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December 21, 2007

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

Re: Medicaid Program; Prescription Drugs Final Rule 42 CFR Part 447
File Code: CMS-2238-FC

Dear Acting Administrator Weems:

On behalf of Pfizer, I am pleased to share with you input on the final rule (CMS-2238-FC) that was published in the *Federal Register* on July 17, 2007, that will implement provisions of the Deficit Reduction Act (DRA) of 2005 related to the Medicaid Rebate Program and prescription drug payment under Medicaid.[1]

In the final rule, CMS requested further public comment on the Average Manufacturer Price (AMP) and the Federal Upper Limit (FUL) outlier provisions of the rule. Pfizer has focused its comments on the AMP provisions, including PBM mail order discounts, lagged price concessions, authorized generics, bundled sales, and proportional Medicaid rebates. Our specific comments are below.

- **Allocating PBM Mail Order Discounts and Rebates**

Pfizer appreciates CMS' efforts to clarify the definition of AMP to ensure consistency in its calculation across manufacturers. The final rule excludes pharmacy benefit manager (PBM) discounts and rebates from the determination of AMP, with the exception of discounts and rebates extended to PBMs' mail order pharmacies. However, due to the limitations of existing data and accounting conventions, many manufacturers may not be able to distinguish the discounts and rebates that are offered to a PBM's general business from those offered to its mail order pharmacy business. As a result, we believe complying with the rule will be a challenge for many manufacturers. We are concerned that without further guidance from CMS, manufacturers will each make their own decisions about how to treat indistinguishable PBM rebates, resulting in continued inconsistency in manufacturers' determination of AMP.

In order to ensure consistency across manufacturers in the determination of AMP, Pfizer requests that CMS clarify how manufacturers should treat discounts and rebates to PBM mail

1 72 Fed. Reg. 39142.

order pharmacies in such instances where manufacturers are unable to distinguish mail order and general PBM discounts and rebates. Pfizer recommends that CMS direct manufacturers whether to include or exclude all PBM rebates in these instances.

- **Lagged Price Concessions**

Pfizer is concerned that the method outlined in the final rule for estimating lagged price concessions will result in significant inaccuracies in the calculation of AMPs. The final rule directs manufacturers to use a 12-month rolling average, including the current month, to estimate the value of lagged price concessions in the calculation of monthly AMPs. However, manufacturers' rebate data are often delayed, sometimes by several months; thus, including in the estimation the current and recent months, for which complete rebate data may not yet be available, would understate the 12-month price concession average, thereby artificially inflating the AMPs.

Furthermore, under the final rule, quarterly AMPs will also be artificially inflated as they are calculated as the weighted average of the monthly AMPs for that quarter. Pfizer is concerned that manufacturers' Medicaid rebates will be inaccurate if manufacturers are not permitted to restate quarterly AMPs to allow for lagged price concessions. (While manufacturers are permitted to restate monthly and quarterly AMPs for up to 36 months following monthly submissions and 12 quarters following quarterly submissions, the final rule indicated that manufacturers should not restate AMPs when the revision is solely to account for lagged price concessions.)[2]

To avoid artificial inflation of AMPs and ensure more accurate price reporting, Pfizer recommends that CMS adopt a four-quarter rolling average, using the four quarters ending two quarters prior to the current quarter, to estimate lagged price concessions. Since rebate claims are generally reported to the manufacturer within two quarters after they are generated, using a four quarter averaging period with a two quarter "lag" would give the manufacturer time to receive data on virtually all rebate claims earned during the averaging period, thereby enhancing the accuracy of the four quarter average.

Alternatively, Pfizer proposes permitting the manufacturer to select the most recent 12-month period for which lagged data are available. This would permit the manufacturer flexibility to choose a 12-month period ending two quarters prior to the reporting quarter, or one quarter, or any other period that suits that company's circumstances which appropriately and accurately reflects discounts. This is the approach adopted by CMS in the Average Sales Price (ASP) rule.[3]

In addition, manufacturers should be permitted to re-state quarterly AMPs, but not monthly AMPs, to reflect lagged price concessions. This methodology would also promote consistency with manufacturers' calculation of ASP.

- **Authorized Generics**

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2 42 CFR 447.510(b)(2) and (d)(4).

3 42 CFR 414.804(a)(3)

To properly reflect the intent of the DRA, we urge CMS to clarify the final rule and make it explicit that authorized generic sales should be included in the related brand drug's AMP. This modification is necessary to ensure that the final rule reflects Congressional intent on this issue. As a general matter, AMP is defined 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."[4] The DRA added a special rule to the AMP definition specifically addressing the treatment of authorized generics. That provision states that, "[i]n the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade."[5] In a notable departure from the general AMP definition, the new authorized generic-specific provision does not specify that a price for an authorized generic must be paid "to the manufacturer" in order to be included in AMP.

Clearly, by explicitly amending the AMP definition, Congress intended to modify the definition of AMP so that the calculation of brand AMP includes at least some of the sales of related authorized generics marketed under the original NDA. As a practical matter, a manufacturer who authorizes the sale of an authorized generic ("primary manufacturer") does not sell the authorized generic to any wholesalers or other entities except the authorized generic distributor ("secondary manufacturer"). Thus, for Congress' amendment to the AMP definition to have any effect, it must be read to encompass either (1) those inter-company sales, or (2) the sales from the secondary manufacturer to its wholesaler customers. An interpretation that the brand AMP includes neither option (1) nor (2) would effectively render the special rule in the definition meaningless, and would thus be contrary to the Congressional intent that the calculation of AMP in cases involving authorized generics be modified.

We believe the absence in the new authorized generic-specific provision of a requirement that a price for an authorized generic must be paid "to the manufacturer" in order to be included in AMP was by design, and indicates a Congressional awareness of the authorized generic market and an intent that the brand AMP include the sales by the secondary manufacturer to its wholesaler customers (option 2). CMS included this option in the proposed rule but rejected it in the final rule, citing implementation difficulties.

We believe that inclusion in the brand AMP of sales by the secondary manufacturer to its wholesaler customers would best implement the plain language of the statute. Nevertheless, if, in CMS's judgment, the difficulties of implementation preclude taking into account sales from a secondary manufacturer to its wholesalers, we believe the intent of the new provision could also be carried out by instead including in the brand AMP the sales from the primary to the secondary manufacturer (option 1). To some degree, the final rule achieves this result by requiring the primary manufacturer to include sales of the authorized generic in the brand AMP "only when such drugs are being sold by the manufacturer holding title to the original NDA directly to a wholesaler." Since a wholesaler is defined as "any entity . . . to which the manufacturer sells the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug," a secondary manufacturer that does not itself relabel or repackage the

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4 42 U.S.C. § 1396r-8(k)(1)(A).

5 42 U.S.C. § 1396r-8(k)(1)(C), added by DRA § 6003(b)(2).

authorized generic would fall within this definition, and the brand AMP would be required to include the inter-company sales of the authorized generic to such a company.

However, the current definition of "wholesaler" would fail to capture in the brand AMP those arrangements in which the primary manufacturer sells the covered outpatient drug in bulk to the secondary manufacturer, who then repackages and relabels the product. There is no sound rationale for treating authorized generic sales in AMP differently depending on which party does the packaging and labeling of the authorized generic, nor can such a distinction reasonably be read into the new statutory provision. A drug is an authorized generic by virtue of being covered by the same NDA as the brand, regardless of the packaging or labeler code, and it should likewise make no difference who performs the packaging or prints the labeler code on the package. Congress intended the AMP (and best price) of the brand to include, rather than be insulated from, sales of the authorized generic. For CMS to base inclusion on such a fine distinction would thwart the Congressional intent.

Pfizer therefore recommends that CMS amend the definition of a "wholesaler" by adding that, in the case of an authorized generic, "wholesaler" includes any entity (including a subsidiary of the manufacturer, another manufacturer, or a distributor) to which the primary manufacturer sells the authorized generic, regardless whether such entity repackages or relabels the authorized generic. Pfizer also recommends that the AMP regulation be amended to explicitly include sales of an authorized generic from the primary manufacturer to a secondary manufacturer or a subsidiary of the primary manufacturer, regardless which entity packages or labels the authorized generic.

- **Definition of Bundled Sales**

Although the final rule indicates that the definition of bundled sales is merely a clarification of the existing definition under the Medicaid Rebate Agreement,[6] we believe that the definition as proposed in the final rule would impose ambiguous new requirements on manufacturers and could lead to miscalculations of AMPs .

The prior definition of "bundled sale" contained in the Rebate Agreement referred only to the "packaging of drugs of different types."[7] In contrast, the final rule defines a bundled sale as "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types, or another product or some other performance requirement or where the resulting discounts or other price concessions are greater than those which would have been available separately or outside the bundled arrangement" (emphasis added). This definition differs substantially from the prior definition in the Medicaid Rebate Agreement as it expands a bundle to include, not only drugs of different types, but also the same drug, or a drug with non-drug products. Moreover, the new definition includes discounts conditioned on performance requirements that do not necessarily require a purchase, whereas previously a bundled sale as defined in the Rebate Agreement required the purchase of more than one drug type. These changes represent a substantial expansion of the definition and a significant change in policy that was not discussed or considered in the proposed rule.

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6 72 Fed. Reg. at 39159.

7 Medicaid Rebate Agreement § I(e).

Moreover, we are concerned that the assertion in the final rule that the bundled sales definition is not a change, but merely a clarification, suggests that it may be implemented retroactively. The significant changes in the bundled sale definition have the potential to impact a great many contractual arrangements, including those that have not been, and should not be, considered bundled sales. For example, a manufacturer may have contractual arrangements in which health plans can receive a more favorable discount on Drug A if they place Drug B on a preferred formulary tier. However no purchase of Drug B is required. Retroactively allocating these contractual arrangements for the recalculation of AMPs would not be feasible. Since there has heretofore not been any regulatory requirement to do so, manufacturers have not tracked and retained the data necessary to allocate performance requirements or other contractual arrangements that did not previously constitute a bundle. Even if manufacturers could retrieve the necessary data, we believe that agreements that could be considered bundled under the new definition, but were not previously defined as bundled, could be so widespread that virtually every manufacturer would have to restate AMP for every quarter for the past three years. This would place an inordinately heavy burden on manufacturers and CMS alike.

As we believe the new definition of bundled sales is materially and significantly different from the existing definition under the Medicaid Rebate Agreement, we recommend that the definition should not be finalized until such time as CMS has completed the ongoing public comment period. Moreover, we ask that CMS clarify that any final change in the definition would only be applied prospectively.

Finally, we believe that the inclusion of "same drug" in the definition of a bundled sale is unnecessarily confusing. We are unable to identify a situation in which sales of or contractual arrangements for the same drug could be considered a bundled arrangement. We reason that many other manufacturers are similarly perplexed, and thus may feel obligated to treat arrangements as bundles that should not be treated as such.

Pfizer recommends that, until CMS issues a rule after the comment period closes on January 2, 2008 ("future rule"), CMS maintain the definition of bundled sales in the Medicaid Rebate Agreement – i.e., arrangements contingent upon the purchase of drugs of different types – and specifically exclude the reference to "same drug" from the definition of a bundled sale. Further, in its future rule, CMS should acknowledge the new definition of bundled sales as a policy change and thus implement the new definition prospectively only.

- **Proportional Medicaid Rebates**

In instances where Medicaid is a secondary payer to Medicare, states pay only a fraction of the cost of a drug. The AMP final rule requires that even in these instances manufacturers must pay the full rebate amount.[8] Pfizer supports the intent of the Medicaid rebate program to ensure access to the best available drug prices for low-income, medically-needy individuals. However, the policy to provide full rebates where the state pays only a share of the drug's cost may result in states obtaining rebates that exceed their payments for the drug. Pfizer believes that this is not the intent of the rebate program.

Pfizer recommends that Medicaid programs be required to report to manufacturers the units of a drug for which they paid only a share of the cost and that manufacturers be permitted to pay proportional rebates for those units.

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8 See 72 Fed. Reg. at 39218 (preamble).

We would welcome the opportunity to speak further with you and your staff about our comments and recommendations. Please feel free to contact me at 212 733 4329 or Sydney Avent at 212 733 9199.

Sincerely,

Ilana Shulman
Assistant General Counsel

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December 28, 2007

VIA FEDERAL EXPRESS AND ELECTRONIC DELIVERY
The Hon. Kerry Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-FC, Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244-8012

RE: CMS-2238-FC, Final Rule – Medicaid Program, Prescription Drugs

Dear Mr. Weems:

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

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), Azor™ (amlodipine and olmesartan medoxomil), WelChol® (colesevelam HCl), (Evoxac® (cevimeline HCl) and Floxin OTIC® (ofloxacin otic).

II. COMMENTS

A. Sales Outside the 50 United States and the District of Columbia

We understand that the definition of AMP excludes "sales outside the 50 States and the District of Columbia" [2] Similarly, CMS's "DRA Policy Questions" document states:

> "Question: Should sales to wholesalers in Puerto Rico and other U.S. territories be included in the AMP calculation?

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1 72 Fed Reg. 39,141 (July 17, 2007), file code CMS-2238-FC.

2 42 C.F.R 447.504(h)(10).

Answer: Sales to Puerto Rico and other U.S. territories are not to be included in the AMP calculation."

However, we seek further clarification regarding the treatment of sales outside of the 50 States and the District of Columbia from an operational perspective. As an initial matter, we believe that it is consistent with the Final Rule and the CMS DRA Policy Questions to exclude direct (ex-factory) sales to Puerto Rico wholesalers. By "exclude", we interpret this to mean that the dollars and units associated with such sales should be deducted from the gross dollars and units used to determine AMP, and any associated discounts would be ignored (e.g., not used to reduce AMP). Please confirm this interpretation.

Additionally, we seek clarification as to the appropriate treatment of indirect sales to entities in Puerto Rico or another territory. Such sales would be initially to a wholesaler within the 50 States or the District of Columbia, but then sold through to an entity in Puerto Rico (or another territory). The manufacturer may be able to identify this end sale through chargeback data. It is our understanding that, assuming such chargeback data constitutes "adequate documentation" as such term is used in the Final Rule, the sale should be excluded. This exclusion would be operationalized by deducting the associated units and dollars (with such dollars being determined by valuing the units at the current wholesale acquisition cost ("**WAC**")).[3]

We understand that such sales should be excluded regardless of whether the end purchaser(s) in Puerto Rico or another territory are determined to be "retail" entities for purposes of the AMP calculation. Please confirm that this interpretation is accurate. Similarly, we seek confirmation that the above interpretation continues to be correct when the end purchaser is an entity that is owned or affiliated with an entity based in the 50 States or the District of Columbia but physically located outside of the 50 States or the District of Columbia.

B. Hierarchy of Excluded/Included Transactions

We appreciate CMS's effort in the Final Rule to identify specific entities that are included or excluded from the AMP calculation. We understand the effort involved in this process, and commend CMS for its attempt to synthesize the input from the various industry stakeholders in this regard. While the specificity of 42 C.F.R. § 447.504 helps to clarify many of the questions that existed prior to the Final Rule, it creates additional confusion where an entity may fit into more than one classification, and, variously be "included" or "excluded". For example, an entity may be a mail order facility ("included" in AMP under 42 C.F.R. § 447.504(g)(9)) that its wholly owned by a managed care organization ("**MCO**") and that distributes to only the MCO's own members ("excluded" from AMP under 42 C.F.R. § 447.504(h)(23)). Similarly, a manufacturer may contract with a mail order facility that is not affiliated with an MCO, but such contract may pertain specifically to the mail order facility's Medicare Part D business ("excluded" from AMP under 42 C.F.R. § 447.505(d)).

We ask that CMS specify the "hierarchy" of exclusions versus inclusions, to help manufacturers to better determine the treatment of entities that may be both included or excluded. To this end, please clarify that the listing of any entity or transaction on the AMP "exclusions" list at 42 C.F.R. § 447.504(h) "trumps" the fact that the same entity or transaction may otherwise be captured in the AMP "inclusions" list at 42 C.F.R. § 447.504(g) or the broader definition of "retail pharmacy class of trade" set forth at 42 C.F.R. § 447.504(e). Alternatively, please create a chart indicating the exclusions and inclusions, and the appropriate hierarchy of each (e.g., what "trumps" what). Additionally, although we understand that the Final Rule has not specifically solicited comments regarding Best

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[3] We note that in valuing the units at WAC, there is a possibility that this number may not represent the actual amount paid for the units sold through to Puerto Rico or another territory, as there is no way to trace the units sold through to a specific ex-factory sale. This is because a wholesaler's inventory may have been purchased across WAC price changes, and the manufacturer is not in a position to be able to determine from which inventory the end sale outside of the 50 States or the District of Columbia was made. However, the current WAC is the best available measure for the ex-factory value of a unit at a point in time.

Price, we note that a hierarchy for Best Price transactions would also be useful, as similar issues may occur in that regard.

