Submitter : Mr. James Abrams **Date:** 02/20/2007

Organization : Mylan Pharmaceuticals Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1352-Attach-1.DOC

CMS-2238-P-1352-Attach-2.DOC

February 20, 2007

ELECTRONIC COMMENTS
Centers for Medicare & 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 Medicaid Program; Prescription Drugs Proposed Rule (CMS-2238-P)

Dear Sir or Madam:

Mylan Pharmaceuticals Inc. ("Mylan") is pleased to have this opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") on the *Medicaid Program; Prescription Drugs Proposed Rule (the "Proposed Rule").*[1] Mylan is a leading manufacturer of prescription medicines specializing in developing and manufacturing generic pharmaceuticals. Mylan's customers include wholesalers, distributors, retail drugstore chains, and government agencies. Mylan manufactures and markets 160 generic products in nearly 400 product strengths, covering 46 therapeutic categories. As generics have become a more critical component of the health care system, consumers, insurers, and other prescription drug buyers have saved billions of dollars each year with the use of generics. These savings have resulted in critical savings to the Medicaid program and private drug benefit plans.

As a manufacturer of both generic and branded pharmaceuticals and a participant in the Medicaid Drug Rebate Program (the "Rebate Program"), Mylan strongly shares CMS' commitment to bring clarity and uniformity to the issues relating to Medicaid prescription drug pricing. The Proposed Rule, the issuance of which was mandated by the Deficit Reduction Act of 2005 (the "DRA"), was intended to "clarif[y] the requirements for, and manner in which, average manufacturer prices [AMPs] are determined..." as well as implement the DRA provisions relating to the various aspects of Medicaid prescription drug pricing.[2]

We appreciate the opportunity to comment on the Proposed Rule and look forward to working with CMS in bringing both clarity and operational feasibility to the Rebate Program. As a company, in general, we endorse the comments that have been submitted by the Generic Pharmaceutical Association ("GPhA"), of which we are a member. We are, however, taking this opportunity to submit additional comments that are more specific to our concerns relating to the Proposed Rule. In particular, we have two primary concerns. First, it is important to recognize

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[1] 71 Fed. Reg. 77174 (Dec. 22, 2006).
[2] Deficit Reduction Act ("DRA") § 6001(c).

that AMP only reflects a snapshot in time that may not bear any relevance to market prices. In addition, as a complicating factor in the calculation of AMP and further limitation on the number's usefulness, manufacturers are often not privy to downstream (or indirect) sales and, thus, do not always have the data necessary to comply with CMS' proposed policies with respect to calculating AMP. Second, given the limitations inherent in AMP, manufacturer-specific AMP should not be made available to the "public," nor was that the intent of the DRA, which we discuss in detail below.

In addition to these fundamental considerations, however, which we have set forth in the beginning of our comments, we have organized our other concerns in their respective sections of the Proposed Rule.

I. Overall Concerns

A. AMP Is An Imprecise Number.

Our primary concern with respect to the Proposed Rule relates to the misconception that AMP is necessarily a price reflective of market prices. A myriad of business transactions cause periodic changes in AMP from month-to-month. Examples of such transactions include – backorders, temporary discontinuation of a product, low demand, and swings in sales and credits. As such, at any particular point in time, AMP may be different from the average price received by the manufacturer. Illustrative of this issue is the example below that demonstrates how the AMP of a single product could change as a result of transaction flow and timing:

- Manufacturer Sells to Wholesaler January 28 $100 / 100 units, January AMP = $1.00
- Wholesaler sells to eligible indirect customer on contract Feb 10 $80 / 100 units, February AMP after chargeback would be $.80
- Manufacturer pays Wholesaler a 10% rebate on purchases made during the quarter on March 31, March AMP after chargeback and rebate would be $.70

In this example, AMP is dependent on the timing of the original sale and downstream transactions that occur after the original sale, perhaps over multiple periods. This example also assumes that data is readily available during the relevant reporting period.

In addition, as mentioned above, while manufacturers have access to information concerning direct sales, they often do not have any information on indirect sales (unless there is a chargeback or some other mechanism to track the sale). Although intending to clarify the determination of AMP, instead, CMS proposes to include in, and exclude from, AMP calculations data that are not readily available, if at all, to manufacturers. As an example, CMS proposes to include Medicare Part D rebates[3] in the calculation of AMP provided that such rebates are applicable to product sold to an eligible Medicare Part D beneficiary. However, manufacturers are rarely aware of whether their products are ultimately sold to an eligible

[3] Our comments with respect to Part D sales are discussed in detail in the "Determination of AMP – Section 477.504" section of this comment letter.

Medicare Part D beneficiary, making this policy operationally infeasible. Consequently, although some of these Medicare Part D rebates will be correctly included as proposed, most Medicare Part D rebates will be inadvertently excluded by manufacturers. Either way, the resulting AMPs submitted to CMS will be inconsistent, at best, across manufacturers.

As such, CMS will need to be exceedingly clear in the guidance that it provides to manufacturers in calculating AMP to ensure that manufacturers are able to determine the sales and associated price concessions that should and should not be included in AMP and to ensure consistency in AMP calculations across all manufacturers.

B. The Publication Of Manufacturer-Specific AMPs To All Purchasers, Payers, And Consumers Is Unintended Under The DRA.

The DRA sets forth that –

> Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States ... the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website....[4]

In a subsequent provision, the DRA sets forth that the Secretary is to disclose "(through a website accessible to the public) average manufacturer prices."[5] Based on these provisions it is clear that Congress intended that AMP data be made available to States and the "public." However, there is no basis to believe that Congress intended to make manufacturer-specific AMP information available on a website accessible to the "public."

We believe that Congress' intent to make AMPs publicly available was to improve the transparency of drug pricing under the Rebate Program for the benefit of payers, which would be accomplished by permitting only States and their Medicaid programs to access manufacturer-specific AMP information on the CMS website. Accordingly, by providing manufacturer-specific AMP data on the agency's public website in a manner that allows only State Medicaid programs (or other authorized users) access, CMS would be in compliance with Congress' directive, as well as with the intent of the statute.

In addition, as addressed by GPhA in its comments, publishing manufacturer-specific AMP information to the public is fraught with significant concerns, including, reduced competition, anticompetitive concerns, and confusion among purchasers and payers. For these reasons, we ask CMS to take a reasonable interpretation of the statute and publish only the aggregated industry-wide weighted average AMPs for multiple source drugs. Publishing manufacturer-specific AMP information would negate other applicable confidentiality provisions

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[4] DRA § 6001(b)(1)(B).
[5] DRA § 6001(b)(2)(C).

that the DRA did not change. A statute should not be accorded a meaning that eliminates the effect of certain of its provisions.

We also believe that these disclosure provisions must be implemented through notice and comment rulemaking, and the failure to do so violates the Administrative Procedure Act ("APA").[6] The APA requires agencies to give interested parties the right to participate in rulemaking through publication of a proposed rule, which includes "the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[7] As explained above, as well as in the comments from GPhA, there are many different possible means by which this provision can be implemented. As such, regulated businesses have a statutory right to notice as to how the information will be presented and to comment on the legal and policy implications of such decisions.

II. Comments to Specific Sections of the Proposed Rule

As mentioned above, AMP is not necessarily reflective of market prices. There are two key drivers of this number: (1) customer classification (e.g., eligible versus ineligible class of trade); and (2) transaction treatment (e.g., inclusion and timing). It is vital that these two components of AMP be applied in a uniform manner to ensure that the AMPs for the same products can be compared consistently across manufacturers. To this end, it is critical that CMS clearly define certain significant terms that are contemplated in the Proposed Rule. The remainder of our comments will address our concerns in the order that is set forth by CMS.

A. Determination of AMP – Section 447.504

1. Bundled Sales

CMS proposes that AMP calculations should be adjusted for bundled sales "by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations."[8] That is, the aggregate discount would be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. In the case of multiple discounted products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all of the drugs in the bundle. The Medicaid Drug Rebate Operational Training Guide (the "Guide") defines the term "bundled sales" as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."

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[6] 5 U.S.C. Chap. 5.
[7] 5 U.S.C. § 553.
[8] 71 Fed. Reg. at 77177.

As proposed, CMS seems to broaden the definition of the term "bundled sales" to potentially include routine multiple drug sales to entities such as wholesalers and group purchasing organizations ("GPOs"). We do not believe that the intent of the Proposed Rule was to require that manufacturers allocate on an item-by-item basis the original price of the drug product had it been sold separately. Accordingly, we recommend that CMS should not broaden the definition of the term "bundled sales."

2. Retail Pharmacy Class of Trade – Nursing Home Pharmacy

In the Proposed Rule, recognizing the concerns that have been raised relating to the inconsistencies in the way manufacturers determine AMP, CMS proposes to clarify such determination by revisiting the definition of "retail pharmacy class of trade." CMS proposes to define the retail pharmacy class of trade as "that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services."[9] Given this definition, CMS proposes to exclude prices to long-term care ("LTC") (or nursing home) pharmacies because LTC pharmacies do not dispense to the general public.

