative fees paid to entities, such as group purchasing organizations and pharmacy benefit managers, who are not themselves purchasers but use the combined buying power of their members or client plans to negotiate prices and administer contracts on their behalf, and fees for other services, such as distribution and inventory management. The proposed rule would exclude both types of fees from AMP and best price if they satisfy the criteria for itemized bona fide services performed on behalf of a manufacturer for fair market value not passed through to a customer or client of the recipient, regardless of whether it takes title to the drugs. We support this exclusion because such fees are necessary business expenditures related to the efficient distribution of drugs and are not price concessions, even if paid to a wholesaler or other entity that has taken title to the drugs. However, we urge CMS to allow categorical exclusion of administrative fees of 3% or less if they fall within the GPO administrative fee safe harbor, including its limitation on ownership of members. Such a categorical exclusion would be consistent with the purpose of the statutory exemption and safe harbor, which encourage group purchasing arrangements, and alleviate the necessity to evaluate each GPO agreement to determine if it is fair market value for bona fide services received by the manufacturer.

In the preamble to the proposed rule, CMS acknowledges that it is adopting the same definition of service fee included in the final rule for ASP (December 1, 2006, 71 Fed. Reg. 69623-70274). As with the ASP rule, the proposed rule does not specify uniform standards for determining fair market value or list bona fide service. We agree with this approach. However, guidance is needed in interpreting these terms, and, unlike the preamble to the ASP rule, the preamble to the proposed Medicaid rule does not provide the same guidance on application of the criteria in the definition of service fee. For example, we believe manufacturers must have the discretion to decide whether a particular service is one useful to or needed by the manufacturer. The ASP final rule provides that a service is bona fide if it encompasses any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs, and further clarifies that a service performed on behalf of a manufacturer includes both those the manufacturer has the capacity to perform and those that can only be performed through another entity. 71 Fed. Reg. 69668. With respect to the determination of fair market value, we believe manufacturers should have the discretion to decide whether the fee for a service is fair and reasonable in light of industry-accepted practices and other factors, even if expressed as a percentage of the purchase price, and that a fee should be able to cover multiple, itemized services. In finalizing the ASP final rule, CMS agreed. It stated that "bona fide service fees means expenses that generally would have been paid for by the manufacturer at the same rate had these services been performed by other or similarly situated entities," and that the appropriate method for determining FMV may depend on the contracting terms, such as the activities to be performed and the mechanism for establishing payment such as percentage of the purchase. 71 Fed. Reg. 69668-9. In addition, when warranted, FMV may be calculated as a single fee for a set of itemized services rather than FMV for each individual itemized service. 71 Fed. Reg. 69669. We also believe the treatment accorded a service fee should not depend on whether the company's books account for the fee as a reduction in cost of sales for financial reporting purposes. Again, for purposes of ASP. *Id.*

Finally, in the ASP rulemaking process, of particular concern to manufacturers was whether a payment of dividends or similar profit-sharing with members or other arrangements to which manufacturers are not privy would be considered a pass through of fees, if the fee was not intended to be passed on. We believe such fees should be excluded from all price calculations if there is no direct correlation between the fee paid and a distribution by the recipient. Moreover, manufacturers cannot ascertain whether a fee is passed on to a customer or client of the recipient. In response to such concerns, and in recognition that manufacturers may have no effective way of knowing whether a fee is passed on, the preamble to the ASP rule reasonably states that if a manufacturer has determined that a fee paid meets the other elements of the definition of bona fide service fee, it may presume the fee is not passed on to a client or customer in the absence of notice or evidence to the contrary. *Id.*

We urge CMS to include in the final Medicaid price reporting rule the same guidance provided in the preamble to the ASP final rule, or expressly incorporate that guidance by reference.

B. Authorized Generics – §447.506

The statutory provisions for treatment of sales of authorized generics are very confusing. In the proposed rule, CMS proposes 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. We support an interpretation that would permit the owner of the NDA to calculate a weighted average using the authorized seller's AMP and units (as CMS does with ASP) without having to obtain and combine all of the authorized seller's transactional data, because it would relieve some of the administrative burden of reporting a combined monthly AMP as well as reducing antitrust concerns in the case of unaffiliated licensees.

Likewise, the proposed rule would require the owner of the NDA to include in its best price the lowest price available from the authorized seller to any manufacturer, wholesaler, retailer, provider, etc., but does not require inclusion of the transaction transferring the drug to the authorized seller. We strongly support this interpretation as consistent with the statutory intent. It would mean the transaction included in best price would correspond with the transaction included in AMP – to the extent the sale was to an entity within the retail pharmacy class of trade. More importantly, it would not differentiate between sales of a drug by the owner of the NDA through a division, licensee, or reseller, and would be consistent with the treatment currently applied to sales by a co-promoter of the brand. Including the transfer transaction between the owner of the NDA and the authorized seller would be extremely difficult to administer because the labeler usually sources the drug through an interdivisional transfer, or, in the case of a licensee, by paying the manufacturing cost plus a royalty on the resale, not a purchase price.

The proposed rule does not address the situation in which the owner of the NDA does not sell the drug, but licenses the right to sell exclusively to another manufacturer that sells under its own NDC – often under a brand name. In our view, this situation is not contemplated by the statute and, as a practical matter, the owner of the NDA could not report a price as it has no NDC of its own. Indeed, because the owner of the NDA is not a source of the drug, the licensed drug would meet the definition of single source drug. Please confirm our interpretation is correct. The proposed rule also states that the authorized seller is to continue to report AMP and best price as it always has based on its own sales. However, in the event the licensee sells both a brand and generic version of the licensed innovator drug, clarification is needed as to whether the licensee, who is not the owner of the NDA, must combine the sales of its two NDCs in its own price reporting or continue to report separately as usual.

Last, clarification is needed that the AMP used as the benchmark for determining nominal price (for purposes of the AMP and best price exclusion) is the reported AMP, which means the combined AMP for the brand manufacturer.

C. Consumer Coupons – §§447.504(g)(11); 447.505(c)(12)

There is a fundamental flaw in CMS' proposal to include consumer coupons redeemed by a pharmacy in AMP and best price. Discounts to consumers off the prescription price charged by a pharmacy should not be included in the average price paid by [or received from] wholesalers for drugs distributed to the retail pharmacy class of trade, because such a discount is not an adjustment to the price paid by or received from the dispensing pharmacy or any other reseller of the drug. The benefit flows solely to the consumer. If a pharmacy is willing to accept a coupon as partial payment for the prescription, its expectation is to be made whole and receive the same retail price it would have without the coupon. While the consumer pays less for the prescription, the amount the pharmacy paid for the dispensed drugs is unaffected. The proposed rule's differing treatment based on whether the consumer redeems the coupon directly or through the pharmacy at the point of sale is an artificial one. In both situations, the consumer pays less than the price charged by the pharmacy and the manufacturer realizes less profit because of its partial payment of the consumer's prescription, but the pharmacy purchase price remains the same. The proposed rule does not indicate whether a payment made to a pharmacy on behalf of a consumer at the point of sale through a debit card provided by the manufacturer is a redemption by the consumer. However, it should not make any difference. Whether the consumer is paid directly by the manufacturer, or the manufacturer pays the pharmacy on behalf of the consumer, the beneficiary of the manufacturer's payment is the consumer not the retail pharmacy.

Paying the pharmacy a portion of a consumer's prescription through a debit card or reimbursing the pharmacy on behalf of the consumer in cash or replacement drugs should also not trigger a best price. First, a coupon represents a discount off the retail prescription price paid by a consumer, and, to the extent the undiscounted prescription price could be determined, the value of the coupon is only available to the consumer, which is not a wholesaler, retailer, provider or other "entity" within the statutory definition of best price. Second, the payment to the pharmacy on behalf of the consumer does not reduce the purchase price available from the manufacturer to the dispensing pharmacy or the wholesaler that sold the drug to the pharmacy. Third, as noted, there is no difference between a coupon redemption at the point of sale and a redemption by the consumer using proof of purchase, in terms of the price available to the pharmacy, the price available to the consumer, and the net amount realized by the manufacturer.