C. Lagged Price Concessions

In the Final Rule, CMS defines "lagged price concession" as "any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts."[4] Manufacturers are instructed to estimate lagged price concessions using a 12-month rolling average methodology in the calculation of monthly AMP.[5] We note that this definition is broad enough to be inclusive of a transaction where a manufacturer realizes the discount or rebate within hours after the sale of the drug. We request that CMS clarify that, where a manufacturer has sufficient data to determine the precise value of a price concession within the applicable reporting period, a manufacturer may at its option elect not to treat the price concession as "lagged".

D. Smoothing Lagged Excluded Sales

In the DRA Policy Questions document published on the CMS website, CMS has posted the following exchange:

> "Question: May a manufacturer opt to smooth sales that are excluded from AMP?
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> Answer: No. For the purposes of Medicaid, only the discounts, rebates, and other price concessions associated with sales included in AMP should be used in the 12-month rolling average to estimate the value of lagged price concessions."

We understand that price concessions associated with excluded sales should not be used to reduce the AMP reported by a manufacturer. However, we are concerned that the above guidance may be incorrectly construed to mean that a manufacturer may not remove lagged excluded sales using a 12-month rolling average. We note that in the ASP context, CMS has acknowledged that "requiring similar methods to estimate both lagged exempted sales and lagged price concessions would be reasonable and reduces potential errors in the manufacturers' ASP calculations, while ensuring that exempted sales are appropriately removed from the ASP calculation. In addition, using an estimation methodology to remove lagged exempted sales would reduce the likelihood of quarter-to-quarter variations in the ASP."[6] Please confirm that a manufacturer may remove lagged exempted sales (for example where such sales are identified through a chargeback or rebate process) using an estimation methodology to better ensure that such sales do not inappropriately skew the AMP.

E. Voucher Programs

The Final Rule specifies that manufacturer vouchers are excluded from the AMP calculation.[7] We note that the preamble to the Final Rule elaborates on this exclusion, stating:

> "We believe that vouchers for free sample products should be excluded from AMP in instances that the, [sic] voucher is not contingent on other purchase requirements and is redeemed by any entity other than the

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4 42 C.F.R. § 447.502.

5 42 C.F.R. § 447.510(d)(2).

6 *See* 71 Fed. Reg. at 69,924, 69,670 (Dec. 1, 2006).

7 42 C.F.R. § 447.504(16).

> consumer, where the full value of the coupon is passed on to the consumer and the pharmacy does not receive any price concessions, it should be excluded from AMP."[8]

In administering a voucher program, a manufacturer will typically contract with a third party administrator to provide access to a pharmacy network for purposes of pharmacy reimbursement for voucher claims, as a manufacturer is unlikely (and often unable) to contract directly with pharmacies in this regard. This is because pharmacy network contracting and claims payment is a business function that is outside the scope of most manufacturers' business operations. Often such third party administrators will not share the actual pharmacy network reimbursement amounts with the manufacturer for proprietary reasons, but will instead charge through to the manufacturer a fixed reimbursement amount per voucher claim redeemed through its network. The manufacturer may be unable to determine whether the fixed per claim reimbursement amount paid to the third party administrator is greater or less than the actual amount paid by the administrator to the pharmacy. We request that CMS clarify that if a manufacturer, in administering a voucher program, utilizes a set formula to pay a third party administrator in connection with pharmacy reimbursement, then CMS will not require the manufacturer to include such a transaction in its AMP.

We further ask for clarification that a voucher program that is excludable from AMP is excludable from a manufacturer's Best Price calculation. We believe that this was the intent of the Final Rule, but we note that this has not been explicitly addressed therein.

Alternatively, if CMS determines to include vouchers in AMP and/or Best Price, 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 voucher prescription (e.g., how many tablets are dispensed with a particular voucher). Similarly, even if the manufacturer were to have such transparency, other valuation issues should be addressed (e.g., if a single voucher 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?).

F. Employee Drug Programs

In the preamble to the Final Rule, CMS states the following:

> "*Comment:* One commenter requested that CMS clarify whether products which are sold directly to patients through company stores that sell only to the company's employees are included in AMP.
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> *Response:* We are unable to respond to this comment as the commenter did not include enough specific information to enable us to do so. However, we have defined retail pharmacy class of trade at § 447.504(e) to mean any independent pharmacy, chain pharmacy, mail order pharmacy or other outlet that purchase drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public. We will continue to respond to such questions via the website or informal guidance when additional information can be obtained."[9]

We note that employee drug programs may take different forms, and may not necessarily be the "company store" described in the preamble. For example, a manufacturer may offer its own drugs at no cost to only its own employees and their dependents through the managed care organization offering its employee health benefits. Operationally, the manufacturer employer would typically reimburse the MCO at a fixed negotiated rate for all

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[8] 72 Fed. Reg. at 39,188.
[9] 72 Fed. Reg. at 39,186.

employee drug claims, similar to the voucher scenario described above. As with the voucher scenario described in Section F above, it is possible that the MCO will not share the actual pharmacy network reimbursement amounts with the manufacturer for proprietary reasons, but will instead charge through to the manufacturer a fixed reimbursement amount per employee drug claim redeemed through its network. The manufacturer may be unable to determine whether the fixed per claim reimbursement amount paid to the MCO is greater or less than the actual amount paid by the MCO to the pharmacy. CMS should clarify that if a manufacturer, in administering an employee drug program, utilizes a set formula to pay an MCO or other administrator in connection with pharmacy reimbursement, then CMS will not require the manufacturer to include such a transaction in its AMP. We further ask for clarification that an employee drug program is excludable from a manufacturer's Best Price calculation.

Alternatively, if CMS determines to include employee drug programs administered by an MCO in AMP and/or Best Price, we respectfully request that CMS provide guidance on how to value such transactions for purposes of the respective calculations. Similar to voucher programs, for privacy reasons, the manufacturer employees responsible for price reporting often do not have full transparency into the dispensing of employee drug prescriptions (e.g., how many tablets are dispensed with a particular prescription).

G. Fees Paid to Group Purchasing Organizations ("GPOs")

In the Final Rule, CMS defines "bona fide service fees" as "fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug."[10] CMS states in the preamble to the Final Rule: "If the manufacturer has an agreement with the GPO that any of these [service fees, distribution fees, and administrative fees and other fees to GPOs] are passed on to the group purchasing organization's members or customers, they would not be excluded as a bona fide service fee. We believe there must be no evidence or arrangement that the fee is passed on to the member pharmacy, client or customer of any entity included in the calculation of AMP in order for the manufacturer to exclude these fees from the determination of AMP."[11]

We understand anecdotally that several of the major GPOs in the United States allow some or all of the administrative service fees paid by pharmaceutical manufacturers to the GPOs to be shared with some GPO members. For example, we understand it is possible for a portion of a GPO's members to also be owners of the GPO and receive revenues by way of dividends in their ownership capacity that would include some portion of the administrative fees paid to the GPO. However, as a pharmaceutical manufacturer, we have no transparency into the various and sundry arrangements that GPOs have with their members to share, or not share, administrative fees. It would be impracticable (and, in some cases impossible) for a pharmaceutical manufacturer to identify the specific GPO members to which a GPO may pass through administrative fees, identify what portion of administrative fees are passed through, and allocate such portion of administrative fees as a discount for purposes of reducing the AMP. This is further complicated by the fact that even the GPOs themselves may not be able to trace, dollar for dollar, what administrative fees are passed through, particularly in the dividend scenario described above.

We believe that the comments offered by the Health Industry Group Purchasing Association ("**HIGPA**") to the 2007 Medicare Physician Fee Schedule in regards to ASP are relevant in this regard. Specifically, HIGPA stated:

> "The fact that some GPOs — pursuant to their by-laws or member agreements — distribute a portion of their <u>own</u> revenues to their hospital members does not mean that any portion of the GPO

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[10] 42 C.F.R. § 447.502.

[11] 72 Fed. Reg. at 39,183.

> Fees paid by manufacturers to the GPOs should be treated as price concessions from the manufacturer to the purchaser. Simply stated, if a GPO decides to make a distribution to its members of its own volition — and not pursuant to any agreement or other legal arrangement between the GPO and the manufacturer — this distribution cannot possibly be deemed a "price concession" by the manufacturer, or otherwise attributed to the manufacturer, for ASP purposes. Put differently, it cannot be that pursuant to their own, independent business decisions, GPOs can unilaterally inflate or deflate drug manufacturers' prices and ASPs. Only the manufacturer of a drug can be allowed to control the price that is attributable to the manufacturer for ASP purposes. (It follows, of course, that if a drug manufacturer enters into an agreement with a GPO pursuant to which the GPO will pay its members 50 percent of the Fees paid by the manufacturer to the GPO, then the 50 percent should be considered a price concession from the manufacturer to the purchaser and, as such, should be included in the calculation of the manufacturer's ASP.)"[12]

We request that CMS clarify that if a manufacturer: (i) has not directed a GPO to pass through administrative fees and (ii) does not know with specificity to what extent administrative fees are or are not passed through, the manufacturer should not use such GPO administrative service fees to reduce AMP or Best Price.[13] This should be true even if the GPO has indicated that it may pass some portion through of its own accord (perhaps by refusing to agree to contract language requiring the administrative fee(s) to not be passed through). Alternatively (or in addition to the above), we request that CMS state in the final rule that GPOs that do not take title to drugs, but merely arrange for discounted pricing to be made available to their members are analogous to pharmacy benefit managers ("**PBMs**") in their non-mail order capacity, and are not "retail class of trade".

H. Pharmacy Benefit Manager Mail Order Rebates

In its DRA Policy Guidance version 11-27-07, CMS states:

> "Question: Rebates to PBMs, except for their mail order pharmacy purchases are now excluded from AMP. However, many PBMs do not separate their data between mail order pharmacy purchases and non-mail order purchases nor do they provide detailed data for plans under them. In these situations, may a manufacturer exclude the entire PBM rebate, consistent with the general meaning of the rule that sales may only be excluded based on actual data?
>
> Answer: The AMP final rule requires that all sales, rebates, discounts and price concessions to mail order pharmacies, including mail order sales to PBMs, be included in AMP. We expect that manufacturers will take steps to obtain the necessary data to exclude non-mail order PBM rebates. Until they obtain such data, manufacturers may make reasonable assumptions consistent with the statute, regulations, and their customary business practices."

Please clarify whether it is CMS's intent that, where a PBM is affiliated or contracted with a mail order facility, a manufacturer must segregate rebate data attributable to the PBM's managed utilization that happens to also be dispensed by a mail order facility affiliated or contracted with the PBM (where such data is not separately reportable by the PBM under an agreement that is specific to mail order business). While it is conceivably possible to identify such data, this process is time-consuming and may not be entirely accurate, as it requires analyzing all

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12 Comments to CMS regarding CMS-1321-FC, by the Health Industry Group Purchasing Association at 2 (filed Jan. 2, 2007).

13 We note that as a practical matter, and partially in response to the federal healthcare anti-kickback statute safe harbor for administrative fees, few if any GPO's request administrative service fees in excess of 3%, and this percentage is well below the minimum rebate for innovator drugs. Therefore, even if GPO administrative service fees are taken into account for Best Price purposes, and even if they "set" a best price, there will be minimal rebate impact. However, to take GPO administrative fees into account for AMP purposes would likely reduce the AMP and thus the resulting Medicaid rebate.

PBM rebate claims for the associated NABP or NPI number, and then tracking that number back to a facility that is affiliated with the PBM. We believe that such an interpretation is not consistent with CMS's intent in carving out the non-mail order facility PBM business, as such rebates are not available to the retail class of trade. Even if a PBM mail order facility sells to the general public as one line of business, the rebates described above would be limited in scope to PBM-managed utilization. We request that CMS specify that manufacturers should not include such rebates attributable to incidental mail order utilization in AMP (e.g., reduce the AMP by the value of these rebates).

I. Other Government Pricing Programs

As you know, there are terms used in the Final Rule that are similar to terms used in other government price calculations, such as the non-Federal Average Manufacturer Price calculation. Please clarify that the treatment of any particular transaction in connection with non-Medicaid pricing programs (e.g., VA Non-Federal Average Manufacturer Price reporting) is not precedential with respect to a manufacturer's treatment of a transaction for purposes of the Medicaid Drug Rebate Program. We would appreciate if CMS would coordinate with its counterparts administering other government price programs at the Department of Veterans Affairs and the Health Resources and Services Administration to better ensure consistency across federal government programs, to the extent possible.

J. Certification of Pricing Reports

In light of the preliminary injunction granted in the ongoing case of National Association of Chain Drug Stores v. Leavitt, Civ. A. No. 1:07cv02017 (D.D.C., *preliminary injunction issued* Dec. 19, 2007), we respectfully request that CMS refrain from requiring manufacturer certifications of their AMP and Best Price reports while that litigation is pending.

K. Additional Requests

We respectfully request that CMS issue both of the following: (i) a sample AMP calculation, and (ii) a chart indicating for each of the various entities and/or transactions that may affect the AMP and BP calculation whether associated sales, discounts, and/or units are deducted from the gross ex-factory dollar and unit numbers for purpose of calculating AMP, and whether those sales and/or units should be smoothed. As you know, on June 5, 1997, CMS attached to Manufacturer Release 29 a chart indicating AMP and Best Price inclusions and exclusions. This chart was tremendously helpful to manufacturers in synthesizing the CMS AMP and Best Price guidance available at that time, as well as in operationalizing that guidance. While the list of entities and transactions may need to be expanded, and the number of columns may also need to be expanded to better indicate CMS's expectations as to what it means to "include" or "exclude" an entity or transaction, we believe that a visual representation summarizing the Final Rule, loosely based on the Release 29 chart, would better ensure consistency across manufacturers' AMP and Best Price calculations. In this regard, we would be happy to assist CMS in putting together such a chart. We would appreciate the opportunity to meet live with CMS to discuss relevant operational issues and walk through our version of the updated Manufacturer Release 29 chart.

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

Sincerely,

Daiichi Sankyo, Inc.

Edward J. McAdam, Sr. (slh)

By:
Edward J. McAdam, Sr.
Director Contract Administration
973-630-2682

With us, it's personal.

January 2, 2008

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS 2238-FC
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-8012

Subject: Medicaid Program: Prescription Drugs; CMS 2238-FC; RIN 0938 AO20

The Rite Aid Corporation is pleased to provide these comments on the final definition of Average Manufacturers Price (AMP), as well as the final outlier policy for the calculation of Federal Upper Limits for generic drugs, both of which were published as part of the final Medicaid Prescription Drug regulation on July 17, 2007,

Rite Aid is one of the nation's largest pharmacy chains, operating 5100 retail pharmacies in 31 states and the District of Columbia. We are a primary provider of pharmacy services to Medicaid recipients and will be significantly affected by the final AMP regulation and the method by which CMS calculated Federal Upper Limits for generics.

Policies Relating to Calculation of the AMP

Rite Aid believes that only those manufacturers' sales to traditional pharmaceutical wholesalers for covered outpatient drugs as defined in Section 1927 of the Social Security Act (in the Medicaid program) that are ultimately sold and distributed to traditional retail pharmacies should be included in the definition of AMP. Only retail pharmacies should be included in the retail class of trade. That is because AMP is supposed to represent the approximate revenues that manufacturers receive from the sales of covered outpatient drugs to Medicaid recipients. That is because AMP serves as the basis for manufacturers rebates paid to state Medicaid programs.

We do not believe, as CMS has broadly construed the statute, that AMP should include any manufacturers' sales (and associated rebates) for covered outpatient drugs provided to the general public. We do not believe that retail pharmacies are synonymous with the general public. "Retail pharmacy" is a commonly known term and generally recognized as independently-operated and chain-operated drug stores. Requiring manufacturers to calculate AMP by including all prescription drug sales to the general public is contrary to the original intent of AMP (as enacted by Congress in OBRA 90) and the intent of Congress in using AMP as a retail pharmacy reimbursement metric (as enacted in DRA.)

Because almost all covered outpatient drugs for Medicaid recipients are almost exclusively dispensed through community retail pharmacies, the only sales that would make AMP valid as a rebate metric are those manufacturers' sales to traditional retail pharmacies. Moreover, because AMP is being used to determine reimbursement to retail pharmacies under the Federal Upper Limit (FUL) program, it makes no sense to include manufacturers' sales and prices to other purchasers if they are not going to be reimbursed under this FUL program.

The use of 250 percent of the lowest AMP to set the FUL has already been shown by numerous government studies to pay pharmacies below their cost of purchasing these generic drugs – even with the 250 percent increase. Use of an even potentially lower AMP – as would result under this final regulation – could result in even more draconian underpayments.

We also believe that CMS has not correctly interpreted the statute with respect to the meaning of "wholesaler". Similar to the case of the definition of "retail pharmacy" in the final regulation, "wholesaler" has a commonly-understood meaning in the marketplace. CMS would however define wholesaler as any entity (including retail pharmacies) to which the manufacturer sells a covered outpatient drug. Wholesalers generally act as middlemen in the distribution of pharmaceuticals between manufacturers and the ultimate users, in this case, the retail pharmacies. Yet, CMS has adopted an expansive definition of wholesaler that would define patients, and other entities such as physicians' offices, as wholesalers.