We are concerned that CMS has not clearly identified those entities that would be considered LTC (or nursing home) pharmacies.[10] Mylan encourages CMS to clearly define the attributes of entities that qualify as LTC pharmacies to avoid disparate treatment among manufacturers as they exclude prices to LTC pharmacies in calculating AMP. If manufacturers were to use different criteria for determining whether an entity is a LTC pharmacy, manufacturers' AMPs would not uniformly reflect the exclusion that CMS intended in the Proposed Rule. As such, CMS should clearly define the term "LTC pharmacy."

In addition, we recommend that CMS establish a list of those LTC pharmacies that should be excluded from the calculation of AMP in a "List of Excluded Class of Trade Entities," similar to the type of document attempted by the Office of Pharmacy Affairs's ("OPA's") list of eligible 340B entities.[11] This list would specify for manufacturers those entities that should be excluded when calculating AMP. As a result, CMS would ensure that manufacturers consistently categorize customers included in and excluded from AMP calculations as there are several types of entities that could (or could not) qualify as LTC pharmacies, depending on the interpretation. For instance, it is not clear whether the following would be considered a LTC pharmacy under the Proposed Rule – LTC pharmacies owned by a hospital, infusion centers, and rehabilitation centers.

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[9] 71 Fed. Reg. at 77178.

[10] According to MedPAC, there are approximately 15,000 skilled nursing facilities. See MedPAC Report to the Congress: Medicare Payment Policy (March 2006). In addition, according to the Long Term Care Pharmacy Alliance ("LTCPA"), there are five major national LTC pharmacies – Kindred Pharmacy Services, Omnicare, NCS Healthcare, NeighborCare, and PharMerica. These LTC pharmacies serve more than 1.5 million people including more than two-thirds of all nursing facility residents. See LTCPA website available at http://www.ltcpa.org/mission/pharmacy/default.asp.

[11] For the reasons addressed in this section, we recommend that CMS establish a similar list for all entities that should be excluded from AMP calculations as guidance to manufacturers.

Further, as we have mentioned, it is often operationally infeasible for manufacturers to identify those sales that are made to a particular type of entity (e.g., a LTC pharmacy), as opposed to another type of entity that might not satisfy the definition of a LTC pharmacy. Manufacturer sales data are captured at the contract level, but any included or excluded class of trade customer could purchase products from any wholesaler source contract. Thus, manufacturers have no way of determining whether final sales are made to excluded customers. Given this inherent difficulty with calculating AMP, it is imperative that CMS provide mechanisms by which manufacturers can calculate AMP as consistently as possible.

3. Pharmacy Benefit Manufacturers ("PBM") Price Concessions

CMS addresses in the Preamble to the Proposed Rule the difficulties involved in the treatment of PBMs for purposes of determining AMP. Both the U.S. Government Accountability Office ("GAO") and the Office of the Inspector General ("OIG") have recognized that the Rebate Program does not clearly address certain financial concessions negotiated by PBMs, and have recommended that CMS clarify the treatment of PBM rebates.[12] According to the OIG, manufacturers treat rebates and fees paid to PBMs in one of three ways – (1) not subtracting rebates or fees paid to PBMs from the AMP calculation; (2) subtracting the rebates or fees paid to PBMs; or (3) subtracting a portion of the PBMs rebates or fees from the AMP calculation.[13]

Based on these inconsistencies, CMS considered both the inclusion and exclusion of all rebates, discounts, and other price concessions to PBMs in the determination of AMP. Although CMS acknowledges the difficulty manufacturers face in determining the apportionment of PBM price concessions to the PBM, the insurer, and, if any, to the pharmacy, CMS states that excluding all PBM price concessions could result in an artificial inflation of AMP. As such, CMS proposes to include all rebates, discounts, or other price concessions provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to the retail pharmacy class of trade.

For several of the reasons addressed by CMS in the Proposed Rule, Mylan agrees that it is necessary to clarify the treatment of PBM rebates and fees in the calculation of AMP. However, the Proposed Rule does not effectively accomplish this goal. That is, CMS fails to define the term "PBM" for the purpose of AMP calculations, which effectively allows manufacturers to include the sales from any entity that a manufacturer considers to be a PBM, including sales to managed care organizations, which are specifically excluded from AMP under the national rebate agreement.[14] We believe that CMS needs to clearly 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 as we discussed in the section above. Doing so will enable

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[12] See GAO, "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns About Rebates Paid to States," (GAO-05-102) (February 2005); see also OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).

[13] 71 Fed. Reg. at 77179.

[14] Id.

manufacturers to use uniform criteria to distinguish between PBMs and non-PBMs for purposes of incorporating rebates and fees into AMP calculations. If, however, CMS fails to set forth guidance regarding PBMs, manufacturers will continue to treat PBM price concessions disparately, resulting in inconsistent AMP calculations across manufacturers. Therefore, it is imperative that CMS clearly identify factors that manufacturers should use in determining whether an entity is in fact a PBM.

As an additional matter, the Proposed Rule seems to include in the calculation of AMP PBM price concessions, but limits this inclusion to those rebates relating to PBM sales to the retail pharmacy class of trade.[15] If this is indeed CMS's intent, then the agency's proposal would not be practicable because manufacturers do not have information concerning these indirect sales. Manufacturers cannot ascertain whether PBMs' downstream sales are to the retail class of trade or not. Thus, they would not be able to ensure that their AMP calculations include only those price concessions related to sales to the retail pharmacy class of trade.

4. Identification of Sales

The Proposed Rule requires that AMP include only those sales to wholesalers "for dispensing to the general public," e.g., sales to wholesalers that result indirectly in sales to the retail pharmacy class of trade.[16] Often, however, a manufacturer will not know if the sale from a wholesaler is to an entity in the retail pharmacy class of trade. Generally, there are three types of direct sales involving manufacturers – direct sales to retail pharmacies, direct sales to wholesalers where wholesalers then sell to retail pharmacies, and direct sales to wholesalers where the wholesaler then sells to an entity that is unknown to the manufacturer. The third arrangement is the one that makes CMS' proposed policies operationally infeasible. That is, once a manufacturer sells to a wholesaler, the wholesaler may then sell to any number of entities.

Manufacturer sales data are captured at the wholesaler-manufacturer level, but any subsequent sale from the wholesaler could be to any entity – one that is either included or excluded from the retail class of trade. A manufacturer would have data to identify downstream indirect sales if they were processed by a wholesaler through a chargeback for a wholesaler program sale or a manufacturer-established contract sale. However, a manufacturer would not have sufficient data to identify indirect sales made by a wholesaler or distributor if a chargeback is not processed for the sale.[17] In the latter case, the manufacturer would not be able to identify the purchaser in the second sale or to assess whether the entity was in the retail pharmacy class of trade. This is also true of SPAP and Part D rebates, which we discuss below.

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[15] Id.

[16] Id.

[17] See Medicaid Drug Rebate Program Release #29 (acknowledging manufacturers' need to often recalculate or refine pricing data due to the improper inclusion or exclusion of certain sales.).

5. State Pharmaceutical Assistance Program ("SPAP") Rebates

As further clarification of the determination of AMP, CMS proposes to include SPAP price concessions in the calculation of AMP. CMS states that similar to the Medicaid program, Medicare Part D prescription drug plans ("PDPs"), Medicare Advantage prescription drug plans ("MA-PDs"), and SPAPs do not directly purchase drugs. Instead, SPAPs are generally third-party payers. Therefore, CMS believes that these sales should be included in AMP to the extent that the sales are to an entity included in the retail pharmacy class of trade. Accordingly, CMS proposes that SPAP sales, as well as rebates paid by the manufacturer to the SPAP, be included in the AMP calculation.

We, however, do not agree with CMS' proposed treatment of SPAP rebates. As CMS mentions, SPAPs are similar to the Medicaid program in that SPAPs represent third-party government payers. Therefore, because Medicaid rebates would be excluded from AMP calculations, the same should be true for SPAP rebates. SPAP data is only available on a quarterly basis with a considerable lag period and no correlation to a SPAP eligible sale. Manufacturers also have the opportunity to refile SPAP data for the quarterly reporting requirement. Accordingly, SPAP rebates should be excluded from monthly AMP calculations.

In addition, CMS' proposed treatment of SPAP rebates conflicts with the treatment required under previous CMS Manufacturer Release #68, which instructs manufacturers to distinguish between "qualified" and "unqualified" SPAPs, based on criteria listed in such release. Under this program release, only rebates to qualified SPAPs are excluded from AMP, whereas rebates to unqualified SPAPs are included in AMP. We request that CMS revisit this program release to address this inconsistency. If CMS ultimately decides to include all SPAP rebates in the calculation of AMP, then the agency should provide guidance regarding the method of inclusion.