It is simply bad policy to include consumer coupons in best price, because it will result in consumers paying higher prescription prices. Coupons redeemed at the point of sale provide relief to uninsured consumers and help defray high co-pays for insured consumers. If reimbursing a pharmacy the value of a redeemed coupon must be

treated as a reduction in the price available to the pharmacy, manufacturers will be forced to either abandon the practice or to provide consumer discounts only through coupons redeemed directly by the consumer. Most coupons, however, are only redeemed if presented at the point of sale because of the length of time it takes to process the claim. More importantly, states are beginning to enact laws that require coupon redemption at the point of sale. Thus, if only manufacturer coupons redeemed directly by consumers are excluded from best price, consumers are unlikely to realize prescription cost savings available through coupons.

Finally, the proposed rule should clarify that coupons for free drugs, such as starter prescriptions, that are not contingent on the purchase of the same or any other drugs, should not be included in AMP or best price. These starter prescriptions (typically a week to a month supply) provide a real cost benefit to patients, just as samples do, particularly if the prescribing physician is unsure how the patient will respond to the therapy, and should not be discouraged.

D. Bundled Sales - §447.502

The proposed rule defines "bundled sale" but does not offer guidance on how manufacturers should apportion discounts in bundled sales arrangements other than to state that "the discounts must be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement." Additional guidance is needed on how to treat a discount where the criteria for earning it is based on utilization levels covering multiple products, since the current CMS guidance on how to apportion the discount in a reimbursement situation is not very clear. For example, if a prescription rebate is paid to a health plan on a drug for achieving a 25% share of the market in its therapeutic class and the market share is based on prescription utilization of that drug and/or a new formulation of that drug, there are no purchase prices involved. The concept of bundled sales does not seem to apply to market share arrangements. It would be very helpful if CMS made it clear the circumstances that necessitate allocation of discounts on market basket contracts and application to rebates for market share covering a family of products.

E. Returns – §§447.504(h)(13); 447.505(e)(1)

The proposed rule would exclude return credits from AMP but include them in best price. We support the exclusion of return credits from AMP because such credits are not discounts or price concessions but reversals of prior sales. Historically, returns have been excluded from Non-FAMP because they were known to cause aberrations creating artificially high or low average prices due to lack of correlation between the original price and return price. More recently, CMS has excluded returns from ASP based on the same concerns. Inclusion of returns in monthly AMP would also make it more difficult to generate a value that reflects the price actually paid in the quarter used to reimburse pharmacies.

On the other hand, we oppose the inclusion of return credits in best price because it is inconsistent with the treatment in AMP and the statutory definition in section 1927(c)(1)(C) of the Social Security Act, which does not include returns. As noted, return credits are not discounts that reduce the price available or the price paid for purchased goods but are refunds for returned goods. In addition, the original sale and return transactions do not share any common identifier, which makes it extremely difficult to reverse the original sale. Finally, regardless of whether the credit for a returned unit is exactly the same as the original sale price for the unit, it makes no sense to treat the return credit as a price concession on the prior sale because the unit was neither available nor sold at the return credit amount. Therefore, we urge CMS to define best price as it is defined in the statute and not to include returns.

III. Best Price and Other Pricing Data

A. Best Price – 447.505

The proposed rule adopts the definition of best price in Section 1927(c)(1)(C) of the Social Security 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.." The National Drug Rebate Agreement likewise defines best price as "the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United States in any pricing structure..." The proposed rule states that best price includes "all sales and associated discounts and other price concessions to any entity." To be consistent, the proposed rule must be interpreted to mean the associated discounts and price concessions are provided to the same entity to whom the drug was sold.

The statutory definition of best price has always been interpreted to mean the single lowest price to a particular customer unless the customer or transaction is exempt. However, language in the preamble to the proposed rule suggests that CMS views best price as the net amount realized by the manufacturer on a sale rather than the lowest price to a particular customer. It is critical that the final rule clarify that only discounts and price concessions to the same entity to which a drug is sold should be included in the computation of best price to that entity. A price available to one customer should not be deemed an adjustment to a price available to an entirely different customer. For example, a discount available to an indirect customer such as a hospital, is not available to the wholesaler that distributes to the hospital, and a prompt payment discount available to the wholesaler is not available to the indirect customer. Likewise, a rebate available to a health plan to reduce its prescription benefit payment to a pharmacy is not available to the pharmacy dispensing the prescription. In sum, prices to unrelated entities in the chain of distribution should not be aggregated in

determining the single lowest price to an entity, even if they concern the same unit of a drug.

In addition to being contrary to the clear language of the statute and rebate agreement, treating a managed care/PBM rebate as an adjustment to a pharmacy purchase is logistically impossible. PBMs do not identify the pharmacy that dispensed the prescription covered by the plan due to HIPAA constraints. Thus, a manufacturer cannot trace a prescription unit reimbursed by a plan back to a particular wholesale package sold to a wholesaler, retailer, or provider.

B. Reporting Issues

1. Monthly Reporting. We support the proposed rule decision to limit monthly reporting to AMP. There is no purpose to monthly best price or CPP and a requirement to report them would greatly increase manufacturers' compliance burden. With respect to product reports, must they be filed monthly? When a new product is launched, there may be no sales to report in the first month. However, the proposed rule suggests a product cannot be reimbursed without a product report. Finally, guidance is needed on monthly reporting of AMP when a product is discontinued.

2. Negative AMP or Zero Sales. The proposed rule does not address what manufacturers are to report when monthly AMP is zero or a negative number. In prior agency guidance, manufacturers were instructed to use last reported AMP and best price if there were no sales or if AMP was a negative value. Exclusion of returns helps prevent occurrences of negative AMP, but that is not the only variable. Please confirm this guidance is to be continued and applied to monthly AMP.

3. CPP and Nominal Price Reporting. The proposed rule specifies that customary prompt pay and nominal prices are to be reported quarterly as total aggregate dollars. However, it is unclear, in the case of authorized generics, whether the CPP paid on the generic version should be combined with the CPP on the sales of the brand, and whether sales of the generic version at nominal price should be included in the reported sales of the brand at nominal price. We do not believe combining the CPP dollars for the two NDCs serves any purpose, as no information can be gleaned from the figure. We also believe there would be no purpose in combining nominally priced sales.

Clarification is also needed as to how CPP is to be reported. The proposed rule indicates that manufacturers must submit their drug pricing data electronically via the CMS web site using specified formats. However, the quarterly report does not include a field for CPP.

4. Corrections. None of the drug data (price or product) reports have fields for corrections. Please provide guidance on how manufacturers are to indicate corrections.

C. Other Matters

1. **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..." A covered drug is approved under a new drug application if it follows the process specified in Section 505 of the Federal Food Drug and Cosmetic Act. Accordingly, biological products approved under section 351 of the Public Health Service should not be included in the definition of single source drug. The proposed rule improperly includes in the definition of "single source drug" biological products that are not single source drugs within the statutory definition.

2. **Effective Date of Final Rule**. Implementation of the proposed rule is going to present significant challenges for manufacturers and the final rule must provide sufficient time to comply with the requirements. Even though we are already in the process of reviewing and upgrading system capabilities and developing solutions to satisfy the new requirements, as CMS has publicly acknowledged, it would be a waste of resources to make changes to accommodate the proposed rule until the rule is final. We urge CMS to establish an effective date at least six months from publication of the final rule.

We hope the information provided in this letter is useful to you and that you will consider it in preparing your final rule.

Sincerely,

Donna Lee Yesner

On behalf of Allergan, Inc., Forest Laboratories, Inc. Otsuka America Pharmaceutical, Inc., and Reliant Pharmaceuticals, Inc.