In addition, the definition of covered outpatient drug in Section 1972(k) of the Social Security Act clearly indicates that drugs that are sold to physicians' offices, outpatient hospitals, and those used for renal dialysis are not covered outpatient drugs. These entities were excluded from the definition of covered outpatient drug in Section 1927(k) to make it clear that these drugs would not be subject to manufacturers' rebates – that is, only covered outpatient drugs sold to Medicaid beneficiaries through retail pharmacies would be included. Thus, CMS' final AMP definition would not provide the marketplace with an accurate benchmark for manufacturers to calculate their rebates to states. The lower AMP that would result from final regulation's definition of AMP would result in lower rebates to states.

In addition, we believe that DRA meant for AMP to approximate the average prices paid by retail pharmacies so that states would have a more accurate and reliable benchmark to determine reimbursements to retail pharmacies. Most of the legislative history of the development of DRA dealt with the prices paid by Medicaid to retail pharmacies, not the prices paid by Medicaid to other entities. Inclusion of purchasers' prices and discounts other than retail pharmacies will result in a benchmark that will not ultimately reflect the prices at which retail pharmacies purchase medications.

As a result, in both these matters, CMS has erred in its final definition of AMP. That is because the AMP definition in the final regulation includes sales to entities that are not traditional pharmaceutical wholesalers and to entities that are not traditional retail pharmacies. Only community pharmacies that dispense outpatient drugs to Medicaid beneficiaries – traditional chain pharmacies, independent pharmacies, mass merchandise pharmacies, and supermarket pharmacies – should be included in the definition of retail class of trade.

The AMP definition in the final regulation would create only a marginally useful reimbursement metric since it would represent everyone's prices, but no ones' prices. By including retail pharmacy sales, mail order sales (and accompanying rebates), physician office sales, sales to patients, outpatient hospital sales and clinic sales, CMS has created an AMP that provides little use to the marketplace. However, many may view it as a reliable benchmark for retail pharmacy reimbursement.

Requirements Relating to Mail Order and PBM Rebates: CMS did appropriately exclude PBM rebates for non-mail order sales from the calculation of AMP, but then required manufacturers to include "discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs to the retail pharmacy class of trade." This latter phrase could include manufacturer rebates paid to PBMs for drugs sold to retail pharmacies.

Mail order pharmacies are not a segment of the retail pharmacy class of trade and are generally not accessible by the general public. Mail order pharmacies are not generally "open to the public" like most traditional retail pharmacies and their sales should be excluded from manufacturers' calculations of AMP. Medicaid beneficiaries cannot walk into a mail order pharmacy to obtain a prescription, and there is limited ability for patients to obtain a prescription from a mail order pharmacy unless they belong to a health care plan that includes mail order as part of its benefit design. Moreover, given that CMS proposes to use AMP to set Medicaid reimbursement for drugs and virtually all of Medicaid covered outpatient drugs are dispensed by traditional retail pharmacies (not mail order pharmacies), it only stands to reason that only prices available to traditional retail pharmacies be included in the calculation of AMP.

In addition, we urge CMS to exclude all PBM rebates associated with mail order pharmacies from manufacturers' AMP calculations because traditional retail pharmacies do not have access to these special prices. The inclusion of these price concessions would result in AMP being lower than the average prices paid to manufacturers by wholesalers for drugs distributed to retail pharmacies.

In addition, it is not likely that all manufacturers can distinguish between PBM rebates associated with non-mail order pharmacies and those associated with mail order pharmacies. This may result in manufacturers inadvertently including some PBM rebates in error which would result in inconsistencies in the reporting of AMP data. This is especially the case given that CMS has included an "adequate documentation" requirement. CMS can eliminate confusion for manufacturers by excluding all PBM rebates – for mail order and non mail order sales.

Finally, and most important, rebates paid by manufacturers to PBMs do not fall within the statutory definition of AMP. That is, AMP should include only prices paid to manufacturers by wholesalers. PBMs are not wholesalers, therefore the rebates paid to them by manufacturers do not fall into the framework for what manufacturers should include and exclude from AMP.

Requirements Relating to Adequate Documentation: The final regulation requires manufacturers to include sales to wholesalers in the calculation of the AMP, "except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities...". These excluded sales would include, among others, nursing homes, non-mail order PBM rebates, and inpatient hospital sales. However, manufacturers have contended that they often times do not know how their products are ultimately distributed after they are sold to the wholesaler.

This provision would appear to place the burden on the manufacturer to show why they excluded certain sales from AMP by documenting that they were, in fact, sold to an excluded entity. This may result in manufacturers adopting a more conservative approach to calculating AMP by including more sales in the AMP than they would otherwise need to, if they do not believe that they can provide adequate documentation as to why particular sales were excluded. This could have the effect of lowering the AMP and thus creating a reimbursement metric that does not reflect retail pharmacy purchasing costs.

Manufacturers should only include those AMP data that they can indicate was sold to retail pharmacies. The burden should be on the manufacturers to demonstrate why a particular sale should be included in AMP, not why a particular sale should be excluded from AMP.

Issues Relating to Associated Retail Pharmacy Sales: The final regulation also permits manufacturers to include in the AMP, "rebates, discounts, and other price concessions...associated with the sales of drugs to the retail class of trade." CMS indicates that the term "associated with" means with respect to the AMP calculation, that manufacturers should include all sales and associated rebates, discounts, or other price concessions which relate to the sale, unless those sales, rebates, or other price concessions are excluded by statute or regulation. Applying this to PBM rebates, manufacturers may include all PBM rebates in the calculations of AMP unless the manufacturer has "adequate documentation" that the rebates are associated with mail order pharmacy sales.

Other AMP Calculation Issues: We agree with the clarification in the final regulation that customary prompt pay discounts extended to wholesalers are a specific type of cash discount that is excluded from the calculation of AMP. We also believe that chain pharmacy distribution centers that function as and are licensed as wholesalers are also eligible for these prompt pay discounts that would be excluded by manufacturers from AMP.

With appreciate that "distribution services" qualify as bona fide service fees that are excluded from the calculation of the AMP. Our distribution centers purchase drugs from manufacturers and act as wholesalers in terms of distributing these drugs to our thousands of pharmacies. Thus, customary prompt pay discounts receive by our distribution centers from manufacturers as well as any service fees provided by manufacturers to our company for distributing these products should be excluded from the calculation of AMP. A provision in the final regulation that excludes these discounts from being excluded from AMP if the they are passed along to the customer of the entity (in this case the Rite Aid distribution center) obviously should not apply given that we own both the distribution centers and the pharmacies.

In addition, pharmacies sometimes receive payments from manufacturers for performing certain patient care programs, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation because they do not reflect prices paid by wholesalers for drug products. These services provide valuable benefits to patients and the health care system because they improve patients' understanding of their medications and enhance patient compliance. They do not reduce the retail pharmacy's cost of purchasing the drugs.

If these payments are included in AMP, pharmacies would not have incentives to conduct these programs because it would reduce the value of the AMP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, since not all pharmacies participate in these programs, it would be unfair to include these payments in the AMP.

Calculation of AMP for Authorized Generic: We agree with the final regulation that a separate AMP should be calculated for the brand name drug and its authorized generic. CMS has originally indicated in its proposed regulation that a single weighted AMP would be calculated for all the sales of the originator drug and the authorized generic. Using a single AMP for these two products could reduce pharmacy reimbursement for the branded version of the drug below its approximate acquisition costs since the sale of the authorized generic – likely at a lower price than the brand – would reduce the AMP for the brand. It would also reduce rebates paid by manufacturers to states for the brand version of the drug.

Policies Relating to Public Release and Use of AMP Data

We do not believe that disclosure of outdated AMP data for each dosage form and strength of each covered outpatient drug is in the best interest of public policy. However, if at some point in the future, if AMP data are to be made public through a CMS-developed-website, we believe that CMS should provide strongly-worded, easily-visible disclaimers on the website that such AMP data:

- Are outdated and not current, because AMPs on the website were calculated using sales transaction data that are anywhere from 3 to 6 months old, depending on whether it is a quarterly-calculated AMP or monthly-calculated AMP;
- Do not reflective of the prices actually paid by retail pharmacies, but are blend of prices of various outpatient purchasers of prescription drugs (as least as published in the final regulation dated July 17th, 2007);
- Are not prices paid by or the cost to the ultimate purchaser because they are prices paid to manufacturers by wholesalers, not prices charged by wholesalers to the ultimate purchaser, or reflective of the ultimate cost to the purchaser to distribute them to their terminal outlets;
- Do not reflect the total cost of the prescription to the consumer because they do not include dispensing costs.

We also do not understand the rationale of publishing monthly and quarterly AMP data for a particular NDC. The website will be confusing enough for the marketplace without having two different AMP values. CMS must also explain the differences between these values on the website.

We also believe that only a single AMP for all manufacturers' versions of each dosage form and strength of a generic drug should be published, not an AMP for each manufacturer's version. That is because there are likely to be wide ranging values to the AMPs for the same generic drug, depending on that manufacturer's AMP calculation assumptions and the timing of the manufacturers' rebates and discounts. The wide ranging AMP values will provide little useful value to the marketplace but might send incorrect signals to other payers and purchasers of the true costs to pharmacies to purchase generic drugs. This can have not only a devastating effect on pharmacies, but force some generic manufacturers from making certain products, or put some out of business totally.

The posting of inaccurate AMP data on a public website would be detrimental to patient access and the retail pharmacy industry. Given that CMS now is collecting data under the new AMP methodology, it should take this opportunity to analyze the data the potential validity and reliability of the data for reimbursement purposes.

Policies Relating to the Calculation of the Federal Upper Limits

With respect to the calculation of the Federal Upper Limits (FULs) for generics, we believe that only those multiple source generic drugs that are therapeutically and pharmaceutically equivalent (as listed in the FDA *Orange Book*) to the innovator drug product, as well as those that are nationally and widely available in all states for pharmacies to purchase, should be used to calculate FULs.

In the past, CMS has not always made a determination that products used to set the FULs were nationally and widely available. This has sometimes resulted in FULs that are lower than widely available market prices, underpaying pharmacies for their full total costs of dispensing generic prescriptions. At times, CMS has also failed to respond appropriately to sudden changes to market situations that have warranted the removal or modification of FULs. We appreciate the times that CMS has responded to requests by the industry for changes in the FULs.

FULs Based on State Availability: The statute is clear that CMS must determine that drugs used to set FULs are available in each state for purchase by pharmacies. That is, the statute indicates that a multiple source drug is one that is "sold or marketed in the state during that (rebate) period". A drug is considered to be "Sold or marketed in the state if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State."

In the final regulation, CMS did not establish a requirement that a multiple source drug was to be sold or marketed "in the state" before it could set an FUL. In fact, the final regulation indicates that CMS only will determine if the multiple source drug is sold nationally.

The final regulation makes no reference to the statutory requirement that multiple source drugs be sold or marketed in the state, or that the products be listed in a national listing of average wholesale prices." "National availability" does not always guarantee that drug products are available in each state in sufficient supply. Consequently, in any final future regulation, CMS must develop a methodology to determine that each multiple source drug is available in each state before an FUL can be set.

Thus, CMS must revise this section of the regulation to assure that FULs are only set on 1) therapeutically and pharmaceutically equivalent drug products where two or more distinct products are listed in the FDA *Orange Book*; 2) drug products that appear in a national listing of average wholesale prices selected by the Secretary; and 3) are sold or marketed in the state during that rebate period and are generally available to the public through retail pharmacies in that State. CMS must in our view determine that a drug product is generally available in each state before it could qualify as a multiple source drug that would be subject to a FUL.

Use of Weighted Average AMP: We also believe that CMS has the authority from the DRA to calculate the FULs for each multiple source drug based on the weighted average of the AMPs for that drug. We do not believe that CMS has to use the lowest AMP. Use of weighted average would assure that the reimbursement metric captures a wide range of market prices for generic drugs, and does not rely on the prices of small generic suppliers or those products that were simply "dumped" in the market by a generic company that was seeking some part of the market share. Use of these AMPs would obviously result in market prices that are not widely and generally available to retail pharmacies.

Outlier Policy: We also believe that the final outlier policy does not adequately address concerns that very low AMPs could ultimately be used to set FULs. This would underpay pharmacies for generic medications, potentially reducing incentives to dispense lower-cost generic medications.

In its final regulation regarding the setting of the FUL, CMS would discard the lowest AMP if it is less than 40 percent of the next highest AMP. However, this does not address situations in which the lowest AMP is less than 40 percent of the next highest AMP, and that AMP is also less than 40 percent of the next highest AMP (Example Below: Product #1 AMPs), or the case where the lowest AMP may be greater than 40 percent of the next highest AMP (Product 2 AMPs below), but that AMP is also low. CMS has said it would only discard the lowest AMP, even if the next highest AMP is also less than 40 percent of the next highest AMP. A table showing these issues is provided below.

In the first case, the product with the 2.5 cents AMP would be discarded, but the 7 cents AMP would be used, even thought it is less than 40 percent of the next AMP. The FUL for this product would be 17.5 cents, although no other suppliers' AMPs would be below 17.5 cents. The pharmacies buying at a higher price would either have to take a significant loss on that generic, or hope that their low-margin generic suppliers would be willing to lower their prices. That would be a significant reduction in the prices that generic companies are charging pharmacies, and may not occur. (This doesn't account for the fact that many states have MAC programs that are even lower than the FULs.)

In the second case, the 3 cents AMP would not be discarded because it is greater than 40 percent of the next highest AMP, even though the FUL would be 7.5 cents. This FUL would clearly not capture the majority of the pricing in the marketplace, significantly underpaying almost all retail pharmacies.

We believe that this outlier policy could result in cases where the FUL – even at 250 percent of the lowest AMP – would underpay retail pharmacies for generic drugs. This situation is best addressed by use of a weighted average AMP as the basis for the FULs. This weighted average would reflect the wide range of market prices, and use of "weighting" would thus make it reflect the purchasing power of those entities that are able to obtain the best prices.

Short of adopting a weighted average policy, CMS should find a way to discard any AMPs that are not reflective of the generally available market prices. This could be done by averaging all the AMPs and discarding AMPs that are beyond a certain percentage of the market average.

Product #1 AMPs	**Product #2 AMPs**
22.5	22.5
21	21
20	20
19.5	19.5
7 (37% next)	7 (37% next)
2.5 (36% next)	3 (43% next)
FUL is 10.5 cents	**FUL is 7.5 cents**

We are also hearing anecdotal information from generic manufacturers that many of their AMPs for the month of October, which were reported at the end of November, are either below their best contract prices, or are negative or zero. If AMPs are below best contract prices, that means that either manufacturers are not smoothing their rebates and discounts appropriately, or are including sales other than traditional retail pharmacy sales (as the final regulation requires) that is lower the AMP below that of traditional retail pharmacy sales. This may mean that manufacturers will have to substitute the last positive AMP number they calculated in order to report any AMP for a month.

This obviously is not a positive development for reimbursement purposes, as these AMPs will not reflect current market prices. These types of serious problems with AMP cannot simply be "fixed by the marketplace", or be fixed by the fact that the lowest AMP is increased by 250% to determine the FUL. CMS must provide for some type of appeals process for products that have an FUL that is lower than widely available market prices, that are in short supply and subject to upward pricing pressures, or should not have an FUL at all.

In addition, manufacturers need to be sure that they "smooth" their AMP data and the associated discounts over a rolling twelve month period of time to avoid wild fluctuations in AMP. While CMS agrees that manufacturers should use this approach, CMS did not provide a detailed methodology to achieve this in the final regulation as they did with the Medicare ASP Part B drug final regulation.

CMS may want to consider a more descriptive methodology to give direction to manufacturers regarding the smoothing process. This will eliminate some of the need for manufacturers to make assumptions when calculating their AMPs.

If an AMP value is recalculated by a manufacturer after the time that it has been reported to the States by CMS, these restatements should not be used by the states as the basis for reducing reimbursements that have already been paid to pharmacies. This potential scenario could cause significant disruption to pharmacies as recoupment activities will be labor intensive and could result in unfair treatment of pharmacies. Few pharmacies have the manpower to review recoupments from AMP adjustments for a 36 month period, and thus there will be little opportunity for pharmacies to review and verify the appropriateness of any Medicaid recoupments.

With respect to the number of products that are subject to FULs, only those products that have two or more distinct therapeutically and pharmaceutically equivalent products listed in the FDA *Orange Book* should be subject to FULs. That is, authorized generics generally are not separately listed in the Orange Book, but are marketed under the originator manufacturer's NDA. Only when the first true ANDA is listed in the Orange Book should CMS set an FUL. This would mean that three generic products would have to be marketed – two under the NDA and one under an ANDA – before an FUL should be set on the product.