6. Treatment of Medicare Part D Rebates

CMS proposes to clarify in the Proposed Rule that the treatment of prices of sales through a PDP, MA-PD, or a qualified retiree prescription drug plan for covered Medicare Part D drugs provided on behalf of Medicare Part D eligible individuals should be included in the AMP calculation. CMS states that similar to the Medicaid program, PDPs and MA-PDs do not directly purchase drugs, but are usually third-party payers. As is the case with Medicaid sales, CMS believes that these sales should be included in AMP to the extent that the sales are to the retail pharmacy class of trade. As such, CMS proposes that these prices, as well as rebates paid by manufacturers to the PDP or MA-PD, should be included in AMP calculations.

Similar to the discussion above concerning SPAP rebates, we recommend that CMS exclude Medicare Part D rebates from AMP calculations. Because Medicare Part D rebates are similar to Medicaid program rebates, which are excluded from AMP calculations, Medicare Part D rebates should be treated similarly.

Further, Medicare Part D rebates are excluded from best price, and the resulting inconsistent treatment of Medicare Part D prices in AMP and in best price calculations would be unjustified. As CMS acknowledges in the Proposed Rule, the law requires that "prices negotiated by a prescription drug plan, by an MA-PD plan . . . or by a qualified retiree prescription drug plan . . .with respect to such drugs on behalf of Medicare Part D eligible individuals, shall . . . not be taken into account for the purposes of establishing the best price...."[18] Because of this statutory mandate concerning best price, we believe CMS should treat Medicare Part D rebates in the context of AMP similarly to ensure parity for both AMP and best price calculations. Thus, we recommend that CMS use its authority to exclude Medicare Part D rebates from AMP.

7. Returned Goods

According to the Proposed Rule, CMS proposes to exclude returned goods from AMP calculations provided that such goods are returned in "good faith." [19] We recommend, however, that CMS clarify that products destroyed by purchasers (and, thus, not returned to the manufacturer) should be treated the same way as returned goods – e.g., excluded from AMP. Likewise, we recommend that recalls be treated the same as returned goods and excluded from AMP. We also urge CMS to clarify the treatment for AMP calculation of any return fees or reasonable recall fees paid by manufacturers.

8. Manufacturer Coupons

In the Proposed Rule, CMS proposes to clarify the way in which manufacturer coupons should be treated. CMS proposes to include coupons redeemed by any entity other than the consumer in the calculation of AMP. Accordingly, CMS proposes that coupons that are redeemed by the consumer directly to the manufacturer would not be included in AMP calculations. We recommend that CMS make clear that manufacturer coupons redeemed by a consumer, whether directly ***or indirectly*** to the manufacturer (e.g., through a pharmacy) should be excluded from AMP calculations.

9. Administrative and Service Fees

According to current policy under the Rebate Program, "administrative fees, which include service fees and distribution fees, incentives, promotional fees, chargebacks, and all discounts or rebates, other than rebates under the [Rebate Program]..." should be included in AMP calculations, provided those sales are to an entity included in the calculation of AMP. The OIG, however, noted that there is confusion among manufacturers regarding the treatment of

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[18] 71 Fed. Reg. at 77183; see Social Security Act ("SSA") § 1927(c)(i)(VI); see also Medicaid Drug Rebate Program Release # 63 (Feb. 19, 2004).
[19] 71 Fed. Reg. at 77181.

such fees.[20] Given the OIG's report, CMS proposes to clarify the treatment of administrative fees by including all such fees in the calculation of AMP.

CMS proposes, however, to exclude from AMP fees paid for *bona fide* services. CMS proposes to define *bona fide* service fees as "fees paid by a manufacturer to an entity, which 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 which are not passed in whole or in part to a client or customer of an entity, regardless of whether the entity takes title to the drug."[21]

We strongly recommend that CMS clearly set forth guidance as to what constitutes a *bona fide* service fee. Although CMS attempts to make this clear in its proposed definition, it would be more helpful for CMS to provide additional parameters and/or specific examples to assist manufacturers in making this determination. Further, we encourage CMS to work with the OIG to establish a "safe harbor" for *bona fide* service fees. We believe that the payment of *bona fide* service fees by manufacturers could implicate the anti-kickback statute.[22] That is, *bona fide* service fees could be viewed as an incentive to purchase drug products from manufacturers. Given the potential for widely varying interpretations of the definition of *bona fide* service fees and the potential anti-kickback concerns, it is important that CMS and the OIG work together to provide clear guidelines and a safe harbor for this term.

B. Authorized Generics – Section 447.506

In the Proposed Rule, CMS proposes to require the primary manufacturer (NDA holder) to include, in its calculations of AMP and best price, sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary. CMS believes that to limit the applicability of the Proposed Rule to the sellers of authorized generic drugs would allow manufacturers to circumvent the intent of the DRA by licensing rather than selling the rights to such drugs. As is currently required, the secondary manufacturer or subsidiary of the brand manufacturer would continue to pay the single source or innovator multiple source rebate for the authorized generic products based on utilization under its own NDC number.

CMS, however, makes no mention in the Proposed Rule of sales from the brand manufacturer to the authorized generic manufacturer (e.g., sales at the "transfer price").[23] For purposes of consistency, we recommend that CMS also include the transfer price of the NDA holder to the authorized generic manufacturer in the NDA holder's best price calculations.

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[20] OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).
[21] 71 Fed. Reg. at 77180.
[22] SSA § 1128B(b).
[23] DRA § 6003.

C. Requirements for Manufacturers – Section 447.510

In the Preamble, CMS sets forth the reporting requirements for manufacturers with regard to pricing data. Specifically, CMS proposes that AMP would be reported both on a monthly and quarterly basis to CMS. CMS proposes that the monthly AMP would be calculated using the same methodology as the quarterly AMP. In an effort to minimize the price fluctuations and to maximize the usefulness of the monthly AMP, CMS proposes to allow manufacturers to estimate the impact of their end-of-quarter rebates or other price concessions and to allocate these rebates or other price concessions throughout the quarter in the monthly AMPs reported to CMS. CMS invites comments on allowing the use of 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP. CMS also seeks comments on allowing manufacturers to calculate the monthly AMP based on updates of the most recent three-month period (i.e., a rolling three-month AMP).

While smoothing is a helpful mechanism to adjust for fluctuations in the calculation resulting from the timing of sales and credits, smoothing does not necessarily result in AMP bearing a more precise market price. Smoothing is dependent on historical data that may or may not be completely applicable to current business activity. However, in order to adjust for variability in monthly reporting periods, we agree with CMS' proposal to allow the "smoothing" of AMP data. In addition, we recommend that CMS permit four quarter smoothing to ensure a more consistent application of a percentage during the months of a quarter. We believe that this is a reasonable smoothing mechanism that would be beneficial to manufacturers and that would enhance the AMP data that are received by CMS.

D. Upper Limits for Multiple Source Drugs – Section 447.514

The currently reported AMP is based on the nine-digit NDC, combining all package sizes of the drug into the same computation. CMS proposed to continue this policy and solicited comments on the alternative approach of using 11-digit NDC to calculate AMP as well as comments on the merits of using both approaches in calculating AMP for the FUL calculation.[24]

In response to CMS' request for comments on the appropriate NDC level for calculating AMP, we support the use of the 11-digit NDC. The primary benefit of the 11-digit NDC, as CMS notes, is the inclusion of package size in the AMP calculation. Also, CMS observes that the 11-digit NDC would align with the State Medicaid drug payments that are based on package size, as well as allow greater transparency. Further, taking into consideration different customer types, e.g., small and large retail pharmacies, and different life cycle management, applying the 11-digit NDC would promote greater consistency and accuracy among AMPs. Accordingly, we recommend the use of the 11-digit NDC for calculating AMP.[25]

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[24] 71 Fed. Reg. at 77187.

[25] See 42 C.F.R. § 447.332(b)(2006).

III. Conclusion

In closing, Mylan looks forward to working with CMS as it finalizes these provisions of the Proposed Rule. If you have any questions or concerns, please do not hesitate to contact us.

Sincerely,

James V. Abrams
Director, Government Pricing & Reporting
Mylan Pharmaceuticals Inc.

February 20, 2007

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that AMP only reflects a snapshot in time that may not bear any relevance to market prices. In addition, as a complicating factor in the calculation of AMP and further limitation on the number's usefulness, manufacturers are often not privy to downstream (or indirect) sales and, thus, do not always have the data necessary to comply with CMS' proposed policies with respect to calculating AMP. Second, given the limitations inherent in AMP, manufacturer-specific AMP should not be made available to the "public," nor was that the intent of the DRA, which we discuss in detail below.

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In addition, as mentioned above, while manufacturers have access to information concerning direct sales, they often do not have any information on indirect sales (unless there is a chargeback or some other mechanism to track the sale). Although intending to clarify the determination of AMP, instead, CMS proposes to include in, and exclude from, AMP calculations data that are not readily available, if at all, to manufacturers. As an example, CMS proposes to include Medicare Part D rebates[3] in the calculation of AMP provided that such rebates are applicable to product sold to an eligible Medicare Part D beneficiary. However, manufacturers are rarely aware of whether their products are ultimately sold to an eligible

[3] Our comments with respect to Part D sales are discussed in detail in the "Determination of AMP – Section 477.504" section of this comment letter.