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February 20, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicaid Program; Prescription Drugs

Dear Ms. Norwalk,

The Specialty Pharmacy Coalition appreciates this opportunity to provide public comments on the Proposed Rule CMS-2238-P, "Medicaid Program; Prescription Drugs; Notice of Proposed Rulemaking (hereafter referred to as NPRM) published in the *Federal Register* on December 22, 2006.

The Specialty Pharmacy Coalition is comprised of the three largest national, specialty pharmacies that provide prescription drugs and biologicals for the recurring treatment of chronic diseases and clinically appropriate related services to Medicaid and non-Medicaid patients. Our members include Caremark, Inc., CuraScript, and Accredo Health, Inc., which currently provide specialty pharmacy services in all 50 states. Specialty pharmacies provide in-home delivery of certain high-cost complex treatments that require special storage and/or handling, as well as additional clinically appropriate patient services in order to ensure fully effective drug therapy.

Specialty pharmacies provide services to specific patients who have been referred by their physician. Our member companies offer patients a wide range of clinically appropriate services integral to optimizing clinical outcomes and reducing unnecessary medical complications and expenses. The following company-specific descriptions provide additional detail regarding the operations of specialty pharmacies, a narrow and highly specialized segment of the health care delivery system.

Accredo Health, Inc., a wholly-owned subsidiary of Medco Health Solutions, is one of the largest providers of specialty retail pharmacy services in the United States. Headquartered in Memphis, Tennessee, Accredo specializes in the sale of high cost drugs for the recurring treatment of chronic and potentially life threatening diseases such as hemophilia, pulmonary arterial hypertension (PAH), respiratory syncytial virus (RSV), multiple sclerosis, growth hormone deficiency, Gaucher disease and other chronic diseases.

Caremark Specialty Pharmacy Services is a leading provider of specialty medicines and biopharmaceuticals, primarily injectibles, to individuals with chronic or genetic conditions throughout the United States. There are 20 Caremark Specialty Pharmacies in 18 states, all dedicated to helping individuals by providing services for various diseases, including but not limited to, asthma, Gaucher's Disease, hemophilia and related bleeding disorders, immune disorders, multiple sclerosis, pulmonary disease, and rheumatoid arthritis. Caremark Specialty Pharmacy Services selects a personalized, pharmacist-led Care Team for each patients, which proactively reviews dosing and medication schedules, troubleshoots injection-related issues, discusses side effect management, and reinforces physician instructions to ensure that the individual's prescribed medication is administered appropriately.

CuraScript, Inc. is a wholly owned subsidiary of Express Scripts that provides managed care clients, employers, government agencies and others with specialty medications and effective specialty medication management. The company, which operates specialty pharmacies around the country, also operates nearly two dozen pharmacies dedicated to patients requiring infusion therapy. CuraScript's hallmark is its high-touch specialty care management programs ensuring that patients maximize their therapy and improve overall compliance, while offering the support patients need to manage their conditions.

The Coalition and its members welcome this opportunity to provide input on the NPRM. Our comments address two aspects of CMS' NPRM: first, the definition of the "retail pharmacy class of trade" and secondly, the definition of the term "dispensing fee." Our comments provide specific information regarding the impact of these two key definitions on the specialty pharmacy segment. Currently, CMS' NPRM does not take into consideration the unique characteristics of the specialty pharmacy environment. Our recommendations are designed to ensure continued patient access to certain highly complex therapies in a clinically appropriate setting.

Background

In the Deficit Reduction Act of 2005 (DRA), Congress fundamentally changed the underlying purpose of why a manufacturer reports an Average Manufacturer Price (AMP) for its drugs to the Secretary of Health and Human Services. The AMP was originally intended to serve as a confidential benchmark for calculating Medicaid drug rebates. The DRA instructs CMS to use AMP as a Medicaid pharmacy reimbursement benchmark for calculating Medicaid federal upper payment limits (FUL) for multiple source drugs. Furthermore, the DRA requires that AMP calculations for all drugs be provided to states and the general public via a publicly accessible website.

Single source drugs are not subject to the Medicaid FUL. However, the DRA does not specifically limit states from adopting AMP-based reimbursement for single source drugs. In the regulatory impact section of the NPRM, CMS acknowledges the possibility of "decreases to State payments for drugs not on the FUL list that may result if States change their payment methodologies."

The Coalition applauds Congress for including in § 6001(c)(3) of the DRA language requiring that the Secretary of Health and Human Services "promulgate a regulation that clarifies the requirements for, and manner in which, average manufacturer prices are determined." The HHS Office of the Inspector General has concluded in several reports that AMPs as currently calculated are flawed.[1] In a report mandated by the DRA, OIG recently concluded "Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent." OIG further concludes that "future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors."[2]

In the preamble section of the NPRM, CMS states "we believe the Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices to the retail pharmacy class of trade." The Coalition concurs with this statement. In order for the AMP calculation to be an appropriate reimbursement benchmark based on actual prices at which retail pharmacies purchase drugs, the term "retail pharmacy" must be clearly defined and drug manufacturers must be given clear and consistent instructions on the types of sales that are included and excluded from the AMP calculation.

Overview of Specialty Pharmacy Coalition Comments

The Specialty Pharmacy Coalition recommends that CMS modify its definition of the "retail pharmacy class of trade" to specifically exclude from the definition sales of drugs and biologicals to specialty pharmacies. Manufacturers should also be instructed to exclude from their AMP calculations all sales to entities that do not meet the definition of "retail pharmacy." The coalition bases these recommendations on the fact that specialty pharmacies are unique entities whose operations differ significantly from those of retail pharmacies. Specialty pharmacies provide high cost drugs as well as patient-specific, clinically appropriate services integral to the treatment of patients with complex chronic, terminal, and/or rare conditions. The types of drugs dispensed by specialty pharmacies, most of which require special storage, handling and preparation, are not stocked and dispensed by retail pharmacies. Similarly, the necessary clinical services cannot be provided by retail pharmacies. The exclusion of specialty pharmacy from the definition of the retail pharmacy class of trade for purposes of establishing the Medicaid AMP calculations is consistent with the definition of retail pharmacy in the Part D Medicare program, which encompasses not only the population served but also the services provided by the entity. CMS, in its preamble, specifically referenced the parallels of Part D to Medicaid. Ensuring consistency between Medicare Part D and the Medicaid program is a valuable public policy consideration.

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[1] See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102, February 2005, p. 12-15. The GAO report summarizes a series of confidential OIG reports on AMP and the Medicaid rebate program.

[2] OIG, *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act,* A-06-06-00063, May 2006, p. 4.

Secondly, the Coalition recommends that CMS instruct states to provide appropriate reimbursement for the broad array of clinical services provided by specialty pharmacies. Because such services are not provided in the retail pharmacy setting, there are no examples of this reimbursement as related to the retail pharmacy class of trade. The patients served by the specialty pharmacy segment of the health care system rely upon these services to help ensure the effectiveness of their treatment regimen. Specialty pharmaceuticals, and the services provided by specialty pharmacies, ultimately help reduce costs to the Medicaid program and should be specifically addressed and appropriately reimbursed.

Determination of Average Manufacturer Price—Section 447.504

Definition of Retail Pharmacy Class of Trade and Determination of AMP

Proposed § 447.504 of the NPRM instructs drug manufacturers to calculate AMP as "the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade." § 447.504(e) defines the "retail pharmacy class of trade" as any:

> independent pharmacy, chain pharmacy, mail order pharmacy, 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.

In the preamble of the NPRM, the agency further states that the "retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services." CMS also excludes from the AMP calculation manufacturer sales to nursing home and long term care pharmacies.