Use of Retail Survey Price (RSP) Data

Rite Aid is concerned about the release to states and the public of Retail Survey Price (RSP) data. CMS has indicated that it will provide these data to states, which are supposed to represent the average reimbursement received by pharmacies in a month for each Medicaid outpatient drug. In theory, this RSP amount would represent a blend of third party payments and cash prescriptions. However, in an earlier iteration of the RSP calculation, we understand that the RSP would include not only retail pharmacy prices, but those of mail order and long term care.

We would have concerns with including mail order and long term care prices in RSP, similar to the concerns that we have including these in AMP. If these prices are included, RSP will provide inaccurate data to the states about the reimbursements being received by retail pharmacies. We also believe that these data will be outdated, and not reflect current market prices for drugs. We urge CMS to refine any RSP data that may be reported to the states to include only prices received by traditional retail pharmacies. We also do not believe that CMS has the legislative authority to release these RSP data to the public.

We thank you for your consideration of these comments and ask that you contact us with any questions. We can be reached at jcoster@riteaid.com or 703-888-0859. Thank you.

Sincerely,

John M. Coster

John M. Coster, Ph.D., R.Ph.
Vice President, Federal Affairs and Public Policy

HDMA
Healthcare Distribution
Management Association

December 27, 2007

VIA HAND DELIVERY

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

CMS File Code: CMS-2238-FC

Federal Register
Publication Date: July 17, 2007

Dear Mr. Weems:

The Healthcare Distribution Management Association (HDMA) appreciates this opportunity to provide public comments on Final Rule CMS-2238-FC, "Medicaid Program; Prescription Drugs; Final Rule (the AMP "Final Rule") published in the *Federal Register* on July 17, 2007.[1]

HDMA and its members are committed to patient safety by delivering life-saving health products and services through a secure and efficient healthcare distribution system. These primary, full-service healthcare distributors are responsible for ensuring that billions of units of medication are safely delivered each year to tens of thousands of retail pharmacies, nursing homes, clinics and providers, in all 50 states. HDMA and its members are the vital link in a healthcare system that assures medicine safety, quality, integrity and availability in the marketplace. HDMA and its members focus on providing value, removing costs and developing innovative solutions to deliver care safely and effectively.

EXECUTIVE SUMMARY

HDMA has limited its comments on the AMP Final Rule to those issues of primary importance to wholesalers. We have endorsed aspects of the proposal with which we agree, have identified those areas of disagreement that we believe deserve additional consideration and have provided explanations for our positions and recommendations for revisions to those aspects of the AMP Final Rule that are of concern to our members. The following is a brief summary of the key suggestions we have made for improving the AMP Final Rule:

[1] *71 Fed. Reg. 39142 (July 17, 2007).*

- **Bona Fide Service Fees:** HDMA supports CMS' decision to exclude bona fide service fees from AMP. We believe that the principles applicable to the treatment of bona fide service fees for ASP under the 2007 Physician Fee Schedule Final Rule should also apply to determinations of AMP under Medicaid. These principles are appropriate for pharmaceutical distribution practices and ensure consistency under both ASP and AMP reimbursement methodologies.

  HDMA also strongly urges CMS to reconsider its position that related administrative services fees that manufacturers pay to wholesalers for administering discounted contracts with the manufacturer's customers (such as manufacturer chargeback contracts), do not qualify for treatment as bona fide service fees and thus are not excluded from the calculation of AMP. These services are vital to improving the economic efficiencies of the supply chain and payments for theses services should be excluded from the AMP calculation as bona fide service fees.

- **Mail Order Sales:** HDMA remains opposed to the inclusion of sales to mail-order pharmacies in AMP. Due to the limitations inherent in the organizational structure of many mail-order pharmacies, substantial numbers of mail-order pharmacies are not able to meet the criteria of being open to the general public, and therefore should be exempted from AMP. Taking this approach would eliminate any distinction between retail and mail-order PBM sales and result in both being excluded from AMP.

  If CMS determines that mail-order sales should remain in the retail pharmacy class of trade, we urge CMS to require manufacturers to report monthly AMPs at the 11-digit NDC level so that it can use the AMP for the package size most commonly dispensed at retail to set FULs. To avoid disruptions to the Medicaid drug rebate program, CMS would continue asking manufacturers to report quarterly AMPs calculated as a weighted average at the nine-digit NDC level.

- **Other Sales Included in the AMP Calculation:** Hospital outpatient departments, sales to physicians, and specialty pharmacies do not serve the general public and, as a result, sales to such entities are not in the retail pharmacy class of trade, and should be excluded from AMP under the final rule.

- **Weighted Average AMP or Cumulative Market Share Methodology:** HDMA believes that establishing FULs using the weighted average AMP of the therapeutically equivalent products available in the market, instead of the AMP of the least costly product, is the most effective way to ensure that FULs are determined on the basis of pricing available to a significant portion of the market.
  If CMS is unwilling to adopt this approach, the AMP Final Rule should include a FUL outlier methodology that examines AMPs on a cumulative market share basis, starting with the lowest AMP and rejecting the next, higher AMP until a cumulative market share of 50% has been reached. This approach would allow CMS to set FULs based on a criterion that distinguishes between low-priced NDCs available only on a limited basis and NDCs priced at true market levels and available in quantities sufficient to satisfy retail pharmacy demand.

  If however, CMS elects to adopt an outlier methodology that uses price as an indirect proxy for availability, the screening percentage used should be set at 50% of the next lowest AMP. The price comparison test should be applied iteratively until the lowest AMP that is within 50% of the next lowest AMP has been identified.

DETAILED COMMENTS

1. Bona Fide Service Fees

HDMA acknowledges and supports the CMS position that bona fide services fees should not be taken into account for the purposes of determining AMP (Average Manufacturer Price). CMS' exclusion of bona fide service fees from the AMP calculation in 42 C.F.R. § 447.504 (h) (19) of the AMP Final Rule issued by CMS in July, 2007 is appropriate from the standpoint of wholesale pharmaceutical distribution industry practices, as well as consistent with its treatment of bona fide services fees under the ASP (Average Sales Price) calculation for Medicare Part B drugs.

We applaud CMS' decision to adopt the principles and positions applicable to bona fide service fees outlined in the 2007 Physician Fee Schedule (PFS) Final Rule in the ASP context for purposes of AMP determinations under Medicaid. The distribution industry particularly appreciates the decision by CMS to expressly incorporate by reference the interpretation of the definition of bona fide service fees found in the preamble to the 2007 PFS Final Rule in the preamble of the AMP Final Rule, which implements the Medicaid prescription drug provisions of the DRA.

HDMA provided extensive input on the subject of determining fair market value (FMV) in its comments on the 2007 PFS Proposed Rule[2]. The discussion of FMV in the context of service fees that CMS presented in the preamble to the 2007 PFS Final Rule is consistent with our position and the views expressed in our comments to the 2007 PFS Proposed Rule. HDMA believes that the same approach is appropriate in the context of FMV for service fees under the AMP Final Rule. HDMA is of the view it is not necessary to precisely define FMV per se in the wholesaler service fee context.

Chargebacks

In the preamble to the AMP Final Rule, CMS discussed whether certain fees manufacturers pay wholesalers for administering discounted contracts with the manufacturers' customers (chargeback contracts) would qualify for treatment as bona fide services fees and therefore be excluded from the calculation of AMP. CMS indicated that it does not believe that administrative services fees related to manufacturer chargeback contracts would qualify as bona fide service fees because such fees are not associated with the "efficient distribution of drugs". With respect to the status of certain fees for inclusion as bona fide services fees, CMS commentary contained in the 2007 PFS Final Rule explained that bona fide services "encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs."[3] They include services that "the manufacturer has the capacity to perform, and those that can only be performed by another entity."[4] In contrast with the position CMS espoused in the AMP Final Rule, this description certainly appears to encompass the fees manufacturers pay distributors for both administering contracts and processing chargebacks.

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[2] *71 Fed. Reg. 48981 (Aug. 22, 2006).*
[3] *71 Fed. Reg. at 69668.*
[4] *Id.*

One of the most crucial services provided by distributors to maintain and improve the economic efficiencies of the supply chain system for suppliers and providers is the administration of manufacturer chargebacks. Chargebacks are manufacturer discounts handled through wholesalers. Manufacturers negotiate discounted prices with certain purchasers who then purchase the manufacturer's products through wholesalers. Wholesalers must purchase the products at the manufacturer's non-discounted price, and then invoice the products to the contracted customer at the negotiated discounted price. Wholesalers then report the transaction and request reimbursement from the manufacturers for the difference between the price paid by the wholesaler, and the discounted price at which the product was delivered to the manufacturer's contracted customer.

Without the manufacturer chargeback system, providers would have to give up convenience in product ordering and savings in inventory costs and buy directly from each manufacturer to obtain discounts on prescription drugs. Because wholesalers administer manufacturer chargebacks, healthcare providers are able to maximize both the savings associated with manufacturer discounts and the savings that accrue from one-stop shopping and just-in-time delivery through a wholesaler.

The pervasiveness of the chargeback service in today's efficient supply chain enables providers to negotiate discounts with manufacturers without compromising the provider's need for order consolidation and daily delivery of product. It is clear that the manufacturer chargeback system does, in fact, contribute to the efficient and cost-effective delivery of goods to providers with the bargaining power to negotiate discounted pricing with drug manufacturers. According to a recent manufacturer survey, manufacturers reported that a median of 83% of prescription sales measured by dollar sales volume were covered by contracts with their customers in 2006 [5]. A large portion of these sales required chargeback processing or other administrative services provided by wholesalers. In the retail pharmacy market, the majority of chargeback sales involve generic drugs.

Because of the importance of the manufacturer chargeback system to healthcare savings, HDMA urges CMS to clarify that contract administration services and chargeback processing constitute bona fide services when it finalizes 42 C.F.R. § 447.504. This clarification would eliminate current confusion of manufacturers unable to reconcile the definition of bona fide service fees contained in the 2007 PFS Final Rule and their understanding of the importance of the manufacturer chargeback system. Fees paid to distributors for chargeback processing services and services related to the administration of contracts should qualify as bona fide services fees because these services are reasonable, necessary and contribute substantial value to transactions associated with the efficient distribution of drugs.

2. Mail Order Sales

We remain opposed to all inclusion of sales to mail-order pharmacies in the calculation of AMP, and ask that all mail order sales, including PBM mail-order sales, be exempted from the AMP calculation under the AMP Final Rule.

[5] *2007-2008 HDMA Factbook*

The definition CMS has suggested for retail pharmacy class of trade, as indicated in 42 C.F.R. § 447.504(e), is based on whether an entity sells drugs to the general public. CMS' rationale for excluding sales to long term care pharmacies from the calculation of AMP was that such pharmacies are closed operations that serve only the qualifying residents of specific long term care facilities, and are not designed to serve as pharmacies inviting walk-in customers and participation from the general public. The same rationale should apply to mail-order pharmacies. A substantial number of mail order pharmacies are affiliated with PBMs or third party payor health plans that administer their own pharmacy benefits. These mail-order pharmacies are not open to members of the general public because most members of the general public are not qualified to enroll as participants or beneficiaries under these sponsoring health plans. Under such plans, specific member qualification requirements are established by the organizations that operate mail order pharmacies (such as employment by a plan sponsor, full-time employee status, etc.), so access by members of the general public to any particular mail-order pharmacy is limited. Thus, these mail-order pharmacies are closed operations in the same manner that long term care pharmacies are closed operations.

Moreover, mail-order pharmacies do not meet the availability to the general public criterion in another important way. The inherent turn-around time on mail-order processing and delivery operations cannot adequately meet the acute pharmacy care needs of the limited population of individuals enrolled or otherwise qualified to use a mail-order pharmacy. Enrollees of health plans with mail-order access must revert to a conventional brick-and-mortar pharmacy when treatment cannot wait for medications to be delivered through the mail-ordering system, or when the expected treatment regimen involves only a single course of therapy lasting a matter of days to a few weeks.

We understand that most pharmaceutical manufacturers currently code mail-order pharmacy sales and brick-and-mortar pharmacy sales as sales to different classes of trade because mail-order pharmacies buy in pallet quantities, not the bottle and vial quantities that conventional pharmacy outlets need to stock their shelves. Consequently, a decision to exclude mail-order pharmacies from the AMP calculation would not present manufacturers with either operational difficulties or sales calculation obstacles.

Many HMO and MCO plans offer a mail-order benefit option, either through the plan's internal pharmacy operation or by outsourcing the administration of the benefit under a contractual agreement with a PBM. Under the AMP Final Rule, drug sales reimbursed by third party payers, including HMOs and MCOs that take possession of drugs, are excluded from the AMP calculation.

The rationale for excluding sales where the HMO or MCO takes possession is that the third party payer is providing services only to its own members - not the general public - and thus, the sale is not part of the retail pharmacy class of trade. In contrast, mail-order sales by a PBM are included in AMP. We do not believe that a third party payer's decision to provide mail-order benefits directly to its members or to outsource that service through a third party vendor such as a PBM should determine whether a mail-order sale is excluded from or included in the AMP calculation. For all practical purposes, whether an HMO or MCO takes possession or ownership of drugs provided via mail-order to health plan enrollees or outsources its mail-order services to a PBM does not change the fact that the mail-order services are limited to the health plan's enrollees and not available to any member of the general public interested in mail-order delivery.

Given these operational facts, we urge CMS to strongly reconsider the position it took in Manufacturer Release No. 29 and in the AMP Final Rule and, instead, add sales to mail-order pharmacies to the list of sales that must be excluded from the AMP calculation. Of course, doing so would also eliminate the need for manufacturers to net out discounts, rebates, or other price concessions paid to PBMs and health plans on sales of drugs to their mail-order operations when they determine AMP.

PBMs

CMS considers PBM mail order sales to be within the retail pharmacy class of trade and they are listed among the types of sales, rebates, discounts or other price concessions included in the calculation of AMP under the final rule. Under the final rule, CMS distinguished its treatment of PBM mail-order sales from all other PBM transactions. Although we support the decision to exempt all non-mail order PBM transactions from the AMP calculation, for the reasons discussed above, we believe that the decision should have been extended to all PBM transactions, even mail-order sales, without distinction. PBMs' participatory roles are performed as closed operations, not extending to the general public. It would be more consistent with other CMS determinations to treat PBM mail-order sales like prescription mail-order benefits available under HMOs and MCOs that take ownership or possession of the drug, and which are designed and marketed as restricted access or closed panel operations.

We believe therefore, that the treatment distinguishing PBM mail-order sales from PBM transactions generally is without merit, and ask that all PBM transactions, both mail-order and retail be excluded from the AMP calculation when CMS finalizes 42 C.F.R. § 447.504.

Nine Digit v. 11 Digit NDC Numbers

HDMA is of the view that it is critical for CMS to revisit its 9-digit v.11-digit NDC choices if it concludes mail-order sales should remain in the retail class of trade when it finalizes the AMP regulation. Otherwise, reported AMPs for multi-source tablets and capsules will be more heavily weighted towards prices available on larger bulk purchase package sizes. Prices weighted toward larger package sizes will disproportionately lower the reimbursement levels for conventional retail pharmacy purchasers of multi-source drugs that, under the normal course of business, purchase smaller package sizes.

During the comment period for the proposed AMP rule, HDMA advocated that the final AMP rule should require calculating AMP for each package size at the 11-digit NDC level. CMS rejected that rationale and decided to retain the requirement for the calculation of AMP across all package sizes at the 9-digit level. CMS indicated that using a weighted AMP calculated at the 9-digit NDC level would result in adequate reimbursement and would adequately reflect pricing for all package sizes.

The problem with using the 9-digit weighted average AMPs will become evident when the weighted average is controlled by a high volume of sales of a larger-sized package with a lower per-unit cost, as compared with smaller package sizes of the same drug, strength and dosage form. Conventional pharmacies could be under-reimbursed when FULs for multi-source product used to treat common chronic ailments like high blood

pressure are set based on AMPs that are skewed toward the lower prices routinely available on the large package sizes that mail-order pharmacies typically buy (e.g., 5000 v. 100s). This price distortion will then be further exaggerated by the volume discounts often available to mail-order pharmacies. The problem with 9-digit AMPs likely will become acute with multi-source products commonly distributed in unit-of-use packages. For example, the per-unit cost of an ointment in a larger 60-gram tube may be substantially less that the unit cost of the same product in 15-gram tube. However, pharmacies would have no choice but to dispense the smaller tube, regardless of the cap the product's FUL places on reimbursement, in order to comply with a physician's prescription that specifies the unit-of-use package size.

Retaining the 9-digit level NDC calculation for reimbursement purposes could discourage current and future efforts to develop improved product packaging techniques designed to increase patient safety and enhance patients' ability to comply with prescription medication requirements in home-use settings. Medications such as Metrol and certain Hepatitis C drugs are designed for patient use according to specific unit-of-use package size levels. There would be no incentive for continuing the development of product packaging designed to enhance patient safety and improve patient compliance with prescription medication requirements – packaging which tends to make drugs more expensive than when they are supplied in bulk containers of pills – if monthly AMPs continue to be calculated and reported at the 9-digit level and skewed by large package size, high volume purchases by mail-order pharmacies.