Medicare Part D beneficiary, making this policy operationally infeasible. Consequently, although some of these Medicare Part D rebates will be correctly included as proposed, most Medicare Part D rebates will be inadvertently excluded by manufacturers. Either way, the resulting AMPs submitted to CMS will be inconsistent, at best, across manufacturers.

As such, CMS will need to be exceedingly clear in the guidance that it provides to manufacturers in calculating AMP to ensure that manufacturers are able to determine the sales and associated price concessions that should and should not be included in AMP and to ensure consistency in AMP calculations across all manufacturers.

B. The Publication Of Manufacturer-Specific AMPs To All Purchasers, Payers, And Consumers Is Unintended Under The DRA.

The DRA sets forth that –

> Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States ... the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website....[4]

In a subsequent provision, the DRA sets forth that the Secretary is to disclose "(through a website accessible to the public) average manufacturer prices."[5] Based on these provisions it is clear that Congress intended that AMP data be made available to States and the "public." However, there is no basis to believe that Congress intended to make manufacturer-specific AMP information available on a website accessible to the "public."

We believe that Congress' intent to make AMPs publicly available was to improve the transparency of drug pricing under the Rebate Program for the benefit of payers, which would be accomplished by permitting only States and their Medicaid programs to access manufacturer-specific AMP information on the CMS website. Accordingly, by providing manufacturer-specific AMP data on the agency's public website in a manner that allows only State Medicaid programs (or other authorized users) access, CMS would be in compliance with Congress' directive, as well as with the intent of the statute.

In addition, as addressed by GPhA in its comments, publishing manufacturer-specific AMP information to the public is fraught with significant concerns, including, reduced competition, anticompetitive concerns, and confusion among purchasers and payers. For these reasons, we ask CMS to take a reasonable interpretation of the statute and publish only the aggregated industry-wide weighted average AMPs for multiple source drugs. Publishing manufacturer-specific AMP information would negate other applicable confidentiality provisions

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[4] DRA § 6001(b)(1)(B).
[5] DRA § 6001(b)(2)(C).

that the DRA did not change. A statute should not be accorded a meaning that eliminates the effect of certain of its provisions.

We also believe that these disclosure provisions must be implemented through notice and comment rulemaking, and the failure to do so violates the Administrative Procedure Act ("APA").[6] The APA requires agencies to give interested parties the right to participate in rulemaking through publication of a proposed rule, which includes "the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[7] As explained above, as well as in the comments from GPhA, there are many different possible means by which this provision can be implemented. As such, regulated businesses have a statutory right to notice as to how the information will be presented and to comment on the legal and policy implications of such decisions.

II. Comments to Specific Sections of the Proposed Rule

As mentioned above, AMP is not necessarily reflective of market prices. There are two key drivers of this number: (1) customer classification (e.g., eligible versus ineligible class of trade); and (2) transaction treatment (e.g., inclusion and timing). It is vital that these two components of AMP be applied in a uniform manner to ensure that the AMPs for the same products can be compared consistently across manufacturers. To this end, it is critical that CMS clearly define certain significant terms that are contemplated in the Proposed Rule. The remainder of our comments will address our concerns in the order that is set forth by CMS.

A. Determination of AMP – Section 447.504

1. Bundled Sales

CMS proposes that AMP calculations should be adjusted for bundled sales "by determining the total value of all the discounts on all drugs in the bundle and allocating those discounts proportionately to the respective AMP calculations."[8] That is, the aggregate discount would be allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. In the case of multiple discounted products in a bundle, the aggregate value of all the discounts should be proportionately allocated across all of the drugs in the bundle. The Medicaid Drug Rebate Operational Training Guide (the "Guide") defines the term "bundled sales" as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."

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[6] 5 U.S.C. Chap. 5.
[7] 5 U.S.C. § 553.
[8] 71 Fed. Reg. at 77177.

As proposed, CMS seems to broaden the definition of the term "bundled sales" to potentially include routine multiple drug sales to entities such as wholesalers and group purchasing organizations ("GPOs"). We do not believe that the intent of the Proposed Rule was to require that manufacturers allocate on an item-by-item basis the original price of the drug product had it been sold separately. Accordingly, we recommend that CMS should not broaden the definition of the term "bundled sales."

2. Retail Pharmacy Class of Trade – Nursing Home Pharmacy

In the Proposed Rule, recognizing the concerns that have been raised relating to the inconsistencies in the way manufacturers determine AMP, CMS proposes to clarify such determination by revisiting the definition of "retail pharmacy class of trade." CMS proposes to define the retail pharmacy class of trade as "that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services."[9] Given this definition, CMS proposes to exclude prices to long-term care ("LTC") (or nursing home) pharmacies because LTC pharmacies do not dispense to the general public.

We are concerned that CMS has not clearly identified those entities that would be considered LTC (or nursing home) pharmacies.[10] Mylan encourages CMS to clearly define the attributes of entities that qualify as LTC pharmacies to avoid disparate treatment among manufacturers as they exclude prices to LTC pharmacies in calculating AMP. If manufacturers were to use different criteria for determining whether an entity is a LTC pharmacy, manufacturers' AMPs would not uniformly reflect the exclusion that CMS intended in the Proposed Rule. As such, CMS should clearly define the term "LTC pharmacy."

In addition, we recommend that CMS establish a list of those LTC pharmacies that should be excluded from the calculation of AMP in a "List of Excluded Class of Trade Entities," similar to the type of document attempted by the Office of Pharmacy Affairs's ("OPA's") list of eligible 340B entities.[11] This list would specify for manufacturers those entities that should be excluded when calculating AMP. As a result, CMS would ensure that manufacturers consistently categorize customers included in and excluded from AMP calculations as there are several types of entities that could (or could not) qualify as LTC pharmacies, depending on the interpretation. For instance, it is not clear whether the following would be considered a LTC pharmacy under the Proposed Rule – LTC pharmacies owned by a hospital, infusion centers, and rehabilitation centers.

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[9] 71 Fed. Reg. at 77178.

[10] According to MedPAC, there are approximately 15,000 skilled nursing facilities. See MedPAC Report to the Congress: Medicare Payment Policy (March 2006). In addition, according to the Long Term Care Pharmacy Alliance ("LTCPA"), there are five major national LTC pharmacies – Kindred Pharmacy Services, Omnicare, NCS Healthcare, NeighborCare, and PharMerica. These LTC pharmacies serve more than 1.5 million people including more than two-thirds of all nursing facility residents. See LTCPA website available at http://www.ltcpa.org/mission/pharmacy/default.asp.

[11] For the reasons addressed in this section, we recommend that CMS establish a similar list for all entities that should be excluded from AMP calculations as guidance to manufacturers.

Further, as we have mentioned, it is often operationally infeasible for manufacturers to identify those sales that are made to a particular type of entity (e.g., a LTC pharmacy), as opposed to another type of entity that might not satisfy the definition of a LTC pharmacy. Manufacturer sales data are captured at the contract level, but any included or excluded class of trade customer could purchase products from any wholesaler source contract. Thus, manufacturers have no way of determining whether final sales are made to excluded customers. Given this inherent difficulty with calculating AMP, it is imperative that CMS provide mechanisms by which manufacturers can calculate AMP as consistently as possible.

3. Pharmacy Benefit Manufacturers ("PBM") Price Concessions

CMS addresses in the Preamble to the Proposed Rule the difficulties involved in the treatment of PBMs for purposes of determining AMP. Both the U.S. Government Accountability Office ("GAO") and the Office of the Inspector General ("OIG") have recognized that the Rebate Program does not clearly address certain financial concessions negotiated by PBMs, and have recommended that CMS clarify the treatment of PBM rebates.[12] According to the OIG, manufacturers treat rebates and fees paid to PBMs in one of three ways – (1) not subtracting rebates or fees paid to PBMs from the AMP calculation; (2) subtracting the rebates or fees paid to PBMs; or (3) subtracting a portion of the PBMs rebates or fees from the AMP calculation.[13]

Based on these inconsistencies, CMS considered both the inclusion and exclusion of all rebates, discounts, and other price concessions to PBMs in the determination of AMP. Although CMS acknowledges the difficulty manufacturers face in determining the apportionment of PBM price concessions to the PBM, the insurer, and, if any, to the pharmacy, CMS states that excluding all PBM price concessions could result in an artificial inflation of AMP. As such, CMS proposes to include all rebates, discounts, or other price concessions provided by the manufacturer to the PBM that affect the net price recognized by the manufacturer for drugs provided to the retail pharmacy class of trade.

For several of the reasons addressed by CMS in the Proposed Rule, Mylan agrees that it is necessary to clarify the treatment of PBM rebates and fees in the calculation of AMP. However, the Proposed Rule does not effectively accomplish this goal. That is, CMS fails to define the term "PBM" for the purpose of AMP calculations, which effectively allows manufacturers to include the sales from any entity that a manufacturer considers to be a PBM, including sales to managed care organizations, which are specifically excluded from AMP under the national rebate agreement.[14] We believe that CMS needs to clearly 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 as we discussed in the section above. Doing so will enable

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[12] See GAO, "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns About Rebates Paid to States," (GAO-05-102) (February 2005); see also OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).