The Coalition is concerned that neither the instructions on the calculation of AMP in § 447.504 nor the definition of the "retail pharmacy class of trade" in § 447.504(e) specifically address the treatment of manufacturer sales to specialty pharmacies. The Coalition recommends that CMS clarify that specialty pharmacies are excluded from the "retail pharmacy class of trade" and that manufacturers should be instructed to exclude from their AMP calculations sales to entities that do not meet the definition of the "retail pharmacy class of trade."

Specialty pharmacies provide in-home delivery of a limited number of primarily single-source injectible and infused drugs and biologicals that typically require special storage and/or handling and clinically appropriate services, and are not typically sold at retail pharmacies. Our products and clinically appropriate services are provided to chronically ill patients that are referred by their physician due to the unique type of drugs prescribed and the services necessary for their treatment. The patients we serve have complex chronic, terminal, and/or rare conditions and represent a very small percentage of the population. These chronically ill patients and their caregivers often require training in the administration of their medications, sophisticated coordination of a range of services and

supplies, patient specific dosing, assistance with side effects, ongoing compliance and safety monitoring by specially trained health professionals, and other clinically appropriate services. With the proper care, specialty pharmacy patients can avoid serious complications related to the disease or the specialty drug therapy, and reduce the need for emergency room visits, doctor visits, hospital admissions, and other medical expenses. As a result, these patients—with the proper medication and care—can lead healthier and happier lives.

These clinically appropriate services are not provided in the retail setting. Specialty pharmacies interface with their patients primarily via telephone and through in-home consultations with nurses and pharmacists employed or contracted by specialty pharmacies. We are not a traditional "walk-in" retail pharmacy. To further illustrate the differences in the breadth and type of clinically appropriate services performed in the retail and specialty pharmacy settings, we would like to provide the following comparison chart. The list on the following page is based on the services offered by our members and the typical services provided at retail pharmacy as listed in the definition of "dispensing fee" in § 447.502 of the NRPM.

Specialty Pharmacy Services	Retail Pharmacy Services
• Checking the computer for information about an individual's coverage • Performing drug utilization review and preferred drug list review activities • Patient specific dosing • Measurement or mixing a covered outpatient drug • Extensive beneficiary counseling and patient and caregiver education for safe and cost-effective use • Storage, handling, and shipping, of drugs with unique and sensitive requirements, including temperature monitoring. • Emergency telephone support 24 hours a day, seven days a week by nurses and pharmacists trained in specific chronic diseases. • Nursing and social work support services such as education, patient monitoring, psychological support, and community resourcing. • Adherence monitoring and education to ensure patients take their medications consistently, in the right amount and dosage, and for the full length of treatment. • Clinical management of disease-specific programs tailored to the unique needs of those with complex chronic	• Checking the computer for information about an individual's coverage • Performing drug utilization review and preferred drug list review activities • Measurement or mixing a covered outpatient drug • Beneficiary counseling • Physically providing or delivering the completed prescription to the individual

illnesses. • Coordination of home nursing services that ensure that patients receive support for ongoing home infusion and self-injection in a cost-effective manner. • Monitor and supervise the utilization of specialty drugs to minimize wastage, ensure the medical necessity of ongoing treatment, and enhance clinical outcomes. • Managing the side effects of chronically ill patients, many of whom are prescribed injectible biologic products and oral cancer drugs with significant side effects.	

This chart clearly demonstrates that specialty pharmacies provide a breadth of clinical services not available in the retail setting. Furthermore, these services are provided only to patients referred by their physicians to specialty pharmacies for treatment.

The Coalition is also concerned that the proposed definition of the "retail pharmacy class of trade conflicts" with the definition of "retail pharmacy" under Medicare Part D. Under 42 C.F.R. § 423.100 of the Medicare Part D prescription drug program regulations, CMS defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy." 42 C.F.R. § 423.120 further clarifies that long-term care pharmacies are not "retail" pharmacies and requires a Part D plan to separately contract with such pharmacies and assure convenient access. The same section also states that "home infusion pharmacies" are not "retail" pharmacies, and are excluded from the definition of "retail" pharmacies due to the "ongoing clinical monitoring, care coordination and home infusion nursing that is provided by staff of or affiliated with the home infusion therapy provider." The operations of specialty pharmacies are very similar to home infusion pharmacies; in fact, our members provide home infusion therapies in addition to other treatment regimens.

A definition of "retail pharmacy" that excludes specialty pharmacy and other entities identified above as outside the retail class of trade is consistent with the Part D definition, and will result in an AMP calculation that more accurately reflects the prices at which retail pharmacies acquire prescription drugs than that proposed in the NPRM The definition of "retail pharmacy" in the NPRM defines retail pharmacy solely based on whether the pharmacy "sells or provides the drugs to the general public." The Part D definition encompasses both the population served and the services provided. The Coalition is also concerned that inconsistent policies in Medicaid and Medicare Part D will lead to confusion and burdensome administrative and recordkeeping requirements for drug manufacturers, health plans, wholesalers, and pharmacies.

Definitions—§ 447.502

Dispensing Fee

§ 447.502 of the NPRM defines the term "dispensing fee" as a fee which: 1) "is incurred at the point of sale and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;" 2) "includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient;" and 3) "does not include administrative costs incurred by the state in the operation of the covered outpatient drug benefit including system costs for interfacing with pharmacies."

§ 447.502 of the NPRM also includes a list of covered retail pharmacy services which CMS proposes to include in the definition of "dispensing fee." This list includes:

> a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy.

This proposed list is an appropriate description of the services performed by retail pharmacies. However, as we have demonstrated above, specialty pharmacies do not meet the proposed definition of the "retail pharmacy class of trade" in § 447.504(e) of the NPRM. Thus, the list of covered activities included in the proposed definition of "dispensing fee" in § 447.502 does not reflect the clinically appropriate services provided by specialty pharmacies that are not available in retail pharmacies.

As states begin to more closely align pharmacy reimbursement with acquisition costs for multiple source and potentially single source drugs, CMS should instruct states to establish appropriate reimbursement for specialty pharmacies that reflects the costs of the unique clinically appropriate services our members provide to chronically ill patients with complex chronic, terminal, and/or rare conditions. The broad array of clinically appropriate services provided by specialty pharmacies for these clinically complex conditions are separate and distinct from those covered under the definition of "dispensing fee" defined by CMS for the retail class of trade. These clinical services reduce overall costs to the Medicaid program and should be specifically addressed and appropriately reimbursed.

We recommend that CMS consider the following two options for the appropriate reimbursement of clinically appropriate services provided by specialty pharmacies. First, CMS should provide guidance to states on the development of a specific "add-on" fee that takes into consideration the clinical services provided by specialty pharmacies to ensure the safety and effectiveness of patient treatment. CMS has recognized the need for this type of payment structure most recently through the development of a Medicare Part B per unit administration fee for blood clotting factor as mandated in the MMA. The Coalition recognizes that an "add-on" fee for clinically appropriate specialty pharmacy services is not directly addressed in the DRA; however, in order to ensure the continued

provision of these necessary services, such "add-on" fees are fundamental. Secondly, CMS could provide guidance to states regarding the importance of dispensing fees specific to specialty pharmacies to compensate for the clinically necessary services required for therapy safety and efficacy. The Coalition believes that these additional dispensing fees could address many of the concerns raised in special handling, clinical monitoring, and management of these fragile patients.

We look forward to engaging CMS and the states in this effort to ensure that chronically ill Medicaid beneficiaries continue to have access to the clinically appropriate services provided by specialty pharmacies.

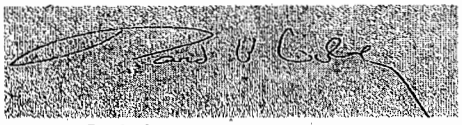
Conclusion

In conclusion, we share the agency's commitment to implementing Congress's intent that AMP calculations reflect actual sales to retail pharmacies. In order to reflect congressional intent, we recommend that CMS modify its definition of the "retail pharmacy class of trade" to specifically exclude from the definition sales of drugs and biologicals to specialty pharmacy. Secondly, we urge CMS to instruct manufacturers to exclude from the AMP calculation sales to entities that do not meet the definition of "retail pharmacy." Lastly, the Coalition recommends that CMS instruct states to provide appropriate reimbursement for the broad array of clinically appropriate services provided by specialty pharmacies.