Since the statutory definition of AMP does not mandate calculation of a weighted average across all package sizes, it is clear that CMS retains the authority to require manufacturers to submit monthly AMP data at the 11-digit NDC level while also requiring them to calculate and report quarterly AMP data at the 9-digit NDC level to facilitate the collection of rebates using the data management systems already in place at CMS, at the states and at the manufacturers. By adopting this dual approach to data reporting, CMS could gather more accurate data to set FULs reflective of the most commonly used package sizes in conventional retail pharmacies without having to disturb existing systems for setting and collecting rebates under the Medicaid drug rebate program and prices under the 340B program.

3. Other Sales Included in the AMP Calculation

Hospital Outpatient Sales

Under the terms of the AMP Final Rule, direct and indirect sales to hospitals where the drug is used in the outpatient pharmacy are considered to be sold under the retail pharmacy class of trade and are therefore included in the calculation of AMP. However, those sales that cannot be clearly identified or otherwise documented as being used in the outpatient pharmacy for outpatient use are excluded from the calculation of AMP.

We acknowledge that sales to walk-up retail pharmacies open to the general public that happen to be located in a hospital should be aggregated with sales to more conventional retail pharmacy outlets, and be treated as sales to the retail pharmacy class of trade for purposes of the AMP calculation. However, we believe that sales to hospitals of prescription drugs furnished to patients that have been admitted to their outpatient department for

care are not retail sales and therefore should not be included in the AMP calculation. As a practical matter, there is no discernable distinction between drugs sold to hospitals for use by their patients admitted on an outpatient basis and sales of drugs that are ultimately administered to the hospital's inpatient population. Due to the admission status of both categories of these hospital patients, sales of drugs used to treat both inpatients and outpatients are neither open nor available to the general public, and therefore should not be included in the calculation of AMP under the Final Rule. Moreover, as is the case in the inpatient situation, third party payers, which include private insurers, Medicare and some Medicaid programs, reimburse for most drugs furnished to eligible beneficiaries during an outpatient stay under the third party payer's medical benefit program, and not under its prescription pharmacy benefit.

Sales to Physicians

In the July AMP Final Rule preamble, CMS reported that many public comments asked the agency to clarify whether sales to physicians are in the retail pharmacy class of trade. Commenters also requested guidance from CMS regarding the treatment of the physician class of trade as it relates to direct and indirect physician sales, since the distinction between direct and indirect sales to physicians was not specifically addressed in the AMP proposed rule.

CMS indicated in section 42 C.F.R.§ 447. 504(g) (13) that sales to physicians fall under the definition of retail pharmacy class of trade and are therefore included in the AMP calculation. The retail pharmacy class of trade definition includes any pharmacy or outlet that purchases, or arranges for the purchase, of drugs from a manufacturer, wholesaler or distributor and subsequently sells or provides the drugs to the general public. To the extent the physician operates to provide drugs to the general public, CMS has determined that sales to physicians should be included within the definition of retail pharmacy class of trade and AMP.

We believe that sales to physicians should be excluded from the AMP calculation. The rationale developed by CMS to determine that such sales qualify under the retail pharmacy class of trade is inconsistent with the agency's treatment of sales to HMOs or MCOs that take direct ownership or possession of drugs. CMS has determined that third party health plans, such as HMOs and MCOs, which take possession or ownership of drugs, are not included in the AMP calculation because the discounts, rebates, or price concessions that the plans receive are not available to the general public. These staff-model plans are buying the drugs for their own use in much the same way that acute care hospitals buy drugs for their inpatient units for their own use. CMS clarified that such discounts, rebates and price concessions to HMOs and MCOs are not included in AMP under 42 C.F.R. § 447.504 (h) (5) of the Final Rule and that sales to hospitals for inpatient use are not included in AMP under 42 C.F.R. § 447.504(h)(4). By the same logic, since physicians take title to and possession of the drugs they buy for administration to their own patients in their offices, those sales, regardless of whether they are direct or indirect, should receive the same treatment as sales to possession-taking HMOs and MCOs and they should be excluded from the calculation of AMP. For the foregoing reasons, we urge CMS to reconsider its determination on physician sales and specifically list all such sales as excluded from AMP.

Specialty Pharmacy Sales

HDMA recommends that specialty pharmacy sales, as listed in section 42 C.F.R. § 447.504 (g)(11) of the July AMP Final Rule should be removed from the list of those sales, rebates, discounts or other price concessions included under the calculation of AMP. Specialty pharmacy sales involve the provision of unique and very customized services to patients with complex and often rare medical conditions. The unique nature of the services attendant to specialty pharmacy sales is comparable to the services offered by long-term care pharmacies. Both specialty pharmacies and long-term care pharmacies are essentially closed operations in that they are designed to serve only a specific class of persons who require specialized reimbursement, safety monitoring and/or drug compliance services in addition to normal dispensing services offered by conventional retail pharmacies. In that sense, specialty pharmacy sales should not be considered as sales to the retail pharmacy class of trade, since such sales do not meet the threshold requirement of being open and available to the general public. Rather, specialty pharmacy sales should be treated like long-term pharmacy sales and excluded from the calculation of AMP.

Moreover, the unique types of drugs dispensed, and the range of patient services provided by specialty pharmacies are not available in traditional retail pharmacies. Many of these drugs, including oncology drugs, often require special handling, storage and/or other preparation that is incompatible with conventional retail pharmacy operations, and the safe and effective use of the drugs often requires the sophisticated coordination of a range of patient care services.

4. Weighted Average AMP, Cumulative Market Share, and Price-Based Approach

HDMA urges CMS to reject a purely price-based FUL outlier methodology in favor of a new approach that takes market-share into account. When FULs are set based upon low AMPs that are not representative of actual, widely available retail market prices, pharmacy reimbursement levels would be established at inappropriate and therefore unrealistic levels. A price-based approach like that in the AMP Final Rule is problematic because AMPs and the FULs derived from them would remain susceptible to unpredictable price volatility due to market dynamics, purchasing practices, and supply and demand.

A price-based approach is subject to unpredictable price volatility. Price volatility can occur for a number of reasons. For example, new entrants to the market are free to offer extremely low and unsustainable prices to a very small sector of the market as a short-term strategy to gain market share for a limited time. Alternatively, a manufacturer may decide to sell a small volume of a short-dated generic product at a very low price to address inventory concerns. Other manufacturers may decide to sell remaining inventory of a product at a clearance price because they are exiting the market for that particular product due to loss of access to a critical raw material. Moreover, certain drug prices may drop dramatically upon the expiration of a manufacturer's exclusive right to sell a drug product, and the introduction of new competitors in the market. In these examples, sales of low-priced products available in volumes capable only of serving the needs of a small percentage of the market could have a substantial and disproportionate effect on reducing AMP to a level that would not accurately reflect actual market conditions. Products priced at such levels would be in such limited supply as to not constitute nationally available prices, as intended by Congress under the DRA.

Weighted Average AMP

HDMA would strongly prefer to see FULs calculated using a metric that is reflective in some way of market share. In our view, the simplest way to ensure that FULs are determined based on pricing available to a significant portion of the market would be to set FULs using the weighted average AMP of the therapeutically equivalent products available in the market, instead of the AMP of the least costly product. This approach would require manufacturers to report sales volumes as well as AMPs on a monthly basis so that CMS could calculate the weighted average AMP for each multi-source product. Manufacturers of drugs covered by Part B of Medicare currently are required to report sales volumes and ASP quarterly so that CMS can set volume-weighted ASPs for HCPCS Codes that aggregate multiple projects. As a result, manufacturers should already have the systems needed to accomplish such reporting.

CMS has the authority to use the weighted averages to set FULs since the DRA does not explicitly specify that FULs must be set at 250% of the lowest AMP for a product family. Rather, under the DRA, CMS is directed to change the regulation at 42 C.F.R. § 447.332 (b) by substituting, "250 percent of the average manufacturers price (as computed without regard to customary prompt pay discounts extended to wholesalers)" for "150% percent of the published price."[6] No express mandate from Congress exists tying FULs to a multiple of the lowest AMP for a product family. Therefore, we believe that CMS continues to retain the discretion to change this aspect of the FUL regulation, pursuant to the authority granted to it under Social Security Act § 1927(e)(4). We request that CMS use that authority to base the FUL on 250% of the weighted average AMP.

Cumulative Market Share Basis

If CMS believes that it has to use a methodology based on lowest AMP, the cumulative market share strategy is a viable alternative to weighted average AMP, and we recommend examining AMPs on a cumulative market share basis. This approach would require manufacturers to report sales volumes along with product AMPs. The cumulative market share approach is based on examining the lowest reported AMP, and then moving up to the next highest AMP iteratively, rejecting AMPs until an AMP representative of sales with a cumulative market share of at least 50% has been reached. This approach would allow CMS to more clearly determine whether a low-priced drug is available only on a "limited basis."[7] Utilizing this methodology should "ensure that a drug is nationally available at the FUL price"[8], because the market-share-based outlier approach will not consider AMPs that were only able, collectively, to satisfy less than 50% of market demand during the reporting period, despite the low price. Such low priced AMPs often do not accurately reflect actual market conditions because products priced at such levels are in limited supply, are highly susceptible to market volatility, and are not available for sale nationally.

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[6] *DRA § 6001 (a) (5)*
[7] *71 Fed. Reg. at 77188*
[8] *Id.*

Price-Based Alternative

We recognize that CMS received many suggestions about which percentage levels should be applied to set the AMP FUL outliers in response to the AMP proposed rule issued in December of 2006. In response to these suggestions and concerns expressed about the adequacy of pharmacy reimbursement under an AMP-based FUL, CMS changed the benchmark for exclusion of the lowest AMP under the outlier AMP methodology at 42 CFR 447. 514 (c) (2) from 30 percent to 40 percent of the next highest AMP. Nonetheless, FULs will still be set based on the lowest AMP after the application of the 40 percent outlier test. We do not believe the FULs will always reflect market prices sufficiently to ensure that drugs are available for sale nationally and that Medicaid patients will have convenient access to pharmacy care. Therefore, we do not support the price-based outlier methodology detailed in the AMP Final Rule.

In the event CMS is not persuaded that a market share methodology would more accurately represent nationally available drug prices, and prefers the price-based approach, we believe that it would be more appropriate to reject any AMP outlier that is 50% or less of the next highest AMP. We suggest that any price outlier test should be applied iteratively until the lowest AMP is selected, regardless of whether satisfying the criteria requires the rejection of a number of lower AMPs. We remain convinced however, that a price-based approach to outlier identification will be inadequate, leaving pharmacies faced with a cost gap that does not adequately cover their acquisition costs for certain products. Accordingly, we urge CMS to reconsider the outlier methodology at 42 C. F.R. 447.514 and to adopt an approach to the determination of FUL that takes market share as well as price into account.

FUL Outlier Recommendation

In summary, HDMA strongly recommends that:

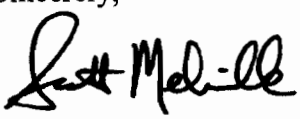
- CMS reject the price-based FUL outlier methodology in favor of a market-share based approach.
- CMS endorse the establishment of FULs based on a weighted average AMP of therapeutically equivalent products available in the market.
- As an alternative, examining AMPs on a cumulative market share basis would enable CMS to more accurately determine product availability under actual market conditions.
- In the event that CMS elects not to accept either of the market share methodologies referenced above and opts for a price-based approach, that it would be appropriate to reject any AMP outlier that is 50% or less of the next highest priced AMP. Such an outlier test should be applied iteratively.

* * * * *

Conclusion

We are grateful for the opportunity to engage in substantive discussions with CMS officials about supply chain issues. On behalf of HDMA and our member companies, thank you for the opportunity to provide our comments on Final Rule CMS-2238-FC. We remain ready to address any questions you may have about the issues, concerns, and suggestions discussed above.

Sincerely,



Scott M. Melville
Sr. Vice President
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GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

December 28, 2007

VIA HAND DELIVERY
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments to the Medicaid Program; Prescription Drugs Final Rule with Comment Period [CMS-2238-FC]

Dear Sir or Madam:

The Generic Pharmaceutical Association ("GPhA") is pleased to submit these comments on the *Medicaid Program; Prescription Drugs Final Rule with Comment Period* ("Final Rule").[1] GPhA shares the commitment of the Centers for Medicare and Medicaid Services ("CMS") to implement the Medicaid Drug Rebate Program reforms mandated by the Deficit Reduction Act of 2005 ("DRA") in ways that save money for the Medicaid program, that are practicable for manufacturers, and that do not adversely impact the care furnished to Medicaid beneficiaries. Accordingly, GPhA appreciates this opportunity to respond to CMS's requests for comments on the Final Rule's discussion of "average manufacturer price" ("AMP") and its outlier policy for calculating Federal upper limits ("FULs") and to address some additional issues of significance relating to these sections of the Final Rule.

GPhA is an association representing the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Together, the members of GPhA manufacture more than 90 percent of all generic pharmaceuticals dispensed in the United States.

As the primary source of generic pharmaceuticals in the country, GPhA members are committed to ensuring patient access to affordable prescription drugs. In our comments on the proposed version of this rule ("Proposed Rule"),[2] we emphasized that continued access to affordable prescription drugs would require CMS to provide

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

manufacturers with clear, precise guidance to ensure that manufacturers understand what is required of them in connection with their calculation and submission of AMP and best price data. We also urged CMS to take care to ensure that compliance with these requirements is, in fact, operationally feasible for manufacturers (e.g., by considering whether manufacturers actually have access to the information that they are required to report).[3] Further, we discussed the widespread detrimental effects that the public posting of manufacturer-specific AMPs in a manner accessible to competitors (as opposed to appropriate Federal and State governmental agencies) would have on the generic pharmaceutical market and, in turn, on consumers, pharmacies, and payers nationwide.

In light of these concerns, GPhA commends CMS for its affirmation in the Final Rule that "[c]larity and consistency of pricing terms is essential for the accurate submission of AMP data" and for its efforts to clarify the definitions of some significant terms as well as the treatment of several sales and prices in manufacturer calculations.[4] However, we continue to have a number of concerns with the Final Rule. Most notably, we urge CMS to reconsider its decision to begin making individual manufacturers' AMP information available to the public at large (including competitors), since this will likely produce a variety of unintended consequences.[5] In addition, we request that CMS modify the Final Rule's requirements as needed to ensure that the AMP data reported routinely are as accurate and consistent as possible across manufacturers.

We open our comments in Section I below by discussing our concerns with public disclosure of AMP data, given the importance of this issue. We then provide comments in Sections II and III below on a number of issues that bear directly on, first, the determination of AMP and, second, the outlier policy for calculating FULs. Within Sections II and III, we organize our various comments based on the corresponding section of the Final Rule in which each issue arises, though we believe all these issues relate more broadly to either the determination of AMP or the FUL outlier policy – i.e., the issues on which CMS has specifically requested comments.

I. Adverse Effects of Public Disclosure of AMP on the Medicaid Program[6]

CMS indicates in the Final Rule that it will begin posting monthly and quarterly manufacturer-specific AMP data for public review on the CMS website when the agency finds the data sufficiently complete and accurate.[7] This decision is one of our primary concerns with the Final Rule, and we wish to take this opportunity to briefly summarize the harmful effects that could be produced by the public disclosure of individual

[3] We note at the outset that this issue of operational feasibility takes on additional significance in light of the certification requirement placed on manufacturers by the Final Rule. Our specific comments on operational feasibility and the certification requirement are provided below in this letter.

[4] 72 Fed. Reg. 39142, 39166.

[5] We understand that CMS is currently enjoined from posting AMP data, and we hope the agency will take this opportunity to revisit its policy on public disclosure of AMP data.

[6] As mentioned above, we are addressing only public disclosure of AMP here and will address other aspects of "Requirements for Manufacturers – Section 447.510," as they relate to the determination of AMP, later in this letter.

[7] 72 Fed. Reg. 39142, 39213, 39223.

manufacturers' AMPs in a manner accessible to competitors.[8] In short, as a matter of economic theory, publicly disclosing manufacturers' most sensitive and proprietary pricing information in a manner that makes this information available to competitors – not just to appropriate Federal and State governmental agencies – will likely ultimately result in reduced competition and higher prices in the generic market, thereby undercutting the benefits that generic pharmaceuticals are widely recognized as bringing to health care cost containment.[9]

In addition, AMPs generally are not representative of market prices but, if made available to the public at large, could be mistaken by purchasers and payers as reflecting widely available prices.[10] In addition to harming manufacturers, this misunderstanding could further harm retail pharmacies, which already face insufficient reimbursement under the Final Rule. According to the OIG, the new AMP-based FULs could be, on average, 36 percent below average retail pharmacy acquisition costs.[11] If payers begin using these new AMP-based FULs with the misperception that AMPs represent widely available prices, many rural and independent pharmacies could be forced to close for economic reasons. Pharmacy closures could, in turn, result in a tremendous patient access problem.