[13] 71 Fed. Reg. at 77179.

[14] Id.

manufacturers to use uniform criteria to distinguish between PBMs and non-PBMs for purposes of incorporating rebates and fees into AMP calculations. If, however, CMS fails to set forth guidance regarding PBMs, manufacturers will continue to treat PBM price concessions disparately, resulting in inconsistent AMP calculations across manufacturers. Therefore, it is imperative that CMS clearly identify factors that manufacturers should use in determining whether an entity is in fact a PBM.

As an additional matter, the Proposed Rule seems to include in the calculation of AMP PBM price concessions, but limits this inclusion to those rebates relating to PBM sales to the retail pharmacy class of trade.[15] If this is indeed CMS's intent, then the agency's proposal would not be practicable because manufacturers do not have information concerning these indirect sales. Manufacturers cannot ascertain whether PBMs' downstream sales are to the retail class of trade or not. Thus, they would not be able to ensure that their AMP calculations include only those price concessions related to sales to the retail pharmacy class of trade.

4. Identification of Sales

The Proposed Rule requires that AMP include only those sales to wholesalers "for dispensing to the general public," e.g., sales to wholesalers that result indirectly in sales to the retail pharmacy class of trade.[16] Often, however, a manufacturer will not know if the sale from a wholesaler is to an entity in the retail pharmacy class of trade. Generally, there are three types of direct sales involving manufacturers – direct sales to retail pharmacies, direct sales to wholesalers where wholesalers then sell to retail pharmacies, and direct sales to wholesalers where the wholesaler then sells to an entity that is unknown to the manufacturer. The third arrangement is the one that makes CMS' proposed policies operationally infeasible. That is, once a manufacturer sells to a wholesaler, the wholesaler may then sell to any number of entities.

Manufacturer sales data are captured at the wholesaler-manufacturer level, but any subsequent sale from the wholesaler could be to any entity – one that is either included or excluded from the retail class of trade. A manufacturer would have data to identify downstream indirect sales if they were processed by a wholesaler through a chargeback for a wholesaler program sale or a manufacturer-established contract sale. However, a manufacturer would not have sufficient data to identify indirect sales made by a wholesaler or distributor if a chargeback is not processed for the sale.[17] In the latter case, the manufacturer would not be able to identify the purchaser in the second sale or to assess whether the entity was in the retail pharmacy class of trade. This is also true of SPAP and Part D rebates, which we discuss below.

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[15] Id.

[16] Id.

[17] See Medicaid Drug Rebate Program Release #29 (acknowledging manufacturers' need to often recalculate or refine pricing data due to the improper inclusion or exclusion of certain sales.).

5. State Pharmaceutical Assistance Program ("SPAP") Rebates

As further clarification of the determination of AMP, CMS proposes to include SPAP price concessions in the calculation of AMP. CMS states that similar to the Medicaid program, Medicare Part D prescription drug plans ("PDPs"), Medicare Advantage prescription drug plans ("MA-PDs"), and SPAPs do not directly purchase drugs. Instead, SPAPs are generally third-party payers. Therefore, CMS believes that these sales should be included in AMP to the extent that the sales are to an entity included in the retail pharmacy class of trade. Accordingly, CMS proposes that SPAP sales, as well as rebates paid by the manufacturer to the SPAP, be included in the AMP calculation.

We, however, do not agree with CMS' proposed treatment of SPAP rebates. As CMS mentions, SPAPs are similar to the Medicaid program in that SPAPs represent third-party government payers. Therefore, because Medicaid rebates would be excluded from AMP calculations, the same should be true for SPAP rebates. SPAP data is only available on a quarterly basis with a considerable lag period and no correlation to a SPAP eligible sale. Manufacturers also have the opportunity to refile SPAP data for the quarterly reporting requirement. Accordingly, SPAP rebates should be excluded from monthly AMP calculations.

In addition, CMS' proposed treatment of SPAP rebates conflicts with the treatment required under previous CMS Manufacturer Release #68, which instructs manufacturers to distinguish between "qualified" and "unqualified" SPAPs, based on criteria listed in such release. Under this program release, only rebates to qualified SPAPs are excluded from AMP, whereas rebates to unqualified SPAPs are included in AMP. We request that CMS revisit this program release to address this inconsistency. If CMS ultimately decides to include all SPAP rebates in the calculation of AMP, then the agency should provide guidance regarding the method of inclusion.

6. Treatment of Medicare Part D Rebates

CMS proposes to clarify in the Proposed Rule that the treatment of prices of sales through a PDP, MA-PD, or a qualified retiree prescription drug plan for covered Medicare Part D drugs provided on behalf of Medicare Part D eligible individuals should be included in the AMP calculation. CMS states that similar to the Medicaid program, PDPs and MA-PDs do not directly purchase drugs, but are usually third-party payers. As is the case with Medicaid sales, CMS believes that these sales should be included in AMP to the extent that the sales are to the retail pharmacy class of trade. As such, CMS proposes that these prices, as well as rebates paid by manufacturers to the PDP or MA-PD, should be included in AMP calculations.

Similar to the discussion above concerning SPAP rebates, we recommend that CMS exclude Medicare Part D rebates from AMP calculations. Because Medicare Part D rebates are similar to Medicaid program rebates, which are excluded from AMP calculations, Medicare Part D rebates should be treated similarly.

Further, Medicare Part D rebates are excluded from best price, and the resulting inconsistent treatment of Medicare Part D prices in AMP and in best price calculations would be unjustified. As CMS acknowledges in the Proposed Rule, the law requires that "prices negotiated by a prescription drug plan, by an MA-PD plan . . . or by a qualified retiree prescription drug plan . . .with respect to such drugs on behalf of Medicare Part D eligible individuals, shall . . . not be taken into account for the purposes of establishing the best price...."[18] Because of this statutory mandate concerning best price, we believe CMS should treat Medicare Part D rebates in the context of AMP similarly to ensure parity for both AMP and best price calculations. Thus, we recommend that CMS use its authority to exclude Medicare Part D rebates from AMP.

7. Returned Goods

According to the Proposed Rule, CMS proposes to exclude returned goods from AMP calculations provided that such goods are returned in "good faith." [19] We recommend, however, that CMS clarify that products destroyed by purchasers (and, thus, not returned to the manufacturer) should be treated the same way as returned goods – e.g., excluded from AMP. Likewise, we recommend that recalls be treated the same as returned goods and excluded from AMP. We also urge CMS to clarify the treatment for AMP calculation of any return fees or reasonable recall fees paid by manufacturers.

8. Manufacturer Coupons

In the Proposed Rule, CMS proposes to clarify the way in which manufacturer coupons should be treated. CMS proposes to include coupons redeemed by any entity other than the consumer in the calculation of AMP. Accordingly, CMS proposes that coupons that are redeemed by the consumer directly to the manufacturer would not be included in AMP calculations. We recommend that CMS make clear that manufacturer coupons redeemed by a consumer, whether directly ***or indirectly*** to the manufacturer (e.g., through a pharmacy) should be excluded from AMP calculations.

9. Administrative and Service Fees

According to current policy under the Rebate Program, "administrative fees, which include service fees and distribution fees, incentives, promotional fees, chargebacks, and all discounts or rebates, other than rebates under the [Rebate Program]..." should be included in AMP calculations, provided those sales are to an entity included in the calculation of AMP. The OIG, however, noted that there is confusion among manufacturers regarding the treatment of

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[18] 71 Fed. Reg. at 77183; see Social Security Act ("SSA") § 1927(c)(i)(VI); see also Medicaid Drug Rebate Program Release # 63 (Feb. 19, 2004).
[19] 71 Fed. Reg. at 77181.

such fees.[20] Given the OIG's report, CMS proposes to clarify the treatment of administrative fees by including all such fees in the calculation of AMP.

CMS proposes, however, to exclude from AMP fees paid for *bona fide* services. CMS proposes to define *bona fide* service fees as "fees paid by a manufacturer to an entity, which 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 which are not passed in whole or in part to a client or customer of an entity, regardless of whether the entity takes title to the drug."[21]

We strongly recommend that CMS clearly set forth guidance as to what constitutes a *bona fide* service fee. Although CMS attempts to make this clear in its proposed definition, it would be more helpful for CMS to provide additional parameters and/or specific examples to assist manufacturers in making this determination. Further, we encourage CMS to work with the OIG to establish a "safe harbor" for *bona fide* service fees. We believe that the payment of *bona fide* service fees by manufacturers could implicate the anti-kickback statute.[22] That is, *bona fide* service fees could be viewed as an incentive to purchase drug products from manufacturers. Given the potential for widely varying interpretations of the definition of *bona fide* service fees and the potential anti-kickback concerns, it is important that CMS and the OIG work together to provide clear guidelines and a safe harbor for this term.