On behalf of the Specialty Pharmacy Coalition and its members, we thank the agency for this opportunity to provide our comments on Proposed Rule CMS-2238-P. We welcome any questions you may have about the unique characteristics of the specialty pharmacy class of trade. Furthermore, the Coalition and its members look forward to working with the agency in the future to ensure the best possible care for chronically ill Medicaid beneficiaries.

Sincerely,

Michael Hess
Chief Legal Counsel
Accredo Health, Inc.



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CMS-2238-P;
Comments to the Medicaid Program
Prescription Drugs Proposed Rule

Dear Sir or Madam

On behalf of Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer Ingelheim" or "the Company"), we are pleased to submit these comments on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Regulation ("Proposed Regulation") implementing provisions of the Deficit Reduction Act of 2005 ("DRA"). The Proposed Regulation would modify how "Average Manufacturer Price" ("AMP") is calculated and implement other changes related to Medicaid Rebate policies.

Boehringer Ingelheim is one of the world's 20 leading pharmaceutical companies, with a broad spectrum of therapeutic products including both branded and multisource products. As a result, it will be directly affected by the changes in AMP and other policies being proposed by CMS.

Boehringer Ingelheim has had an opportunity to review other comments being submitted by the various industry trade associations representing manufacturers of branded and multisource products, and in general, we support the points being made there about the need for greater clarity in the Proposed Regulation. However, the Company has two significant points that it wishes to emphasize and therefore, we are taking this opportunity to discuss those points here.

Boehringer Ingelheim

A. Uniformity between 340B and the Medicaid Programs.

As with other pharmaceutical companies, Boehringer Ingelheim participates in various federal programs that affect reimbursement of its products. Under the Medicaid Program, Boehringer Ingelheim pays rebates to the states that are calculated, in large part, based on the drug's Average Manufacturer Price or AMP. Similarly, the Company also participates in the federal government's 340B Program, which requires manufacturers to charge at or below certain defined prices (usually referred to as the 340B ceiling price) to qualified entities, including community health centers, public hospitals, and various Federal grantees. Like the Medicaid Program, the 340B ceiling price also is based, in major part, on AMP. However, while the DRA changed the definition of AMP for the Medicaid Program in order to exclude from AMP prompt payment discounts, the AMP used in the 340B *includes* the prompt pay discounts. This inconsistency requires manufacturers to maintain two separate sets of calculations, increases the costs and burdens of compliance, and will significantly increase the risk of error.

In order to understand how this situation arose, it is helpful to review the history of the AMP calculation. Prior to the passage of the DRA, in 2005, AMP was defined in statute as being based on prices paid to manufacturers by wholesalers for drugs distributed to the retail class of trade, "after deducting customary prompt pay discounts." However, when Congress revised the definition in the DRA, it required that AMP be calculated, without regard to prompt pay discounts (i.e., prompt pay discounts are no longer deducted from AMP.) In its January 30, 2007 letter to pharmaceutical manufacturers, the Office of Pharmacy Affairs ("OPA"), which is part of HHS' Health Resources and Services Administration ("HRSA"), clarified the definition of AMP to be used in 340B ceiling price calculations. The OPA states:

> Although the Deficit Reduction Act amended the statutory definition of Average Manufacturers Price for purposes of Medicaid by removing the deduction for customary prompt payment discounts, Section 340B(c) of the Public Health Service Act states, "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section." Accordingly, manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts.[1]

Thus, while AMP is used in both the 340B and Medicaid programs, the calculation for each program will differ, at least in relation to the treatment of customary prompt pay discounts.

Clearly, calculating the same reference price in two different ways seems illogical, burdensome, and likely to result in errors. As noted above, both 340B ceiling prices and Medicaid rebates are based on the same reference price—"average manufacturer price." In fact, the 340B ceiling price is basically the AMP minus the amount of the rebate paid on a single unit of the

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[1] Jimmy Mitchell, Director of OPA, "Dear Pharmaceutical Manufacturer Letter Clarifying the Definition of Average Manufacturer Price" (January 30, 2007), *available at* http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm.

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product. The OPA policy will require that manufacturers maintain two separate sets of calculations for their AMP, one including prompt pay discounts, and one excluding them. To have to maintain separate calculations for all such products will increase the time and expense of participating in the 340B and Medicaid programs, and will almost certainly result in errors, as manufacturers try to keep track of two separate sets of prices for each of their numerous products. Moreover, the OPA has given no guidance on how to handle other issues that will now defined by the Proposed Regulation. For example, the Proposed Regulation clarifies how numerous other issues are to be treated for AMP under Medicaid, such as SPAPs, administrative and bona fide service fees, authorized generics and bundled sales, just to name a few. OPA has given no guidance, however, concerning whether or not these areas should be treated the same under the 340B program, or whether, as with prompt pay discounts, they are subject to different treatment. Obviously, the calculation will become even more difficult, if there are numerous differences in how these various items are treated.

Boehringer Ingelheim recognizes that OPA is not directly responsible for the issuance of the Proposed Regulation, and thus, the issues raised here may not seem germane to these comments. Nonetheless, these comments represent the best opportunity to raise this troubling issue and, we hope, to obtain an expeditious resolution. Moreover, OPA has stated that it welcomes comments on how best to implement the 340B program in light of the recent DRA changes; thus, it is important to raise the question here, in the hope that CMS and OPA can define terms consistently, to the extent possible. We believe there are other ways to resolve this issue that would reduce the burden on all parties, while still giving OPA access to the information that it needs for the 340B program. Therefore, we are requesting the opportunity to meet with CMS and OPA to discuss possible solutions that could be implemented to achieve those goals.

Further, as CMS and OPA (and its parent HRSA) are components of the Department of Health and Human Services, we believe it is vital that all of the affected entities work with the Secretary's office to resolve what is clearly an illogical situation. If necessary, the agency should seek assistance from Congress to make the definitions of these two terms consistent. In that way, at least manufacturers would be spared having to recalculate the same basic information in two different ways.

B. CMS should permit "smoothing" over a 12-month period

In the Preamble to the Proposed Rule, CMS also requests comments on how to adjust for rebates or other price concessions that will not be ascertainable until after the end of the month. As CMS itself notes, "if the monthly AMP were calculated simply using sales in that month, these pricing practices might result in fluctuations between AMP for the first two months and the AMP for the third month in the calendar quarter."[2] CMS therefore states that it will permit end of quarter rebates and other price concessions to be allocated to the monthly AMPs reported. However, it also

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[2] 71 Fed. Reg. at 77186

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However, it also asks for comments on whether it should allow a 12 month rolling average estimate of all lagged discounts for both monthly and quarterly AMPs.

Boehringer Ingelheim appreciates CMS' request for comments on this area. We recognize that CMS is attempting to keep the information reported as accurate as possible, while minimizing fluctuations that will affect its reliability. However, because of the nature of many types of price concessions commonly used in the pharmaceutical industry, such as chargebacks and rebates, there must be a mechanism in place to adjust the AMP to reflect changes in a prior month's sales. Moreover, all of these adjustments will not occur within a single quarter. Thus, a rebate or chargeback may often apply to a sale that took place not in the current quarter, but rather to one that occurred in the previous quarter or one even further removed. Thus, Boehringer Ingelheim does not believe it is sufficient simply to revise monthly AMPs based on the expected lagged discounts during that quarter. It is preferable to calculate a percentage that reflects a 12 month rolling average, just as is done in the case of the ASP. [3] That allows for a more accurate reporting of lagged price concessions, and ensures that discounts paid in one quarter are properly captured, even if they relate to sales that occurred one or even two quarters earlier. As a result, we urge CMS to utilize a 12 month rolling average, comparable to that used for ASP.