Moreover, under the Final Rule, CMS essentially would be serving as a third party surveying competing manufacturers' AMPs, but would be ignoring the competitive safeguards recognized as crucial by the Federal Trade Commission ("FTC") and the

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[8] We would be happy to provide you with additional information, or discuss with you in more detail, the dangers of publicly disclosing company-specific AMP should you find this helpful.

[9] Although the AMP changes are directed to Medicaid, the impact of those changes will be seen in other government health programs. For example, during his tenure as Administrator of CMS, Dr. Mark McClellan, testified before the Senate concerning the critical role played by generic prescription drugs in cost containment under the Medicare Part D program. "Generic Drug Utilization in the Medicare Prescription Drug Benefit," Testimony before Senate Special Committee on Aging (Sept. 21, 2006), available at http://www.hhs.gov/asl/testify/t060921.html. In addition, CMS issued a press release acknowledging the role of generic drugs in reducing prescription drug costs for both consumers and payers nationwide. "Generic Drug Utilization on the Rise: Consumers and Payers Benefit as More Americans Turn to Generics as One Way to Save Money and Improve their Health" (Feb. 8, 2007), available at http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2081&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

[10] Though often mistakenly believed to indicate market prices, AMPs in fact bear little relevance to market prices for several reasons. For one, a variety of normal business activities (e.g., backorders, temporary discontinuations of certain products) cause periodic deflations or inflations of AMP from month-to-month. Because purchasers and payers viewing these prices on a publicly accessible website would not know the reasons for any extremely low AMPs (e.g., caused by fluctuations in the ordinary course of business or by discounted prices for bulk sales), they might mistakenly think the posted prices are widely available and that the prices they have paid are unreasonable in comparison. Moreover, all the publicly disclosed prices – even those that were not unusually low or temporarily deflated – would represent wholesale prices and not prices to the ultimate consumers, which would include dispensing fees and wholesaler/distributor markup fees. Thus, even publicly disclosed prices that were widely available *as wholesaler prices* would seem low to certain purchasers, who would likely be unaware of the nature of the publicly disclosed prices.

[11] *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs* (GAO-07-239R) (Dec. 22, 2006), available at http://www.gao.gov/new.items/d07239r.pdf.

Antitrust Division of the Department of Justice ("DOJ") for protecting against the potential competitive misuse of such pricing survey data. Specifically, in Statement 7 of the DOJ and FTC's "Statements of Antitrust Enforcement Policy in Health Care," the agencies recognized that "[w]ithout appropriate safeguards . . . information exchanges among competing providers may facilitate collusion or otherwise reduce competition on prices . . . resulting in increased prices, or reduced quality and availability of health care services."[12]

Further, the agencies set forth an "antitrust safety zone" for participation in written surveys of prices by providers. The agencies stated the surveys should: (1) be managed by a third party; (2) pertain to information based on data more than three months old; and (3) ensure that there are at least five participants reporting data on which each disseminated statistic is based, that no individual participant's data represent more than 25 percent on a weighted basis of that statistic, and that any information disseminated is sufficiently aggregated such that it would not allow recipients to identify the prices charged or compensation paid by any particular participant.[13] From an antitrust standpoint, the DOJ and FTC's safeguards for provider price surveys would be just as applicable to price surveys of generic pharmaceutical manufacturers.

While the CMS "survey" (i.e., collection and public disclosure of individual manufacturers' AMPs, pursuant to the Final Rule) satisfies the first criterion, it is inconsistent with the second and third recommendations of the DOJ's Antitrust Division and the FTC for appropriate price surveys. In particular, by not aggregating the pricing information before publicly disclosing it, CMS would be enabling competing manufacturers to have access to individual manufacturers' AMP data. At a minimum, GPhA would strongly recommend that CMS obtain public comments from the DOJ's Antitrust Division and the FTC specifically pertaining to the potentially harmful effects that CMS's survey could have, given that CMS does not plan to aggregate the AMP data before posting them on a publicly accessible website. Unless the antitrust agencies state publicly that they have no objections to the survey described in the Final Rule, GPhA will remain concerned that CMS may be inadvertently exposing survey participants to potentially serious threats of antitrust lawsuits. Such lawsuits would be very expensive to defend and would, as a result, substantially increase manufacturers' costs of doing business and the prices of their products – generic pharmaceuticals – to consumers and government payers.

For these reasons, we recommended in our comments on the Proposed Rule that multiple source AMPs be posted on the CMS website only in an aggregated, industry-wide weighted average format that combined individual manufacturers' AMPs into one AMP for each drug, not in a manufacturer-specific format – so that the individual pricing of an individual manufacturer would not become known to its competitors. We also recommended that, among other things, CMS take the following steps to further prevent the harmful effects of public disclosure of AMP data on the generic pharmaceutical

[12] Department of Justice/Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (Aug. 1996), available at http://www.usdoj.gov/atr/public/guidelines/0000.htm.
[13] Id.

market: (1) provide for a 90-day testing period (after the date on which AMPs are first made publicly available) during which AMP information may be used for research and verification purposes only (not reimbursement purposes), so manufacturers can gain experience with the new system; (2) allow manufacturers to refile monthly AMPs for up to three years after initially submitted, in recognition of the complexity of AMP calculations and of the timing issues surrounding the availability of the data needed in these calculations; and (3) provide a disclaimer with any public disclosure of AMP, identifying the limitations on AMP data and advising purchasers and payers that these data may not necessarily reflect the prices that are available to all consumers.

In the Final Rule, CMS acknowledges our recommendation against making manufacturer-specific AMPs publicly available (in a manner accessible to competitors) but indicates its plan to begin publicly disclosing such data. CMS explains its decision on the grounds that it believes aggregated, industry-wide weighted average AMPs would not bring about the transparency contemplated by the DRA's amendments – transparency that, according to CMS, is intended to help contain prescription drug costs.[14]

In response to CMS's expressed concerns, we wish to point out that: (1) the DRA does not require public disclosure of *manufacturer-specific* AMP data;[15] and (2) the public disclosure of manufacturer-specific AMPs would likely produce the very effects CMS wishes to avoid – i.e., reduced competition and, ultimately, increased prescription drug costs. For the reasons discussed above, our recommendation that CMS publicly disclose only aggregated, industry-wide weighted average AMPs would, in fact, effectuate the intent of the DRA amendments, whereas the policy in the Final Rule, which goes beyond the intent of the DRA, would have the reverse effect. We share CMS's desire to maximize the cost-saving potential of generic prescription drugs, as contemplated by the DRA amendments, and we urge CMS to reconsider our discussion of the probable impacts of publicly disclosing individual manufacturers' AMP data on the generic pharmaceutical marketplace before implementing its decision in the Final Rule – a decision that would, ironically, produce the opposite outcome intended by CMS.

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[14] 72 Fed. Reg. 39142, 39223.

[15] In our view, CMS is statutorily prohibited from publicly disclosing manufacturer-specific AMP data. Section 1927 of the Social Security Act ("SSA") requires manufacturers that enter into rebate agreements with the government to provide various pricing information to the government, including AMP data, and requires that the confidentiality of pricing information received from manufacturers be preserved. 42 U.S.C. § 1396r-8(b)(3)(D). Section 1927 of the SSA specifically prohibits disclosure of data "in a form which discloses the identity of a specific manufacturer or wholesaler" or the "prices charged for drugs by such manufacturer or wholesaler." Id. Prior to adoption of the DRA, Section 1927 provided for three exceptions to this broad rule, and the DRA added two new exceptions to the requirement that the government maintain confidentiality of pricing information provided by the manufacturer, including allowing disclosure of manufacturer-submitted pricing information "to the Secretary to disclose (through a website accessible to the public) average manufacturer prices." Pub. L. 190-171 § 6001(b)(2) (Feb. 8, 2006). The exception permitting the Secretary to disclose AMP on a website accessible to the public must be read in context with its parent paragraph, which prohibits CMS from disclosing any information "in a form which discloses the identity of a specific manufacturer or wholesaler[.]" 42 U.S.C. § 1396r-8(b)(3)(D). Notably, there is nothing in the DRA that addresses the disclosure of the identity of a specific manufacturer. Thus, in GPhA's view, CMS cannot disclose the identity of a manufacturer or the prices charged by such manufacturers. To do so would eviscerate all confidentiality protections established in Section 1927 of the SSA insofar as AMP data are concerned.

In the Final Rule, CMS also indicates that it will consider comments relating to customer and payer confusion (with respect to the meaning of publicly disclosed AMP data) when preparing further guidance regarding the Final Rule's requirements.[16] We appreciate CMS's attention to this issue and encourage the agency to consider the potential damage to the pharmaceutical market – and resultant impediment to health care cost containment – that could result from confusion surrounding publicly disclosed AMP data. As mentioned above, ultimately, if the Final Rule is implemented as is, we believe beneficiaries will be harmed by decreased access to pharmacies.

We also appreciate CMS's partial acceptance of our recommendation that the agency post a disclaimer concerning the various limitations on AMP data along with any public disclosure of these data. Specifically, CMS acknowledges the existence of "limitations" on AMP data and indicates that it will inform States and other relevant parties that monthly AMP data will likely be 45-60 days old when posted.[17] We urge the agency to expand this communication to include a discussion of other limitations on AMP data (especially the fact that these data do not reflect market prices) and to ensure that this discussion also appears on the CMS website in conjunction with any AMP information posted by CMS. Should CMS persist in its decision to post manufacturer-specific data on a website accessible by the public at large (including competitors) – despite the many negative effects we believe this decision would produce – the inclusion of a disclaimer with the posted data would be particularly imperative. In those circumstances, it would be essential for the disclaimer to include a more full discussion of why AMPs fluctuate regularly and sometimes significantly in the ordinary course of business, along with the other limitations on AMP mentioned above.

II. Issues Impacting the Determination of AMP

As noted above, issues raised in Section II of our comments relate generally to the determination of AMP. Some of these issues arise specifically from Section 447.504 of the Final Regulations – the section devoted to the "Determination of AMP" – while others arise from other sections of the Final Regulations. Still, all issues discussed in Section II below present concerns that CMS should address when finalizing its regulation on the determination of AMP.

A. Definitions – Section 447.502

With regard to the "Definitions" section of the Final Regulations, we have one specific comment regarding the definition of "dispensing fee." While the definition of this term itself does not affect manufacturers' calculations of their AMPs, dispensing fees will play a major role in ensuring the continued availability of generics to the extent that States begin using AMP-based FULs to set pharmacy reimbursement. Thus, the practical application of the definition of "dispensing fee" relates to the practical application of AMP under the Final Rule. Because the interplay between these sections of the Final

[16] 72 Fed. Reg. 39142, 39222.
[17] Id. at 39210.

Regulations has such significant ramifications for generic utilization, we discuss our concerns about the Final Rule's treatment of dispensing fees below.

In the Final Rule, CMS notes that it provides a definition of "dispensing fee" to "assist States in their evaluation of factors in establishing a reasonable dispensing fee" and finalizes its proposal not to mandate a specific formula or methodology that States must use to determine the dispensing fee.[18] CMS slightly modifies the final definition from its proposed version (by adding "or service" after "point of sale" in the definition) to recognize different service settings.[19] The Final Rule also indicates that States maintain authority to vary payment rates by rural areas as well as by the type of provider (e.g., for specialty pharmacies) to ensure appropriate reimbursement.[20] Dispensing fees must be approved as part of the Medicaid State plan, and CMS indicates that it will review State requests to change dispensing fees as to their reasonableness.[21] CMS also encourages States to set "reasonable" dispensing fees to appropriately pay pharmacies for their costs.[22]

We commend CMS for explicitly encouraging States to set reasonable dispensing fees. However, we note that there is no requirement in the Final Rule that States must pay a fair dispensing fee that accurately reflects the actual costs associated with providing the full range of pharmacy services. Further, it is not yet clear what CMS will view as a "reasonable" dispensing fee and, as a result, how drastically pharmacy reimbursement will change in light of the Final Rule. This uncertainty raises concern because, with the potential reduction in generic drug reimbursement that will be triggered by the switch to AMP, dispensing fees become increasingly important in ensuring that pharmacies are paid fairly for filling generic prescriptions. This will influence the extent to which pharmacies can promote generic utilization. As discussed in the previous section, generic utilization has been a key force behind the reduction in prescription drug costs for consumers and for the government. Further, the adequacy of dispensing fees will play an important role in determining whether pharmacies will continue to be able to dispense generic drugs and, in fact, whether many rural and independent pharmacies can remain open. Adequate dispensing fees are, thus, essential to the preservation of beneficiary access to pharmacies and to affordable generic drugs.

To preserve these cost-saving opportunities, CMS must keep in mind the need to incentivize generic usage when making changes to the Medicaid Drug Rebate Program. To ensure continued and aggressive dispensing of generic products by Medicaid, CMS should strengthen its encouragement to States to set reasonable dispensing fees by issuing State program releases that advocate fair dispensing fees. CMS's comments in the Final Rule reveal that the agency recognizes the importance of States incentivizing generics, and we urge CMS to interpret "reasonable" (for purposes of evaluating dispensing fee change requests) in a way that appropriately recognizes pharmacies' costs and

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[18] Id. at 39160.
[19] Id.
[20] Id. at 39197.
[21] Id. at 39161.
[22] Id. at 39161, 39169.

encourages generic utilization. In addition, we believe that either States or CMS (or both) must be able to react and adjust dispensing fees as quickly as FULs can change, since a FUL that has decreased from the previous month can have a drastically negative impact on reimbursement, causing the reimbursement for a drug to fall further below the pharmacy's cost of filling the prescription.

B. Determination of Average Manufacturer Price – Section 447.504

In our comments on the Proposed Rule, we made several requests for clarification of the definitions of key terms and of the treatment of specific sales for purposes of the AMP calculation. Our comments also included a number of recommendations for modifications to the AMP requirements that, along with the requested clarifications, would help ensure that manufacturers could actually implement the requirements CMS imposed. Because many of our requests and recommendations reflected general concerns that could have far-reaching implications for every aspect of the calculation of AMP, we take this opportunity to briefly summarize our overarching concerns and to discuss the extent to which CMS addresses these concerns in the Final Rule. Following our discussion of these broad areas of concern, we make a few other suggestions on specific issues in the "Determination of AMP" section of the Final Rule.

1. *Broad Concerns*

a. *Calculation of AMP*

i. *Need for Operational Feasibility*

Our first broad concern is that the requirements for calculating AMP be operationally feasible for manufacturers.[23] While manufacturers are aware of the location of their drug product after the first sale, they frequently have no way of knowing where their products end up after that first purchaser resells or redistributes the product. If manufacturers are required to discriminate among particular types of sales but do not have access to the information that would enable them to do so, then it could be difficult for manufacturers to comply with the requirements through no fault of their own. The AMP data reported will be much more complete and consistent if CMS imposes requirements that are clear and operationally feasible. For these reasons, the agency must be careful to formulate these requirements in consideration of which information is, in fact, available to manufacturers.

In the Final Rule, CMS acknowledges manufacturers' lack of downstream information with respect to sales to hospitals. Whereas CMS had proposed to require manufacturers to include sales to hospitals if the drug is used in the outpatient pharmacy

[23] An understanding of what is operationally feasible requires familiarity with the typical distribution chain for generic drugs. This pathway works as follows: generic pharmaceutical manufacturers distribute their products directly to warehousing chain pharmacies, mail order pharmacies, various managed care entities, wholesalers and distributors (who themselves resell to non-warehousing chain pharmacies, independent pharmacies, hospitals, clinics, etc.).

and to exclude hospital sales if the drug is used in the inpatient setting, CMS acknowledges in the Final Rule that "manufacturers often do not know what drugs sold to hospitals are used in the hospital outpatient pharmacies or other hospital facilities, such as clinics."[24] Accordingly, the Final Regulation requires manufacturers to exclude these sales unless the manufacturer can identify with adequate documentation that the drug was used in the outpatient pharmacy for outpatient use.[25] By providing manufacturers with a default option (i.e., exclude sales from AMP when adequate information is not available), CMS makes compliance with the AMP calculation requirements more operationally feasible for manufacturers in this respect. We commend CMS for this recognition and modification of the requirement.

To account for operational challenges in data collection, the Final Rule allows for the use of reasonable assumptions when specific guidance is unavailable. Throughout the Final Rule, CMS states that, "in the absence of specific guidance, manufacturers may make reasonable assumptions, consistent with the statute, Federal regulations, and customary business practices."[26] In addition, the Final Rule provides that where sales to excluded entities are adequately documented, they should be excluded from AMP.[27] Again, we are grateful for CMS's recognition of the limitations on information available to manufacturers and for the agency's efforts to take these limitations into account in the Final Rule.

The flexibility to make reasonable assumptions may or may not be helpful to manufacturers, since, depending on how CMS interprets "reasonable" in practice, a manufacturer forced to make assumptions (which it believes are reasonable) to address a lack of information needed in its AMP calculation could still be subject to sanction by CMS or other Federal regulators. This outcome would be unfair to manufacturers, since they would be attempting to comply with the regulatory requirements but prevented from doing so through an information deficiency that was not their fault.