B. Authorized Generics – Section 447.506

In the Proposed Rule, CMS proposes to require the primary manufacturer (NDA holder) to include, in its calculations of AMP and best price, sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary. CMS believes that to limit the applicability of the Proposed Rule to the sellers of authorized generic drugs would allow manufacturers to circumvent the intent of the DRA by licensing rather than selling the rights to such drugs. As is currently required, the secondary manufacturer or subsidiary of the brand manufacturer would continue to pay the single source or innovator multiple source rebate for the authorized generic products based on utilization under its own NDC number.

CMS, however, makes no mention in the Proposed Rule of sales from the brand manufacturer to the authorized generic manufacturer (e.g., sales at the "transfer price").[23] For purposes of consistency, we recommend that CMS also include the transfer price of the NDA holder to the authorized generic manufacturer in the NDA holder's best price calculations.

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[20] OIG, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063) (May 2006).
[21] 71 Fed. Reg. at 77180.
[22] SSA § 1128B(b).
[23] DRA § 6003.

C. Requirements for Manufacturers – Section 447.510

In the Preamble, CMS sets forth the reporting requirements for manufacturers with regard to pricing data. Specifically, CMS proposes that AMP would be reported both on a monthly and quarterly basis to CMS. CMS proposes that the monthly AMP would be calculated using the same methodology as the quarterly AMP. In an effort to minimize the price fluctuations and to maximize the usefulness of the monthly AMP, CMS proposes to allow manufacturers to estimate the impact of their end-of-quarter rebates or other price concessions and to allocate these rebates or other price concessions throughout the quarter in the monthly AMPs reported to CMS. CMS invites comments on allowing the use of 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP. CMS also seeks comments on allowing manufacturers to calculate the monthly AMP based on updates of the most recent three-month period (i.e., a rolling three-month AMP).

While smoothing is a helpful mechanism to adjust for fluctuations in the calculation resulting from the timing of sales and credits, smoothing does not necessarily result in AMP bearing a more precise market price. Smoothing is dependent on historical data that may or may not be completely applicable to current business activity. However, in order to adjust for variability in monthly reporting periods, we agree with CMS' proposal to allow the "smoothing" of AMP data. In addition, we recommend that CMS permit four quarter smoothing to ensure a more consistent application of a percentage during the months of a quarter. We believe that this is a reasonable smoothing mechanism that would be beneficial to manufacturers and that would enhance the AMP data that are received by CMS.

D. Upper Limits for Multiple Source Drugs – Section 447.514

The currently reported AMP is based on the nine-digit NDC, combining all package sizes of the drug into the same computation. CMS proposed to continue this policy and solicited comments on the alternative approach of using 11-digit NDC to calculate AMP as well as comments on the merits of using both approaches in calculating AMP for the FUL calculation.[24]

In response to CMS' request for comments on the appropriate NDC level for calculating AMP, we support the use of the 11-digit NDC. The primary benefit of the 11-digit NDC, as CMS notes, is the inclusion of package size in the AMP calculation. Also, CMS observes that the 11-digit NDC would align with the State Medicaid drug payments that are based on package size, as well as allow greater transparency. Further, taking into consideration different customer types, e.g., small and large retail pharmacies, and different life cycle management, applying the 11-digit NDC would promote greater consistency and accuracy among AMPs. Accordingly, we recommend the use of the 11-digit NDC for calculating AMP.[25]

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[24] 71 Fed. Reg. at 77187.

[25] See 42 C.F.R. § 447.332(b)(2006).

III. Conclusion

In closing, Mylan looks forward to working with CMS as it finalizes these provisions of the Proposed Rule. If you have any questions or concerns, please do not hesitate to contact us.

Sincerely,

James V. Abrams
Director, Government Pricing & Reporting
Mylan Pharmaceuticals Inc.

Submitter : **Miss. Dana Thomas** **Date: 02/20/2007**

Organization : **National Association of Community Health Centers**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

The National Association of Community Health Centers is pleased to submit comments on the proposed rule requiring changes to drug pricing calculations in the Medicaid program.

CMS-2238-P-1353-Attach-1.DOC

National Association of Community Health Centers, Inc.

February 20, 2007

BY ELECTRONIC MAIL
http://www.cms.hhs.gov/eRulemaking

U. S. Department of Health and Human Services
Att: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: CMS-2238-P
Proposed Rule on Medicaid Program: Deficit Reduction Act; Prescription Drugs

RINs 0938-AO20
71 Fed. Reg.77174 et seq. (December 22, 2006).

Dear Sir/Madam:

The National Association of Community Health Centers ("NACHC") appreciates the opportunity to submit comments on the proposed rule issued by the Centers for Medicare and Medicaid Services (CMS) on implementing the Medicaid drug pricing calculations, sections 6001 (a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 ("DRA") (Pub. L.109-171). NACHC is a membership organization that represents Federally Qualified Health Centers (FQHCs) nationally. At present, approximately 1,000 FQHCs with 5,000 sites serve 16 million patients across the country. The vast majority of these patients are impoverished individuals living in medically underserved areas. More than 35 percent of health center patients are Medicaid beneficiaries and close to 40 percent are uninsured.

Approximately one-third of health centers operate pharmacies and almost all of them participate in the 340B Drug Pricing Program. The 340B Program provides health centers with discounts on drugs ranging from 15% to 60%. Under Section 340B of the Public Health Service Act (PHSA), drug manufacturers must enter into agreements with the U.S. Department of Health and Human Services (HHS) to provide drugs to "covered entities" at discounted prices. Health centers are considered covered entities, and thereby able to purchase drugs at discounted prices for the patients they serve. In addition to centers with their own licensed pharmacies, many health centers contract with community pharmacies to dispense prescription drugs that the centers purchase at 340B prices and have shipped to their contracted pharmacy for dispensing to health center patients in accordance with Health Resources Services Administration (HRSA)-issued guidelines.

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OVERALL COMMENTS

The proposed rule implements sections of the Deficit Reduction Act (DRA) that are designed to reduce overall pharmacy costs in the Medicaid program. **Taken together, the various provisions of the DRA are projected to negatively impact the financial solvency both of health centers with their own licensed pharmacies and the community pharmacies with which many health centers contract for provision of pharmaceutical services to their patients.** This is likely to occur because of the ratcheting down of reimbursements for generic drugs (health centers purchase and dispense high percentages of generic drugs in order to keep costs down), the lack of any requirement that dispensing fees must reflect actual costs of providing pharmaceutical services, changes in the calculations for Average Manufacturer's Price for community retail pharmacies that often contract with health centers, and the proposal to make physician-administered drugs subject to a Medicaid rebate.

Thus, the final rule issued by CMS to implement the DRA provisions should take into consideration these projected negative impacts on safety net pharmacies and include provisions to ensure that safety net pharmacies do not bear a disproportionate burden of reductions in Medicaid payments to the extent that their solvency is threatened. Safety net pharmacies are unique in that they are located near and serve the most vulnerable, low-income patients. They have established the capacity to provide linguistically and culturally appropriate pharmacy services for highly diverse patient populations with limited financial means, including homeless individuals, migrant farm-workers, the elderly on fixed incomes, single parents with dependent children, and members of many ethnic and linguistic groups. These safety net pharmacies need to be preserved in order to assure the disenfranchised of the country access to needed pharmaceuticals.

AVERAGE MANUFACTURERS PRICE

There are a number of ways in which the proposed rule will impact health centers. The statute and proposed rule revise the current definition of AMP and require that drug manufacturers remove the customary prompt payment discount from their AMP calculations. In effect, the new rule would increase the AMPs and consequently manufacturers' rebate payments to the states. This would have the effect of increasing 340B prices and could mean the loss of significant savings to 340B safety net entities. However, a letter to manufacturers distributed on January 30, 2007 by HRSA has indicated that calculation of 340B prices must be based on the provisions of the 1992 340B statute which included prompt pay discounts. This interpretation would enable 340B entities to retain the savings which they already receive by continued inclusion of prompt pay discounts in the calculations. **We would urge CMS to support HRSA's interpretation and to provide the data required for calculation of two AMPs, one for 340B entities, and another for other providers.**

In addition, the proposed rule will lower the Federal Upper Limit (FUL) for a number of drugs and thus reduce Medicaid payment for drugs to thousands of small pharmacies. This change in the rule will substantially reduce Medicaid payments to health center pharmacies that purchase both 340B and non-340B stock. A number of health centers operate pharmacies that

maintain 340B drugs for their patient populations that are uninsured or lack sufficient drug coverage, as well as retail pharmacy stock for other health center patients. By maintaining the different drug stocks, health centers can offset some of the prescription drug losses they experience serving their uninsured and underinsured patients with small margins from other payers.