We appreciate the opportunity to comment on these significant and far reaching proposals. If you have any questions or need any further information, please do not hesitate to contact us.

Sincerely yours,

Christine G. Marsh

Christine G. Marsh
Executive Director, Contracts and Pricing

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[3] *See* 42 C.F.R. §414.804.

FOOD MARKETING INSTITUTE

Your Neighborhood Supermarkets

February 20, 2007

Via Courier

Leslie Norwalk, Esq.
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Rec'd FEB 20 2007

RE: Proposed Rule To Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program; (Docket No. CMS--2238--P)

Dear Administrator Norwalk:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). FMI is highly concerned about the impact of the proposed rule on its supermarket pharmacy members. As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Understanding the difficulties that the agency faces in reconciling these conflicting roles for AMP, we believe that several of the decisions CMS has proposed would unduly reduce AMP. Our comments and recommendations are discussed more fully below and in the attached Appendix A, which translates our comments into regulatory language for your consideration.

FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies - food retailers and wholesalers - in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion - three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

FMI's retail members also operate more than 10,000 in-store pharmacy departments. We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward

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larger store formats and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

A. Executive Summary

FMI urges CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Recent studies suggest that Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.[1] While FMI is not certain that this situation can be fully addressed in regulations, we believe that CMS should take the following steps to mitigate this problem:

- Restrict the scope of discounts included in the "retail class of trade" to reflect only those prices that are provided to wholesalers for drugs distributed to retail pharmacies;
- Define "wholesaler" in a manner that better reflects current law and practice;
- Remove from the proposed rule's definition of AMP sales to PBMs, outpatient hospitals, clinics and mail-order pharmacies that fall clearly outside of the statutory definition of AMP;
- Remove from AMP those prices that Congress excluded from "best price" to allow for deep discounts that could otherwise artificially deflate AMP;
- Set FULs based on the average AMP of various therapeutic alternatives, rather than the lowest cost alternative;
- Exercise discretion to delay publication of AMP information to ensure that the consequences of publishing this information are fully understood;
- Reduce the potential for volatility in the AMP-based reimbursement system by removing a larger number of outliers when establishing FULs;
- Base FULs on the AMPs of those products that are nationally available and in sufficient supply to meet the needs of pharmacies over time;
- Revise the regulatory definition of "dispensing fee" to ensure that all pharmacy costs are identified; and
- Require states to update their Medicaid dispensing fees to be sure that these fees are adequate in light of newly implemented DRA policies, particularly to ensure appropriate utilization of generic drugs.

The remainder of this letter provides more details on each of these issues as well as proposed regulatory language in Appendix A.

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[1] Government Accountability Office "Medicaid Outpatient Prescription Drugs: Estimated 2007 Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs", Letter to Rep. Joe Barton (R-TX) (December 22, 2006).

B. Policy Context

Supermarket pharmacy profit margins are generally only a very small percent of total revenue, far lower than most other businesses. In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. FMI and its members are particularly concerned about the impact of the DRA's FUL policies on retail pharmacies. According to the GAO's comparison of AMP-based FULs to pharmacy acquisition costs, AMP-based FULs were 36% lower than average pharmacy acquisition costs when calculated using information from the first quarter of 2006. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our members may find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts at the state level that are far below the costs our members incur to dispense prescription drugs to Medicaid patients.

FMI is aware that the use of AMP in setting FULs is dictated by the DRA, and of the difficulty facing the agency in balancing between the use of AMP for reimbursement and its use in the calculation of manufacturer rebates to the Medicaid program. Along with others in the pharmacy community, FMI is involved in efforts to address this problem legislatively. However, as we discuss in the balance of this letter, we believe that CMS has significant discretion to mitigate the severity of the problem, discretion that the agency has not fully exercised. We urge CMS to emphasize the role of AMP as a reimbursement benchmark in the final rule to ensure that our member pharmacies can continue to serve Medicaid patients.

C. Analysis of Issues

1. Revise Proposed AMP Definition To Exclude Sales to Mail Order and PBMs That Are Outside the Statutory Definition of AMP.

While FMI recognizes the difficulties that the DRA has imposed on CMS by requiring AMP to be used for a very distinct new purpose, we believe that CMS errs in the proposed rule by defining AMP as encompassing a variety of sales that are outside of the statutory definition of AMP. The statute is clear: AMP is 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.*[2] In contrast, CMS proposes to include price structures that are beyond the statutory definition either because they do not reflect prices paid by true wholesalers or because they do not reflect discounts and concessions that are ultimately realized by the retail class of trade. Accordingly, and as explained more fully below, CMS has proposed a regulatory definition for AMP that is neither adequately supported by the statute nor an effective benchmark for pharmacy reimbursement.[3]

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[2] §1927(k)(1) of the Social Security Act (42 U.S.C. 1396r-8(k)(1).

[3] As noted, FMI does not believe that AMP – even as defined by the statute – can be an effective benchmark for pharmacy reimbursement under the Medicaid program. Nonetheless, given the enactment of the

a. Exclude Discounts Given to PBMs and Mail Order Pharmacies Because These Businesses are Outside the Retail Class of Trade.

FMI's primary concerns with the proposed definition of AMP are the overly broad view of retail class of trade and the definition of wholesaler. Section 1927(k)(1) of the Social Security Act defines AMP in relevant part 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.*" We believe that this definition in fact counsels that AMP "should only reflect prices of sales to those pharmacies which dispense drugs to the general public", an option that CMS chose to reject as inconsistent with "past policy."[4] We would note, however, that the "past policy" to which CMS refers was implemented at a time when AMP was not being used for pharmacy reimbursement purposes, but only for the purpose of calculating rebates owed by manufacturers to CMS and the states. Accordingly, CMS is not bound by its past policy, nor should the agency feel constrained to operate within it. Rather, given the new task imposed on CMS by the DRA, CMS should establish a new policy reflective of the multiple purposes that AMP must now serve.

Indeed, reading the statutory definition of AMP in light of its new use as a reimbursement benchmark counsels for excluding sales to PBMs, mail-order pharmacies and other entities that are outside the retail class of trade. The inclusion of PBM discounts and mail order prices that are clearly not accessible to retail pharmacies artificially deflates AMP, potentially impeding the convenient access of Medicaid beneficiaries to supermarket pharmacies if these retail outlets cannot receive adequate reimbursement for their pharmaceutical acquisition costs for generic drugs.

In addition, it is our understanding that some manufacturers consider both mail order pharmacies and PBMs to be separate and distinct from the retail class of trade. Indeed, it is difficult to describe PBMs as falling within the retail class of trade, as their pharmacy benefit management functions are not directly involved in the supply chain for pharmaceuticals. Only in their role as mail order pharmacies do PBMs typically participate directly in the purchase and delivery of prescription drugs, an activity which is also outside the retail class of trade. Mail order pharmacies take title and deliver products to patients but are a separate and distinct option for consumers in contrast to the supermarket and community pharmacies that are typically considered "retail". Indeed, in its rule implementing the Medicare Modernization Act, CMS explicitly excludes mail order pharmacies from its definition of "retail pharmacy."[5]

DRA, we recognize that Congress has made a determination in this regard, and CMS is obligated to implement that legislative decision.

4 71 Fed. Reg. at 77178.

5 70 Fed. Reg. 4493, 4535 (January 28, 2005).

b. Discounts Given to PBMs and Mail Order Pharmacies – Entities Typically Outside of the Wholesaler Distribution System – Cannot Be Included in AMP

Not only does the statute limit the data to be used to calculate AMP to prices paid for drugs distributed within the retail class of trade, the statute expressly defines AMP as the price *paid by wholesalers*. Therefore, although discounts to PBMs and mail order pharmacies may affect the "net price realized by manufacturers," as asserted by CMS, the statute requires the use of wholesaler pricing in the determination of AMP. Indeed, many of the sales to PBMs and mail order do not flow through wholesalers at all, so the discounts received by PBMs and mail order generally do not affect the price paid by "wholesalers," as this term is typically defined.