Further, while some of these changes made by CMS in the Final Rule may help make the AMP calculation more operationally feasible (e.g., the policy regarding sales to hospitals), the Final Rule does not make other needed modifications. For instance, in addition to hospitals, manufacturers may also experience a lack of information on downstream sales when selling to entities including, but not limited to, wholesalers and mail order pharmacies. To avoid inconsistency or incompleteness in AMP data (by creating AMP calculation requirements that potentially cannot be met), CMS should reconsider its policies with respect to sales to these entities.

We emphasize that our comments regarding operational feasibility arise out of a desire to provide CMS with the most accurate and consistent data possible. While we

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[24] 72 Fed. Reg. 39142, 39173.
[25] Id. at 39241.
[26] Id. at 39164, 39166-39167, 39211.
[27] See, e.g., id. at 39167. Adequate documentation includes, but is not limited to, chargeback data or data from which an outside auditor, certified public accounting firm, CMS, the OIG, or another authorized government agency could reconstruct the transaction.

recognize that the agency may be statutorily bound to issue some requirements that are operationally difficult for manufacturers, we strongly encourage the agency to recognize that it will best effectuate the intent of the DRA by ensuring that its AMP calculation requirements are capable of being met by manufacturers in light of the information actually available to manufacturers. By ensuring that all AMP calculation requirements are operationally feasible for manufacturers, CMS can help guarantee that AMP data reported will be uniform across all manufacturers, which was one of the purposes of the DRA.

Finally, we encourage the agency to issue a regulatory "safe harbor" for manufacturers who rely in good faith on reasonable assumptions either in the absence of specific guidance or in the absence of the information required to complete the AMP calculation in accordance with the Final Regulations. We note that even if CMS begins taking steps to modify the regulations to enhance operational feasibility (as we suggest in these comments), we expect that there could be instances in which the AMP calculation requires manufacturers to use information that is, in fact, unavailable to them – or that is available, at best, only indirectly from third parties. In recognition of this possibility, we urge CMS to issue a regulation clearly indicating that manufacturers may: (1) make reasonable assumptions in those instances when the manufacturer is unable, in the ordinary course of business, to obtain information which may be relevant for the calculation of AMP; and (2) rely in good faith on information provided by third parties. This regulation should also specify that manufacturers will not be held liable for data submissions resulting from information provided to the manufacturer by third parties as long as the manufacturer does not act in reckless disregard of the accuracy and completeness of the information.

ii. *Need for Clarity*

In addition to operational feasibility, we are also concerned about the problems related to ambiguous (or absent) definitions of key concepts related to the AMP calculation. Imprecise definitions could lead to inconsistent treatment of various transactions, so we emphasize the need for CMS to clearly indicate what is meant by certain terms. In particular, in our comments on the Proposed Rule, we requested that CMS unambiguously define the following terms: "repackagers/relabelers," "nursing home pharmacies," and "pharmacy benefit managers" ("PBMs")/"managed care organizations" ("MCOs"). Manufacturers need clear and meaningful guidance from CMS.

In the Final Rule, CMS registers its agreement with one commenter that "[c]larity and consistency of pricing terms is essential for the accurate submission of AMP data."[28] CMS also clarifies the definitions of many terms (e.g., "manufacturer"), as well as the appropriate treatment of certain sales and associated price concessions for the AMP calculation (e.g., sales to hospitals). In addition, CMS notes that it expects to "continue to issue further guidance and answer specific questions to the extent necessary to provide

[28] Id. at 39166.

additional clarity."[29] We commend CMS for its affirmation of the vital importance of clear definitions and requirements, for the clarifications that it does make in the Final Rule, and for its commitment to issuing further guidance when necessary.

However, we note that CMS refrains in the Final Rule from clarifying the definitions of "repackagers/relabelers," "nursing home pharmacies," and "PBMs/MCOs," as we had requested. With respect to the definition of "repackagers/relabelers," CMS indicates that it believes the definition of "manufacturer" sufficiently answers any uncertainty about the definition of "repackagers/relabelers."[30] CMS also declines to define "nursing home pharmacies," indicating that it does not believe such definition is necessary and that manufacturers may make reasonable assumptions in the absence of specific guidance.[31] In regard to PBMs, CMS indicates that because it excludes all PBM price concessions from the calculation of AMP (except for purchases through PBM mail order pharmacies), it does not need to define the "attributes of entities qualifying as PBMs for purposes of including price concessions from such entities and/or establish a list of excluded entities."[32] Regarding "MCOs," CMS acknowledges that its use of this term (as well as the related term "health maintenance organizations" ("HMOs")) varies, and then clarifies that its "intent is that sales to HMOs and MCOs that purchase and take possession of drugs are excluded from AMP."[33] However, CMS does not issue definitions of either of "MCOs" or "HMOs."

Despite these explanations from CMS of its rationale for not defining these terms, we renew our request for definitions for the following reasons. First, we do not believe that the final definition of "manufacturer" adequately explains the meaning of "repackagers/relabelers." Regarding CMS's decision not to define "nursing home pharmacies," we are concerned that the flexibility to make reasonable assumptions may not be helpful and, thus, may lead to inconsistent treatment among manufacturers. Further, the fact that PBM price concessions (except those to PBM mail order pharmacies) are excluded from AMP does not mean that a definition of "PBM" is not needed. Manufacturers still must determine which entities are "PBMs" in order to ascertain whether to exclude from AMP any price concessions to these entities. Similarly, with respect to "MCOs" (and "HMOs"), CMS's direction to manufacturers to exclude sales to these entities from AMP does not in any way eliminate manufacturers' need for clear definitions of these terms.

Further, our specific requests for definitions in our comments on the Proposed Rule were meant to be representative – not exhaustive – of the terms in need of precise definitions. We continue to believe that CMS should provide some definition, or a source for the definition, of all the classes of trade specifically mentioned in the Final Rule. Such terms include (but are not limited to) the following: "home health care," "hospice," and "specialty pharmacy." Definitions of these and other terms relating to classes of

[29] Id. at 39168.
[30] Id. at 39164.
[31] Id.
[32] Id. at 39193.
[33] Id. at 39181.

trade would promote uniformity in customer classifications and, as a result, in the AMP calculation across manufacturers. We believe that CMS intended to create a well-defined AMP to serve as the basis for reimbursement, but in the absence of so many key definitions, CMS necessarily allows for interpretation by manufacturers and leaves open the possibility that AMP calculations could be inconsistent across manufacturers.

b. *Need for Consistency with Medicaid and 340B Programs*

Another issue of particular importance to GPhA is the need for consistency between the Medicaid Drug Rebate and 340B Drug Pricing Programs. Because AMP is used in both the Medicaid and 340B programs, any differences in the definition of "AMP" between these two programs could result in the placement of an undue administrative burden on manufacturers, the creation of unnecessary confusion for organizations involved in the delivery of health care services, and the maintenance of duplicative reporting requirements that would waste time and energy within the Federal programs.[34] In the Final Rule, CMS acknowledges our request (in comments on the Proposed Rule) that CMS work to prevent these problems by coordinating its approach with the agency responsible for administering the 340B program – the Office of Pharmacy Affairs ("OPA"), within the Health Resources and Services Administration ("HRSA"). However, CMS indicates that the question of whether HRSA should use the same definition of AMP for the 340B program that CMS uses for the Medicaid program is beyond the scope of this regulation and that HRSA, not CMS, is responsible for administering the 340B program.[35] Given the changes to the AMP calculation and the implications for the 340B program, OPA sent a letter to manufacturers on May 9, 2007, directing them to comply with CMS's AMP requirements when calculating their 340B ceiling prices – until further notice is given.[36]

We appreciate HRSA's recent recognition (through OPA) of the significance of the AMP calculation requirements on manufacturers, and we support OPA's current approach in directing manufacturers to use CMS's definition of "AMP" for the 340B program as well. Still, we recognize that inconsistencies between each program's definition of "AMP" could arise in the future if OPA decides to institute different AMP calculation requirements on manufacturers. In virtue of the significance of the negative consequences that could result from such a decision, we reiterate our request that CMS work with OPA to address any such inconsistencies. Should the need arise, we urge

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[34] In recognition of the magnitude of these burdens, the Office of Pharmacy Affairs ("OPA"), within the Health Resources and Services Administration, stated in a January 30, 2007 letter to pharmaceutical manufacturers: "We welcome comments from all parties about how to best implement the 340B Program requirements in the wake of changes in related areas impacted by the DRA. Our goal would be to minimize the burden on pharmaceutical manufacturers in submitting the required data." Jimmy Mitchell, Director of OPA, "Dear Pharmaceutical Manufacturer Letter Clarifying the Definition of Average Manufacturer Price" (Jan. 30, 2007), available at http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm.

[35] 72 Fed. Reg. 39142, 39205, 39224.

[36] Jimmy Mitchell, Director of OPA, "Dear Pharmaceutical Manufacturer Letter Clarifying the Definition of Average Manufacturer Price" (May 9, 2007), available at http://www.hrsa.gov/opa/pharm-mfg-ltr050907.htm.

CMS to take steps on its own to align the Medicaid program's definition of "AMP" with the 340B program's definition or actively to solicit cooperation from OPA to address any such issues. CMS could adopt either of these approaches without infringing on HRSA's responsibility as regulator of the 340B program.

2. *Specific Concerns on Particular Sections: Administrative and Service Fees – Section 447.504(h)*

CMS indicates in the Final Rule that administrative and service fees should be excluded from AMP if they are "bona fide service fees" paid to any entities included in the retail pharmacy class of trade, but that these fees should be included in AMP if they are not "bona fide service fees" but are made to an entity included in the calculation of AMP.[37] The Final Rule defines "bona fide service fees" as "fees paid by a manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug."[38] Further, CMS indicates that the agency is adopting the CY 2007 average sales price ("ASP") reporting final rule's interpretation[39] of the definition of "bona fide service fees" and of how manufacturers may apply this definition for purposes of AMP (and best price).[40] Responding specifically to comments on the Proposed Rule's treatment of fees to group purchasing organizations ("GPOs"), CMS clarifies that to the extent that fees to GPOs meet the definition of "bona fide service fees," they should be excluded from AMP.[41]

GPhA appreciates CMS's efforts to clarify the definition of "bona fide service fees" and the treatment of administrative and service fees under the Final Regulations. However, we are concerned that one criterion for a fee to be "bona fide" is that no part of that fee is passed on to an entity's clients or customers. This concerns us because, in many instances, manufacturers cannot ascertain whether these fees are, in fact, passed on to such clients or customers. In addition, even if a manufacturer learns that some part of an administrative fee may be passed on to an entity's client or customer, the manufacturer has no way to determine how much of that fee eventually does get passed on (for pro-ration purposes) by the entity. With GPOs in particular, the GPO would not disclose this information to the manufacturer, since such information is proprietary to the GPO. The inaccessibility of this information for manufacturers not only could make this requirement operationally infeasible for manufacturers but also could force additional discounts into the calculation of AMP that were formerly carved out as fees and excluded from this calculation. To address these problems, we recommend that CMS remove this "pass through" standard, since it is too difficult for manufacturers to determine and could

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[37] 72 Fed. Reg. 39142, 39182, 39183.
[38] Id. at 39240.
[39] 71 Fed. Reg. 69624, 69668 (Dec. 1, 2006).
[40] 72 Fed. Reg. 39142, 39182, 39183.
[41] Id. at 39183.

reduce the uniformity in reported AMPs when some manufacturers exclude, and some include, fees to the same customer/group.

C. Determination of Best Price – Section 447.505

Also related to the Final Rule's requirements for the determination of AMP are its requirements for the determination of best price. With respect to both AMP and best price, manufacturers bear substantial administrative burdens in complying with Medicaid Drug Rebate Program requirements for data submission and retention. These burdens are also increased by new reporting and retention requirements imposed on manufacturers by the Final Rule. In order to reduce manufacturers' already significant administrative burdens, we believe that CMS should maintain as much consistency as possible between the treatment of underlying transactions in best price and in AMP calculations.

In the Final Rule, CMS makes some clarifications of the treatment of specific sales and rebates for the determination of best price (e.g., administrative and service fees) and finalizes many of the policies in the Proposed Rule with respect to best price. However, CMS's policies in the Final Rule do not seem to take into account our request that CMS harmonize the treatment of various items for purposes of AMP and best price calculations. For example, whereas customary prompt pay discounts must be excluded from AMP by statute, CMS elects not to exclude customary prompt pay discounts from best price in the Final Rule on the grounds that "Congress did not exclude customary prompt pay discounts from the determination of best price."[42] Because the policies in the Final Rule do not alleviate manufacturers' administrative burdens, we renew our recommendation that CMS consider ways in which it can require parallel treatment of sales and rebates in the AMP and best price calculations to the greatest extent possible.

D. Requirements for Manufacturers – Section 447.510

The Final Rule places a number of reporting and retention requirements on manufacturers in connection with their AMP data. These requirements are directly connected to the Final Rule's requirements for the determination of AMP, which govern how manufacturers should calculate the AMPs that they must report and concerning which records they must retain. Below we present our comments concerning the Final Rule's requirements for manufacturers.[43]

1. *Timeline for Use of Monthly AMPs*

As noted above, most provisions of the Final Rule became effective October 1, 2007. Also noted above, the Final Rule indicates that CMS will begin posting individual manufacturers' monthly AMP data on a public website as soon as it finds the data sufficiently accurate and complete and that it will inform States and other relevant parties

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[42] Id. at 39199.

[43] We note that we discussed our concerns relating to the public disclosure of AMP data – a concern arising from the "Requirements for Manufacturers" section of the Final Rule – first in this letter, since this is the most important issue raised by the Final Rule for manufacturers.

that monthly AMP data will likely be 45-60 days old when posted.[44] In addition to our overall concerns about the public disclosure of manufacturer-specific AMP data, we have some concerns about the timing for the use of monthly AMP data. In our comments on the Proposed Rule, we recommended that CMS follow the model it used to implement ASP for Medicare Part B drugs when implementing AMP pricing for Medicaid drugs.[45] To this end, we urged CMS, among other things, to indicate that the first reporting period would commence 90 days after a 180-day "implementation period," and that only at the end of this 90-day "testing period" could State Medicaid agencies rely on AMPs for reimbursement purposes.

While we are grateful that CMS has not yet released AMP data and has expressed a commitment to ensuring that these data are accurate and complete before publicly disclosing them, we continue to have concerns that the data could be prematurely publicly disclosed and relied on by States for reimbursement purposes.[46] For many of the reasons discussed throughout these comments (e.g., CMS has not adequately clarified certain terms relating to the AMP calculation), we believe the AMP data currently being reported should not be publicly disclosed. Most importantly, however, we believe the data should not be publicly disclosed at all in the format in which CMS plans to disclose them (i.e., manufacturer-specific prices). Therefore, we renew our requests that CMS establish a 90-day testing period once the rule is final (i.e., no longer actively subject to a comment period) and that CMS make these timing issues clear by publishing a timeline indicating how new monthly AMPs will be used over time. We also reiterate our requests that CMS publicly disclose only aggregated, industry-wide weighted average AMPs and establish a regulatory safe harbor for manufacturers' good faith submissions of pricing data.

Finally, the Final Rule identifies CMS's plans to issue future operational guidance establishing a procedure for manufacturers to follow when they believe their monthly AMP on CMS's website is inaccurate.[47] While we appreciate CMS's recognition of the potentially detrimental effects of publicly disclosing AMP data that are inaccurate, we believe that CMS should not post any manufacturer-specific data on its publicly accessible website. As discussed in detail above, any manufacturer-specific AMP data that are made available to the public at large (including competitors) could potentially be misunderstood by consumers and payers and could ultimately result in higher prices for generic drugs and reduced beneficiary access to pharmacies and affordable generic drugs. Thus, we would prefer that CMS address this concern about potentially inaccurate posted AMP data by publicly disclosing only aggregated, industry-wide weighted average AMPs.

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[44] 72 Fed. Reg. 39142, 39210, 39213, 39223.

[45] When CMS implemented ASP pricing for Medicare Part B drugs, the agency provided manufacturers with a "test" period of several months. During this period, manufacturers could gain an understanding of the new requirements and make the necessary system-level adjustments to implement these requirements to ensure accurate reporting. Moreover, CMS guaranteed that it would not use ASP for reimbursement during this test period.

[46] As stated above, we recognize that CMS is currently enjoined from posting AMP data, and we encourage the agency to use this time to address the issues raised in this letter.

[47] 72 Fed. Reg. 39142, 39209.