Furthermore, a number of health centers contract with local community pharmacies to provide their patients with easier access to prescription drugs. The proposed rule may force many pharmacies to close their doors due to lack of profitability, particularly those in rural underserved areas, thus jeopardizing these contractual arrangements. A report released by the Government Accountability Office (GAO) estimates that the proposed rule will result in pharmacists being paid substantially less for their Medicaid patients. A number of pharmacists have indicated that this reduction in reimbursement may prevent them from serving Medicaid beneficiaries. **It is imperative that the final rule safeguard against the potential harm caused to Medicaid beneficiaries by a decrease in reimbursement for safety net pharmacies – both health center pharmacies and community pharmacies.**

340B DRUG CALCULATIONS

The practical effect of the interpretation of the 340B statute and the DRA and proposed rule regarding prompt pay discounts will necessitate manufacturers to calculate different AMPs for 340B covered entities and non-340B providers. The rule reads, "prices to these entities [340B covered entities] should be excluded from AMP because the prices to these entities are not available to the retail pharmacy class of trade." 71 Fed Reg. at 77197. In order to implement these provisions, it is absolutely critical that HRSA have access to the data they need to calculate the 340B prices. We urge CMS to require that drug manufacturers submit both sets of drug prices to CMS/HRSA so that HRSA may accurately calculate 340B ceiling prices for covered entities. The information should include specific prompt pay discount information on drugs by NDC so that 340B prices may be accurately computed. Currently, there is no mechanism in the regulations mandating that this information be provided to HRSA. If HRSA does not receive the requisite data, they will be unable to supply heath centers and other safety net providers with the appropriate 340B drug pricing. Health center pharmacies and their patients depend on the 340B drug program in order to provide prescription drugs to their patients at discounted prices. The new AMP should in no way impede the ability of 340B patients to access their drugs. **The final rule should specify that HRSA will receive from manufacturers and/or CMS the specific needed data by NDC code to calculate 340B prices, and the rule should establish a mechanism for doing so on a timely basis.**

DISPENSING FEES

The DRA does not guarantee that pharmacies will receive cost-based or related reimbursement for their dispensing fees. However, the final rule should establish such a guarantee. Dispensing fees should include reimbursement for dispensing and associated costs such as patient counseling, packaging, inventory management, ordering and billing,

and overhead costs. Given the reductions in reimbursement for generic drugs and other provisions of the DRA, health centers and other 340B providers will have to rely upon reasonable, cost-based dispensing fees to stay in business. Safety net pharmacies that serve a high proportion of Medicaid providers will be disproportionately affected by the lack of any guarantees as to reasonable cost for dispensing.

PHYSICIAN-ADMINISTERED DRUGS

There are not reliable data available on the extent to which health centers provide physician or clinic-administered drugs in health center and other ambulatory settings; nonetheless, depending on their size and sophistication, we know that some health centers do provide such drugs in the clinic setting. In the past, these have not been subject to a Medicaid rebate, and thus health centers have either billed them distinctly on a fee for service basis or, more likely, they have bundled the cost of provision of such drugs into their all-inclusive Medicaid and Medicare reimbursement rates which are either cost-based or cost-related. Making these drugs subject to rebates would most likely trigger a requirement that they be billed at acquisition cost to avoid a "duplicate discount" with the Medicaid rebate program. This could significantly reduce reimbursements to health centers and other 340B covered entities, such as disproportionate share hospitals that are an important part of the pharmaceutical care safety net. These physician-administered drugs include many drugs that are essential to treatment for significant diseases and conditions, including chemotherapy drugs for cancer patients. There is no system in place at this point to implement such changes; implementation now could likely result in chaos and disruption of care for vulnerable patients. **We would urge CMS to change the proposed rule and exempt such drugs administered by 340B covered entities from the definition of drugs subject to the Medicaid rebate. Furthermore, if CMS insists on including physician-administered drugs in the rebate program, CMS should guarantee pharmacy dispensing fees that adequately compensate for the cost of the drug and other costs associated with providing it to patients.**

HHS/CMS have an obligation to ensure that the safety net provider structure for the medically underserved throughout the country is not dismantled or significantly weakened through reimbursement policies. The safety net provider structure saves taxpayers on health care costs in the long run by providing needed health services and prescription drugs to low-income and vulnerable populations on an ongoing basis, diverting them from emergency rooms, and preventing and controlling conditions that, if left unattended, often result in inpatient hospitalizations and more costly surgeries and treatments.

NOMINAL PRICE EXEMPTIONS

The proposed rule appears to waive away HHS's authority to establish nominal price exemptions for additional classes of providers beyond those specified in the DRA. Health center nominal prices are exempted from best price calculations in the DRA (which is good), but health centers procure prescription drugs at local levels through a variety of arrangements – including relationships with family planning purchasing groups and other such organizations. Some of these relationships depend upon long-established patterns of nominal pricing from

manufacturers. We cannot understand why HHS/CMS would want to relinquish its authority to establish such exemptions on a case by case basis for different categories of entities – such as free clinics – or other safety net providers that play a major role in pharmaceutical access for low-income patients. **We urge CMS not to relinquish, through the rule-making process, this important authority delegated by the DRA to HHS to establish additional nominal price exemptions, but rather, to preserve it, and use it as needed to extend the pharmaceutical safety net.**

ELEVEN DIGIT NATIONAL DRUG CODE

NACHC notes that use of 11-digit National Drug Codes (NDC) to calculate the AMP most likely would result in the greatest transparency and accuracy for calculation of 340B prices, a desired 340B program integrity goal. On the other hand, it appears that the use of the 9-digit NDC favors smaller volume purchasers (such as health centers), and that many health centers could experience revenue losses if the 11-digit NDCs were used.

For further information, feel free to contact NACHC staff Dana Thomas, JD., Associate Director of Regulatory Affairs or Freda Mitchem, Director of Systems Development and Policy Administration at 301-347-0400.

Respectfully submitted,

Roger Schwartz, Esq.
Director of State Affairs

Submitter : **Mr. Bradley Crump** **Date: 02/20/2007**

Organization : **Fairmount Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FML) program for generics. My pharmacy is located in Fairmount,IN. We are a major provider of pharmacy services for this community and your consideration of these comments is essential.

1. Definition of "Retail Class of Trade"- Removal of PBM's and Mail Order Pharmacies

Excluding PMBs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the "general public". The more extensive comments submitted by Indiana Pharmacy Assoc. have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculations of AMP-Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies.

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent. (as well as detrimental to a retail pharmacy such as ours that cannot obtain this same pricing advantage).

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize the Medicaid pricing is heavily regulated by the state and federal authorities.

4. Manufacturer Data Reporting for Price Determination-Address Market Lag and Potential Manipulation

The actual implementation of the Amp Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, Indiana Pharmacy Assoc. proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11-Digit NDS versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit size is used.

In conclusion, I support the more extensive comments that are being filed by the Indiana Pharmacy Association regarging this proposed regulation. Please remember we who carry the load of this job are retail pharmacies, not PBMs or Mail Order. Pricing formula should reflect retail pharmacies true purchase ability, not diluted by other minor or non-participating purchase entities. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Bradley Crump RPh
Fairmount Pharmacy
124 N Main St
Fairmount, IN
765-948-4111
fairmountrx@yahoo.com

Submitter : Ms. Annette Mann **Date:** 02/20/2007

Organization : Solvay Pharmaceuticals, Inc.

Category : Drug Industry

Issue Areas/Comments

Background

Background

See Attachment

Collection of Information Requirements

Collection of Information Requirements

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1355-Attach-1.DOC

Background

- The DRA requires AMP to be calculated on a monthly basis. This will increase the frequency of calculations from four per year to 16 per year (12 monthly and four quarterly) for every manufacturer. This dramatic increase in work is extremely resource intensive, especially for small to medium sized manufacturers who have limited staff. We will have to increase staff or shift responsibilities to comply with the monthly calculations. In addition, the systems we have in place cannot calculate AMP on a monthly basis and will require an upgrade or the installation of a replacement solution. The increased staffing and system support will increase our expenses significantly.

- The DRP requires that manufacturers submit to CMS the CPP discount each month. However, there is no direction on what format the information should be provided, such as, in whole dollar or unit or by percentage. In addition, the Drug Data Reporting System (DDR) does not contain a field for CPP. CMS needs to clarify what format CPP is to be submitted to CMS and how it is to be submitted to them.

- Our system does not capture actual CPP discount paid on an NDC level but, rather, only in total dollars paid. Will reporting an accrued amount by NDC suffice?

Regulatory Impact Analysis

- The Office of Pharmacy Affairs (OPA) is insisting that the AMP calculation utilized for 340B pricing be calculated using pre-DRA methodology. The result is that manufacturers will have to calculate AMP using two separate methodologies each quarter resulting in 20 calculations per year (one per month plus two per quarter). This is extremely burdensome to our limited staff. Further, our system can only calculate the quarterly AMP using a single methodology. Maintaining two different AMP methodologies will require system upgrades or replacement systems. Having two different AMPs for each quarter will no doubt cause confusion and potential errors in the future. It is extremely burdensome and problematic to maintain two separate methodologies for calculating AMP. There needs to be one single guideline for determining AMP.