Specifically, CMS proposes to define "wholesaler," as follows:

> Any entity (including a pharmacy, chain of pharmacies or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drugs.

Proposed 42 CFR 477.504(f). The proposed regulatory definition, which includes retail outlets, overreaches common and statutory wholesaler definitions resulting in a situation that is contrary to state licensing practices and conflicts with related federal statutes.

First, treating pharmacies as wholesalers is inappropriate and could unduly burden FMI's members with new licensing requirements at the state level. Supermarket pharmacies are licensed as pharmacies – not wholesalers, to which different licensing and regulatory requirements apply. Accordingly, supermarket pharmacies are not properly considered wholesalers.

Moreover, the distribution functions typically performed by wholesalers are far different from the administrative functions performed by PBMs. Section 510(g) of the Federal Food, Drug, and Cosmetic Act defines "wholesale distributor" as an entity "who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user."[6] As discussed, PBMs generally do not take title to prescription drugs except in limited instances, and then generally because they are operating as mail order pharmacies and not in their traditional functions as PBMs. Therefore, CMS should not include PBMs within the regulatory "wholesaler" definition either.

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6 21 U.S.C. 360.

c. AMP Should Not Include Discounts that Fall Outside the Medicaid Program

Many of the discounts that CMS seeks to include within the definition of AMP are given by manufacturers to entities that are able to increase the market share of particular products through therapeutic switching and other mechanisms. Under the Medicaid program, which prohibits formularies and a variety of other cost containment tools, pharmacies cannot engage in these practices and are, therefore, ineligible for many of the discounts predicated on these practices. Consequently, it is inappropriate to apply these discounts to AMP when it will be used as a Medicaid pharmaceutical reimbursement benchmark.

For these reasons, FMI believes that CMS has erred in its proposed definition of AMP. We urge CMS to promulgate a final regulatory definition of AMP consistent with the recommendations in Appendix A of our comments that omits pricing given to PBMs and mail order pharmacies from the definition and, therefore, will better reflect the retail class of trade and wholesaler elements of the statutory definition.

2. Revise Proposed AMP Definition To Exclude Sales Excluded from Medicaid's "Best Price"

CMS proposes to include within the definition of AMP certain sales, notably sales to Part D plans and State Pharmacy Assistance Program (S-PAPs), that are excluded from Medicaid's "best price". These sales are excluded from "best price" to provide deeper discounts to S-PAPs and Part D plans. Indeed, the Congressional Budget Office specifically scored the exemption from "best price" for sales to Part D plans as producing savings because it "gives those plans more leeway to negotiate steeper price discounts from manufacturers since those manufacturers will not have to pass on the same discount to Medicaid."[7]

The "best price" exclusion reflects the policy judgment of Congress that deeper discounts should be available for particular classes of sales than are typically available to the retail marketplace. The exclusion has been available for many years for various government sales and was extended to prescription drug plans under Medicare Part D in the Medicare Modernization Act.

In contrast to S-PAPs and Part D plans, sales to retail pharmacists are not exempt from best price, and pharmacists are unlikely to receive the level of discounts available to those entities. Thus, including sales that are exempt from "best price" in AMP will artificially lower AMP as a reimbursement benchmark by including discounts in AMP to which

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7 "A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit." (July 2004). http://www.cbo.gov/ftpdocs/56xx/doc5668/07-21-Medicare.pdf

pharmacists do not have access. FMI therefore urges CMS to exclude from the definition of AMP those sales that are exempt from "best price" under §1927(c)(1)(C)(i) of the Social Security Act.

3. Statute Requires CMS To Use Weighted Average of AMPs to Set FULs, Not Lowest Cost Therapeutic Alternative

CMS proposes to set AMP-based FULs at 250% of the AMP of the lowest cost therapeutic alternative. While the DRA requires FULs to be set at 250% of AMP, the statute itself does not reference the lowest therapeutic alternative – that benchmark was defined in previous CMS regulations.

Thus, CMS retains the discretion to improve pharmacy reimbursement by using a weighted average of all therapeutic alternatives of a particular prescription drug and should, in fact, do so to reflect the standard set by the statute properly. Particularly in light of the GAO's findings that AMP-based FULs are below pharmacy acquisition costs, FMI believes that the use of a weighted average could mitigate the number of instances where pharmacies are to be reimbursed below their acquisition costs and urges CMS to change to a weighted average FUL calculation in the final rule.

4. CMS Should Exercise Its Discretion To Delay Publication of AMP Data

FMI believes that the publication of AMP data has the potential to distort the marketplace for generic drugs, with potentially serious anti-competitive effects. Publishing AMP data could create a floor on the price discounts that generic manufacturers are willing to offer, reducing the level of competition between generic manufacturers with potentially significant negative effects on the Medicaid program.

If AMP data are published, manufacturers may find it difficult to offer discounts to some customers and not to others, as most customers will be unwilling to pay more than the average price. In this scenario, manufacturers will be more likely to sell to all buyers at the same rates, eliminating the benefits of competition that could otherwise accrue to the marketplace. In the case of Medicaid, the government will bear most of the consequences of this reduced competition -- the prices paid prices paid to manufacturers on average will increase, driving AMP-based reimbursement up also.

FMI and others are exploring legislation to ensure that AMP data remain confidential. In the interim, we believe that CMS has the discretion to delay publication of this information and we urge the agency to exercise this discretion.

5. CMS Should Reduce Volatility by Excluding Outlier Prices Less than 10 Percent of Next Highest AMP, Implementing Smoothing Mechanisms Similar to ASP

FMI is concerned about the potential for volatility in the drug reimbursement system, particularly in light of the CMS decision to rely on monthly AMP reports in setting FUL rates. We believe that relying on monthly AMP reports to set FULs and seeking to update FULs on a monthly basis could create significant volatility in the system, along with an undue burden on states seeking to administer FUL rates. We understand that Average Sales Price (ASP) based rates for certain products reimbursed under Medicare Part B have been highly volatile – even though ASP rates are calculated quarterly – and we believe that smoothing mechanisms will also be needed for AMP-based rates.

a. Possible Range Between AMP of Lowest Therapeutic Alternative and Next Highest AMP Should be Reduced

To avoid setting FULs based on "very low" AMPs, CMS proposes to set each FUL based on the lowest AMP "that is not less than 30 percent of the next highest AMP for that drug."[8] However, as the competition between generic therapeutic alternatives tends to reduce differences between competing products to very small levels, the proposed 70 percent range would still capture and incorporate a wide range of outliers in AMP-based FULs.

Thus, to reduce volatility and ensure a nationally available AMP, we encourage CMS to exclude "outlier" percentages that are more than 10 percent below the next highest AMP. A wider gap between therapeutic alternatives would likely be indicative of problems in AMP data or temporary spikes that would not actually reflect prices nationally available in the marketplace. Using a small percentage range will also improve the ability of pharmacists to purchase prescription drugs at prices below the FUL and better serve the agency's stated purpose of ensuring that drugs are "nationally available at the FUL price."[9]

b. AMP Should Employ "Smoothing" Mechanisms Similar to Those Used in the ASP Reporting System Under Medicare Part B.

In Medicare Part B, CMS created various mechanisms for "smoothing" ASP reporting to limit volatility. For example, manufacturers must calculate "lagged discounts" using a percentage methodology that reduces the potential for these discounts to be over-stated or understated in a particular quarter. The proposed rule for AMP does not employ such a smoothing methodology, which could contribute to volatility in Medicaid reimbursement for generic drugs. FMI urges CMS to require manufacturers to "smooth" those discounts that are included in AMP.

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8 71 Fed. Reg. at 77188.