2. *Reporting Requirements*

In the Final Rule, CMS clarifies that customary prompt pay discounts are to be reported for each covered outpatient drug as an aggregate dollar amount at the nine-digit NDC level so as to include discounts extended to all wholesalers in the rebate period.[48] CMS also acknowledges the comment we made on the Proposed Rule that the new file formats that have been provided to manufacturers from CMS for quarterly reporting do not include specifications for reporting customary prompt pay aggregate dollars. In response, CMS promises to "issue a revised record layout to manufacturers to include customary prompt pay discounts in accordance with this final rule."[49] We thank CMS for acknowledging our concern but note that CMS has not yet released the data layout that includes the prompt pay amount. Because the first quarterly reporting is due in just over 30 days, CMS should issue this revised record layout as soon as possible.

3. *Certification Requirement*

In the Final Rule, CMS finalizes its proposed requirement that manufacturers must certify the pricing reports they submit to CMS. CMS slightly modifies the requirement from the proposed version, indicating that this certification must be made by the manufacturer's Chief Executive Officer ("CEO"), Chief Financial Officer ("CFO"), an individual with another title who has authority equivalent to one of those positions, or a person who has the authority directly delegated from a CEO, CFO, or equivalent position to perform the certification on behalf of that individual. CMS also provides that this certification can be made electronically.[50] While we support the concept of certification as a policy matter, the particular requirements for certification under the Final Rule are impractical. We are concerned about the burdensome and impractical nature of the requirement that a high-ranking officer of a company must log into the CMS Drug Data Reporting system each month to certify AMP data. We request that CMS provide a way for manufacturers to certify the data more easily.

4. *Negative AMPs*

The Final Rule indicates that when the current monthly AMP is zero or negative, manufacturers should report the most recent positive AMP value. CMS believes that the most recent positive AMP "best represents the AMP for each drug" and that this policy is consistent with past CMS policy, ensures that manufacturers will pay a rebate, and prevents offsets due to a negative AMP.[51] While we are grateful that CMS has provided instruction on how manufacturers should handle negative AMPs, we believe CMS should, instead, require manufacturers to report negative AMPs. Reporting positive AMPs from previous periods is not reflective of the actual pricing fluctuations that naturally occur with respect to AMP. CMS should seek to ensure that AMPs accurately

[48] Id. at 39207.
[49] Id. at 39206.
[50] Id. at 39211.
[51] Id. at 39208.

reflect manufacturers' current pricing data by requiring the reporting of negative AMPs. Still, because we recognize the potentially adverse effects on pharmacy reimbursement of using negative AMPs to calculate FULs, we believe CMS should ignore any monthly reported negative AMPs when calculating FULs.

III. FUL Outlier Policy

Pursuant to the DRA, the Final Rule stipulates that upper limits are to be placed on multiple source drugs when there are two or more therapeutically and pharmaceutically equivalent formulations, regardless of whether all additional formulations are rated as such.[52] The Final Rule also outlines the "outlier policy" CMS intends to use when determining FULs to ensure that the FULs represent nationally available prices. Specifically, CMS announces that it will set the FUL based on the lowest AMP that is not less than 40 percent of the next highest AMP for that drug. This represents an expansion from the outlier policy under the Proposed Rule, which would have used a 30 percent threshold. CMS has specifically solicited comments on the outlier policy.[53]

We are pleased that CMS has recognized the importance of soliciting industry feedback to help the agency develop an outlier policy that ensures that drugs are nationally available at the FUL prices. To this end, we wish to present the following two concerns. Our first concern, relating directly to the outlier policy, is that CMS's policy does not guarantee that the AMPs determining the FULs are widely available prices. Our second concern relates more directly to the application of FULs (once calculated pursuant to the outlier policy). This concern is that the Final Rule's policy for the application of FULs does not adequately take into account the package size, form, or route of administration of different drugs. These concerns are discussed in more detail below.

A. Widely Available Prices

Overall, with regard to the outlier policy, we support the intent of CMS's methodology (i.e., use of a percent threshold), which is designed to ensure that the FUL represents a nationally available price. However, we do not believe that a threshold percentage alone will accomplish this objective. Specifically, we note that the Final Rule's outlier policy would allow the FUL for a drug to be determined either by a small manufacturer with a thin sales base or by a large manufacturer with a very small market share in a particular drug. Such a determination of the FUL would be undesirable because the FUL, which would apply to the whole market, could be controlled by a manufacturer that was not capable of supplying even a significant share of the market.

To address this concern, we believe CMS should add two steps to its current one-step outlier policy. That is, instead of using only a threshold percentage (i.e., 40 percent under the Final Rule), we propose that CMS use the following three-step process for calculating FULs:

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[52] Id. at 39244.
[53] Id. at 39216.

(1) CMS should first remove any AMPs less than 40 percent of the next highest AMP.[54] This step is the same as CMS's current outlier policy in full. The following two steps are additions to this policy that we recommend.

(2) CMS should then apply a volume criterion to this set of AMPs. Specifically, we recommend that CMS require manufacturers to report their net units shipped for each product and, then, use this information to identify products per manufacturer that are not widely available to the retail pharmacy class of trade.[55] This information, in conjunction with other factors (such as whether the product is available from several wholesalers), could help CMS determine whether a product is widely available and, thus, whether its AMP should be included in the FUL calculation or removed as an outlier.[56]

(3) Third, after all outliers (i.e., AMPs below 40 percent of the next highest AMP, and AMPs of products identified as not widely available based on net units shipped and other criteria) are removed, from the remaining set of AMPs, CMS should calculate the aggregate, industry-wide weighted average AMP. This number would then be used as the FUL and would more likely represent a nationally available price.

By using this three-step process, CMS could ensure that generics are nationally available at the FUL prices – the objective of the outlier policy, as indicated by CMS in the Final Rule.[57]

B. Package Size, Form, and Route of Administration

In addition to this concern that only widely available prices should set FULs, we also wish to raise our concern that FULs should take into account the package sizes, forms, and routes of administration of different drugs. Regarding package size, we note that certain package sizes, such as unit doses, command a premium price in the market, whereas other package sizes (e.g., bulk or bottled products) have lower market prices. Accordingly, FUL reimbursements that blend bulk or bottled pricing with smaller package sizes into one AMP – and, thus, one FUL – will subject a small package size drug to a lower FUL than if each package size received its own FUL. This could cause

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[54] CMS could use the 90-day testing period (proposed above in these comments) to develop a meaningful empirical outlier standard of percentage variance to be used to identify which products are widely available.

[55] CMS could use the 90-day testing period (proposed above in these comments) to develop a sales volume standard (which could be used in conjunction with an empirical outlier standard of percentage variance) to identify which products are widely available.

[56] The usefulness of net unit information for this purpose has been demonstrated by the current requirement for manufacturers to submit net units shipped (excluding returns) for each product in ASP reporting. In the AMP context, this information could also be used for weighting, as required for the rebate calculation, though we emphasize that this information is confidential and, therefore, should not be posted on CMS's website or otherwise released to the public.

[57] 72 Fed. Reg. 39142, 39216.

access issues for small package size users (often beneficiaries and other individuals), since the lower FULs might prevent some pharmacies from being able to carry small package sizes.

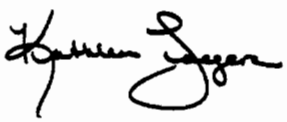
To avoid this undesirable outcome, we believe that CMS must take package size into account for purposes of calculating and applying the FUL.[58] In addition, CMS should modify the definition of "formulation" to take into account each product's package size, which would ensure that different FULs were applied to drugs of different package sizes.

Similarly, the definition of "formulation" does not currently, but should, take into account each product's form and route of administration.[59] The Final Rule fails to define the term "formulation" in a way that refers to products of the same form and route of administration (i.e., tablet to tablet, controlled release tablet to controlled release tablet, liquid to liquid, etc.). It would not be appropriate for a liquid or controlled release tablet to be set at the same level of reimbursement as a standard tablet formulation. Such a comparison is unreasonable, since the products will have different prices and be sold separately. For example, the AMP for a tablet could be so different from the AMP for the liquid form of that drug that each AMP could be viewed as an outlier with respect to the AMP for the other form of the drug. To avoid such an unreasonable comparison, CMS should clarify the definition of "formulation" in guidance such that the definition properly takes into account each product's form and route of administration – as well as its package size, as noted above. Such clarification would also prevent the FULs for particular drugs from being determined by AMPs that would be considered outliers if the AMPs were properly sorted in light of the package sizes, forms, and routes of administration of the various drugs.

* * *

Thank you for the opportunity to submit these comments. GPhA looks forward to working with CMS while the agency considers comments on this Final Rule with Comment Period. Please do not hesitate to contact us if you have any questions or concerns.

Sincerely,



Kathleen D. Jaeger

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[58] CMS could use the 90-day testing period (proposed above in these comments) to establish standards for formulations and package configurations that would separate items such as unit doses, bulk, liquids, and injectables.

[59] We understand that reporting at the nine-digit NDC level will provide CMS with information on form and route of administration, but we still seek clarification of the definition of "formulation."

January 2, 2008

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-FC
Post Office Box 8012
Baltimore, Maryland 21244-8012

RE: CMS-2238-FC

Dear Centers for Medicare and Medicaid Services:

I am writing on behalf of the Healthcare Compliance Packaging Council (HCPC) with regard to the request for additional comments on the Average Manufacturer Prices (AMP) provisions contained in the final rule published by the Centers for Medicare and Medicaid Services (CMS) as published in the July 17, 2007, edition of the *Federal Register*. Specifically, the HCPC is concerned that the CMS decision not to require the calculation of AMP for each package size at the 11-digit level will profoundly affect the treatment of reimbursement for sales to mail order pharmacies under 42 CFR 447.504(g) of the AMP final rule, and urges CMS to use an 11-digit National Drug Code (NDC) designation to calculate AMP to reflect the use of special packaging for reimbursement purposes generally.

Background

The HCPC is a not-for-profit trade association that was created in 1990 to promote the many benefits of unit dose packaging as a means of better protecting over-the-counter (OTC) and prescription (Rx) drug products, and helping to ensure that OTC and Rx drugs are consumed correctly. Pharmaceutical noncompliance – which is generally defined as people not taking their drugs as intended and/or prescribed – is a massive, documented problem in the United States that is estimated to drain nearly $200 billion from the national economy every year.

Unit dose packaging comes in numerous different formats, but the defining feature of all unit dose formats is that each dosage unit is housed in its own container. One type of unit dose format that has commonly been used to package Rx drug products in the United States is the "blister pack" console for oral contraceptives (i.e., birth control pills) that have been the standard for distributing these drug products in the U.S. for nearly fifty years. In addition to blister packs, however, other forms of unit dose packaging include blister strips where each dosage unit is in a separate cavity on the strip, single-dose ampoules, and pre-filled syringes.

When used as original packaging by OTC and Rx drug manufacturers, unit dose formats offer a number of benefits, two primary ones being: 1) assurance that each dose of drug comes out of the package exactly as it was when the manufacturer put it in the package; and 2) elimination of the

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need for Rx drugs to be repackaged in the pharmacy. For these two reasons alone, unit dosing is common in most of the rest of the world.
Indeed, the U.S. is somewhat unique compared to virtually every other country in the world in that we allow manufacturers to ship product in bulk containers such that virtually all Rx drugs must be repackaged in the pharmacy before they can be dispensed to consumers. Throughout the European Union (EU), Asia, and Latin America, however, the same manufacturers who ship product in bulk containers to the U.S. market routinely use unit dose formats when they ship the exact same drugs to these overseas destinations.

Unit dose, in fact, is widely used throughout most of the rest of the world because, in addition to the primary benefits listed above, unit dose:

- is inherently more child-resistant than bulk containers
- prolongs the shelf-life of drug products;
- serves as a platform for including patient leaflets and other printed literature that helps ensure the drugs are taken properly;
- is tamper evident to the individual dosage level;
- allows for disposal of expired and/or unneeded drugs without environmental release; and
- creates a platform for overt and covert technologies that help reduce opportunities to introduce counterfeit product into the supply chain.

In addition to all of these benefits, unit dose formats can also be designed with compliance-prompting features that help consumers take their medications as prescribed and/or intended. Birth control pills, for example, score higher compliance rates than any other class of drug product sold in the United States. According to data developed in mid-1990's by the National Council on Patient Information and Education, in fact, compliance rates with birth control pills are nearly ten percent higher than compliance rates for organ rejection drugs which are typically shipped in bulk containers in the U.S. market and – if not taken properly – can result in organ rejection and death.

Corporate members of the HCPC are primarily involved in the manufacture of components used in the construction of unit dose packaging (e.g., pharmaceutical-grade film, foil, and paperboard), as well as machinery used to create unit dose formats. Other HCPC corporate members are contract packaging firms that put product into unit dose formats on behalf of pharmaceutical manufacturers, as well as repackaging firms that purchase drug product in bulk, repackage it into unit dose formats, and then sell the drugs to hospitals and other healthcare settings. Individual members of the HCPC are primarily packaging designers and engineers, many of whom work directly for the pharmaceutical manufacturing industry.

For more information about the HCPC, or members and our mission, I invite you to visit our website at www.unitdose.org.

Unit Dose Packaging and AMP

Over the years, greater use of unit dose formats has been advocated by numerous healthcare policy organizations. The Institutes of Medicine, for instance, endorsed unit dose formats in its 2000 report entitled "To Err is Human: Building a Better Health System" and again in its 2006 report entitled "Preventing Medication Errors: Quality Chasm Series" where the IoM notes that:

> The strategy of using calendar blister packs could help large numbers of patients

(including seniors, children, and those challenged by cognitive, physical, or functional impairment) take their medication more reliably and safely, and enhance their treatment outcomes." August 2006, Page 250.

Greater use of unit dose formats has also been endorsed by: the National Association of Health System Pharmacists, the American Hospital Association, the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations), the American Medical Association and others.

The U.S. Food and Drug Administration (FDA) has also encouraged greater use of unit dose formats on numerous occasions, and both the reports released by FDA's Anti-counterfeiting Task Force have recommended use of special packaging as a means of discouraging the introduction of counterfeit drugs into the U.S. pharmaceutical supply chain.

For its part, the HCPC has supported FDA's efforts to promote greater use of unit dose formats in the United States. Most recently, in fact, the HCPC filed comment with FDA on October 25, 2007, in which we advocated that the Agency require special packaging whenever a drug product must be dispensed with a Medication Guide.

Yet despite this advocacy in favor of unit dosing, pharmaceutical manufacturers have stubbornly clung to bulk distribution for most of their products sold in the United States. Why is this? As the 2006 IoM report notes, part of the reason is the "lack of regulatory requirements [for unit dosing]" that exists in the United States.

But another – and potentially far more serious – obstacle to greater use of unit dose formats in the United States is our reimbursement system for Rx drugs. As the HCPC explained to FDA in our October 2007 comments, a major reason why Rx drugs continue to be shipped in bulk to the U.S. market is that, by and large, reimbursement is based on pills instead of packages.

It is for this reason that the HCPC is concerned with some of the language contained in the preamble to the final rule that CMS published on July 17, 2007.

Specifically, the HCPC urges CMS to reconsider its conclusion that use of 11-digit NDCs would "...offer minimal advantages (page 39155)." Quite the contrary, since the benefit of an 11-digit NDC is that it documents the type of packaging used to dispense the drug product, the HCPC contends that support of an 11-digit NDC by CMS could provide a tremendous benefit in the collective effort to foster greater use of unit dose formats.

Simply stated, the HCPC is concerned that instructions to always calculate and set Federal Upper Limit (FUL) reimbursement at the 9-digit NDC level for purposes of calculating AMP could hinder greater use of unit dose formats. We urge CMS, therefore, to modify the Rule to require manufacturers to calculate and report AMPs at the 11-digit NDC level, especially when product is distributed to pharmacies in unit dose formats.

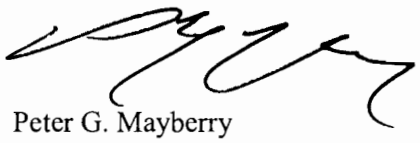
As other comments have noted, the HCPC shares concern that restricting all AMP reporting and FUL setting to the 9-digit NDC may discourage innovation in packaging that has been shown to improve healthcare outcomes and reduce overall treatment costs. We contend, therefore, that insistence on the 9-digit NDC could have the unintended consequence of eschewing patient compliance in favor of reimbursement recognition.

The HCPC also notes CMS's conclusion in the preamble to final rule that "However, the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that the Congress intended that AMP should be restructured to collect it by the 11-digit NDCs." While this may be true with regard to the Deficit Reduction Act of 2005, CMS should be aware that Congress *did* specifically reference "special packaging" as a desirable element of Medication Therapy Management (MTM) programs under legislation that created the Medicare Part D benefit (PL 108-173,Title 1, Section 1860D).

The HCPC contends, in fact, that greater use of special packaging as a means of compliance with MTM programs has been hampered, in part, due to use of the 9-digit NDC for the FUL calculation. If CMS were to use the 11-digit NDC to compute a FUL, the HCPC asserts it would be in keeping with Congressional legislative intent under PL 108-173.

On behalf of the entire HCPC, I thank you for the opportunity to submit these comments. Please feel free to contact me directly should you have any questions or need any additional information.

Sincerely,



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