9 *Id.*

c. CMS Must Ensure That FULs Are Based on Nationally Available Prices.

Finally, CMS should ensure that no FUL is based on an AMP for a generic pharmaceutical produced by a manufacturer that does not make the product nationally available. It is common for generic manufacturers to work directly with select pharmacy chains and wholesalers to meet market share goals in a manner that may not provide national access to their products. Consistent with others in the industry, FMI believes that AMP should only be calculated based on generic products that are AB-rated in the FDA *Orange Book* and are consistently available from the three major national wholesalers in supplies adequate to afford national distribution. Products that are erratically available or that are available only in limited supplies should be excluded from the weighted average AMP calculation. We are particularly concerned that a FUL could be set by a manufacturer undercutting the market, but without enough supply to meet market demands for an extended period of time. Particularly if CMS does not move to a FUL based on weighted average AMP, we would urge the agency to take steps to ensure that each AMP used to represent a FUL reflects a product that continues to be available to all retail pharmacies.

6. CMS Should Take All Necessary Measures To Ensure Adequacy of State Dispensing Fees

In order to protect convenient access to prescription drugs for Medicaid beneficiaries, CMS must ensure that the final regulatory definition of "dispensing fee" captures all of the applicable pharmacy operating costs. Specifically, the definition of dispensing fee in the proposed rule should be amended to include medication therapy management services and a reasonable return for pharmacies. As Medicaid may no longer adequately reimburse pharmacies for the ingredient costs of generic drugs, setting dispensing fees adequate to cover pharmacy costs in delivering pharmaceuticals to Medicaid beneficiaries is absolutely essential. (Suggested regulatory language for CMS's consideration in this regard is included in Appendix A.)

According to various sources, the current average dispensing fee at the state level is approximately $4.50. Recent studies of the actual costs to pharmacists to dispense prescription drugs have placed those dispensing costs at between $9 and $14 per prescription, depending on the state, with a national average of more than $10.[10] Thus, dispensing fees at the state level are clearly inadequate to cover pharmacy costs.

Accordingly, CMS should take an active role in informing the states about the need to adjust dispensing fees, especially in light of the DRA FUL policy. CMS should require each state to make a specific finding that the existing dispensing fee structure is not only adequate

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[10] "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies", Grant Thorton LLP (January 2007). Also, C. Mullins and A. Davidoff, et al, "Analysis of Cost of Prescription Drug Dispensing in Maryland" (December 2006).

to cover pharmacy costs (including a reasonable return), but also that these fees provide adequate incentives for generic usage in light of the revised FUL policy. CMS should direct states to increase dispensing fees that will not allow for adequate generic usage.

These suggestions reflect Congressional intent in enacting the DRA. Specifically, during the DRA debate, Senator Grassley stated that "states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions" in response to the revised FUL policy.[11] Without significant changes in state dispensing fees, pharmacy incentives to encourage generic utilization will be significantly reduced, with the corresponding potential to reduce greatly the savings that the DRA's imposition of AMP-based FULs was intended to provide. Given that brand name prescriptions cost an average $12 while generic drugs average $20 per prescription, the impact of reduced generic utilization could be significant indeed. State dispensing fees should be set in a manner that provides adequate incentives for the use of generic drugs and protects the convenient access of Medicaid beneficiaries to retail supermarket pharmacies.

D. Conclusion

FMI appreciates the opportunity to offer these comments on the impact that CMS's proposed regulation will have on supermarket pharmacies. We respectfully request that you consider our comments fully on the record and that you utilize the regulatory changes proposed in Appendix A of our comments.

We look forward to working with CMS on these issues in the future. Please feel free to call me or Deborah White, FMI's Associate General Counsel and Vice President of Regulatory Affairs at 202-220-0614, with any questions you might have.

Sincerely,

Tim Hammonds

Tim Hammonds
President and CEO

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[11] See Congressional Record, Senate, November 3, 2005, p. S12326 (Colloquy between Senators Grassley and Reed).

APPENDIX A:

Specific Regulatory Proposals

§447.502 Definitions

Amend paragraph 2 of the definition of "dispensing fee" as follows:

Dispensing fee means the fee which – …

"(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling (including medication therapy management services), physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy (including a reasonable profit); and".

S447.504 Determination of AMP

(e) *Retail pharmacy class of* trade means 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.

(f) *Wholesaler* means any entity ~~(including a pharmacy, chain of pharmacies or PBM)~~ to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug that is licensed in a state as a wholesale distributor of pharamaceuticals.

Amend subsection (g) by striking paragraphs 3, 6, 7, 8, 9 and 12 and re-designating paragraph numbers accordingly.

Amend subsection (h) by inserting a new paragraph after paragraph 3 (and re-designating paragraph numbers accordingly) that reads as follows: "Sales exempt from best price (as defined by §447.505)."

Amend subsection (i)(1) by striking "PBM price concessions,".

§447.514 Upper Limits for multiple source drugs

(b) *Specific upper limits*. The agency's payments for multiple source drugs identified and listed periodically by CMS in Medicaid program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the weighted average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for ~~the least costly therapeutic equivalent~~ all therapeutic equivalents for sale nationally (as described in subsection (c).

Amend subsection (c) by:

(1) striking "30" in paragraph 2 and replacing it with "90"; and
(2) inserting a new paragraph as follows:

"(4) Any product that is not consistently available from the three largest wholesalers in amounts reasonably adequate to supply the retail pharmacy sector will be excluded from the FUL group."

§447.518 State plan requirements, findings and assurances

Amend subsection (b)(1) by:

(1) in clause (i) by striking at the end "and";
(2) in clause (ii) striking the period at the end and inserting in lieu thereof "; and"; and
(3) inserting the following new clause:

"(iii) In the aggregate, the dispensing fees paid to pharmacies cover the costs described in §447.502 and are designed to encourage the utilization of multiple source drugs where appropriate."

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Rec'd
FEB 20 2007

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

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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).

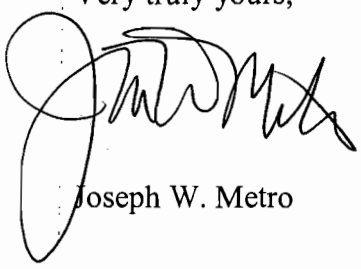
CMS has acknowledged in its response to Senator Grassley that section 1927(a)(7)(A), as amended by the DRA, requires physician-administered single source drugs to be identified in order to secure Medicaid rebates for which Medicaid payments are made. CMS nevertheless concludes that rebates for which 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,



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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
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Room 445-G, Hubert H. Humphrey Building
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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.

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.

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[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).

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

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		

Product	Units Sold	WAC	Sales at WAC	Percent-age Discount	Unallo-cated Discount Amount	Allocated Discount Amount	Unallo-cated Net Sales	Allocated Net Sales	Potential Best Price without Alloca-tion	Potential Best Price with Alloca-tion 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

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

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.

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,

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February 20, 2007

BY HAND DELIVERY

The Honorable Leslie V. Norwalk, Esq.
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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.

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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]

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[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.

- 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

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[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

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[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 billon in 1990 to $188.5 billion in 2004[13] — eliminating these discounts will serve only to further exacerbate the financial burden of safety net providers.[14]

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[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.

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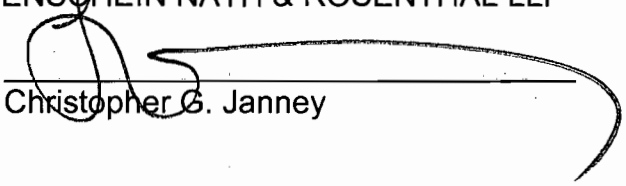
[15] 42 C.F.R. § 447.504(h)(6) (proposed).

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,

SONNENSCHEIN NATH & ROSENTHAL LLP

By: 

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February 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.

<u>Recommendation:</u> 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

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[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 on 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