- CMS has proposed that manufacturers can restate Baseline AMPs using the DRA methodology (currently, this opportunity has been postponed). Given that most of our products are more than 15 years old, the change in technology, systems, and resources makes this burdensome at best and, more likely, impossible to find the appropriate transactions and calculations. Furthermore, for products acquired from other manufacturers, the Baseline AMP was inherited and the original data is not available. Not being in a position to restate Baseline AMP will increase Medicaid rebate liabilities; the proposed AMP would exclude Customary Prompt Pay (CPP) discounts while the original Baseline AMP will include CPP discounts. For older products and transferred products, CMS needs to consider an alternate

methodology to restate Baseline AMP when the original source data or systems are not available. A simple calculation that increases the Baseline AMP by 2% or the normal CPP discount is one possible solution.

Provisions of the Proposed Regulations

- The proposed CMS guidelines allow for certain eligible Rebates to be deducted in determining AMP. But the vast majority of Rebate payments are made on a quarterly basis while the AMP calculation represents monthly results. Manufacturers will need to determine a methodology to convert the quarterly data into appropriate figures for monthly reporting. Without clear CMS guidelines, manufacturers will have differing methodologies for converting rebate data, resulting in discrepancies across different drugs. CMS needs to provide clear options as to how manufacturers should allocate quarterly rebates into monthly calculations.

- The proposed DRA requires that the CEO, CFO, or one of their direct reports certify the AMP calculations and submission. Obtaining an actual physical signature from one of these limited sources on a monthly basis will be a significant challenge. Will an electronic signature or e-mail suffice in complying with this requirement?

- Without clear and concise guidance from CMS as to how AMP is to be calculated, including what Classes of Trade (COT) are eligible and which COT are not eligible, manufacturers who compete in the same therapeutic area could have differing methodologies resulting in unfair physician reimbursement calculations. CMS needs to provide clear guidance on the calculation of AMP in order to maintain a fair and level playing field for physician reimbursement.

- CMS is requiring that manufacturers submit the monthly Pricing Data via the Drug Data Reporting System (DDR). The instruction to access the DDR state that use of an SSN is voluntary, but when we inquired CMS told us that providing a SSN is required to access the DDR and that the DDR is required to submit Pricing and Product Data. This puts manufacturers in an awkward position of requiring staff to submit personal information when they are not comfortable doing so. Manufacturers access many systems that contain confidential data without requiring the use of an SSN. Would CMS consider an alternate identification to allow manufacturer's access to the DDR such as the Federal EIN which is unique to each manufacturer?

Submitter : Mr. Brian Romig **Date:** 02/20/2007

Organization : Moses Cone Health System

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1356-Attach-1.DOC

February 20, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

On behalf of The Moses H. Cone Health System, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. The Moses H. Cone Health System is a 1000 bed health system located in North Carolina, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our health system by requiring the reporting of NDC information on drugs administered in the hospital outpatient settings. Our hospital's billing system is not configured to have the capacity to substitute NDC numbers as identifiers for clinic administered drugs. To obtain this capacity, we would have to make significant changes to our billing system at extreme expense in terms of money, staff resources, and disruption of administrative operations. Medications administered in our clinic are often composed of various drugs with different NDC numbers that would require extended time if we were to manually bill all clinic drugs.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. Manufacturers would pass on to us (in the form of price increases) any discount or rebate they return to Medicaid. We currently experience $10.8 million per year in savings related to the 340B program and suspect that we would lose much of that savings if States imposed rebates on manufacturers.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. We would experience at least $300,000 in cost increases if manufacturers were not allowed to offer drugs at nominal pricing.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Brian Romig
Executive Director Pharmacy Services
Moses Cone Health System

Submitter : Mr. Glen Mathis **Date:** 02/20/2007

Organization : Mathis Drug Store, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

We are an independant rural pharmacy in the midwest. We can no longer fill prescreptions for 4.00 fee when they cost $10.00. As soon as I see that we have been paid below cost, we will opt out of this program. I already have the opt out fax written. I can't fill them for nothing.

Submitter : Mr. Clifton Bishop **Date:** 02/20/2007

Organization : Bishop Drugs Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1358-Attach-1.DOC

February 20, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of BISHOP DRUGS, INC.a community retail pharmacy located at 101 West Commercial Ave Monterey, TN 38574. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

1. Definition of "Retail Class of Trade" – Removal of PBMs and Mail Order Pharmacies

CMS is proposing an overly broad inclusive definition of "retail class of trade" for use in determining the AMP used in calculating the FULs. The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies can purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBMs and mail order pharmacies from the AMP determination recognizes that these are not community pharmacies, where the vast majority of Medicaid clients have prescriptions dispensed. Mail order pharmacies do not meet the "open to the public" distinction, as they require unique contractual relationships for service to be provided to patients. PBMs do not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Both these types of organizations do not dispense to the "general public" and, therefore, should be excluded from the information used in the calculation of the AMP to be used for determining an FUL. The more extensive comments submitted by the Tennessee Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP – Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including the elements defined in the proposed regulations is counter to Congressional intent. Rebates and other concessions paid by manufacturers to entities such as mail order pharmacies and PBMs are not shared with community retail pharmacies and, thus, do not reduce the prices pharmacies pay for drugs and are not available to the "general public." These rebates and concessions must be excluded from the calculation of the AMP used to determine the FULs.

While the AMP data is not currently publicly available, so that retail pharmacies can actually determine what the relationship will be between the proposed AMP-based FULs and the prices retail pharmacies pay to acquire the drugs, the GAO has conducted an analysis of this relationship. The GAO used the highest expenditure and the highest use drugs for Medicaid in the analysis. The GAO reported that retail pharmacies will be reimbursed, on average, 36% less than their costs to purchase the drugs included in the analysis. A business can not be sustained if it is forced to continuously sell its products below its actual acquisition costs.

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy, where over 90% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

Medicaid pricing is heavily regulated by the state and federal governments. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

4. Manufacturer Data Reporting for Price Determination – Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, the Tennessee Pharmacists Association (TPA) proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the TPA comments on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date before it could be dispensed. It simply would not be feasible or practical to purchase in these quantities. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

CLIFTON BISHOP P.D.
101 WEST COMMERCIAL AVE
MONTEREY, TN 38574
cc: Senator Lamar Alexander
Senator Bob Corker
Congressman Bart Gordon

Submitter : Mr. Edward Heckman **Date:** 02/20/2007

Organization : PAAS National

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1359-Attach-1.DOC

PAAS National, Inc.
Expert Third-Party Contract and Audit Advice
160 Business Park Circle • Stoughton, WI 53589 • 608-873-1342 • Fax: 608-873-4009

February 19, 2007

VIA http://www.cms.hhs.gov/eRulemaking

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

RE: CMS-2238-P
COMMENTS PERTAINING TO THE RULE TO IMPLEMENT PROVISIONS OF THE DEFICIT REDUCTION ACT OF 2005 (DRA)

PAAS National, Inc. (PAAS) is pleased to submit these comments on behalf of their membership to CMS for consideration of the proposed rule to administer and calculate AMP and new Medicaid Federal Upper Limits (FUL) values for generic pharmaceuticals.

PAAS National, Inc. is a support organization assisting retail pharmacies to prepare and respond to PBM and third-party payor prescription drug claim audits. Over 3,200 retail pharmacies representing all 50 States are members of PAAS National, Inc.

OVERVIEW

The spiraling costs of health care in the United States and in particular, the greater inflation rate on the prices of prescription drugs is cause for concern for all Americans. Prescription drugs have steadily increased their percentage of total health care expenditures for the past ten years or more. The passage of the Deficient Reduction Act of 2005 (DRA) is an attempt by Congress to control the money spent to fund Medicaid programs.

CMS must take extreme caution in implementing the provisions of DRA to assure that Medicaid maintains the quality of care of recipients and should not jeopardize patient safety and care to save money.

The primary component of the DRA and concern is a change in the methodology of establishing Federal Upper Limit (FUL) prices for generic or multi-source pharmaceuticals to an AMP based calculation. PAAS acknowledges the concerns by Congress and CMS of the deficiencies

associated with the current FUL system, that identifies a limited number of multi-source drugs with infrequent adjustments that are far behind market trends.

Currently, payors view FULs as the ceiling and pay less. Stakeholders in the pharmacy industry recognize the FUL system as antiquated and deficient. Virtually none of the State Medicaid Programs or commercial prescription drug benefit programs, reimburse retail pharmacies an Estimated Acquisition Cost on any multi-source drug the complete FUL value.

In spite of these shortcomings, multi-source prescriptions represent a significant savings over brand name, single source prescription drugs. Brand drug prescriptions typically average five to eight times the cost of an average multi-source drug prescription. It is important for CMS to recognize the significance of generic drugs on overall costs. Any disincentive to generic dispensing will produce devastating results; inflating program drug spends far beyond the savings derived from AMP based FULs. A one percent decrease in generic dispensing rate inflates a plan's overall costs by 1.5%.

PAAS views the new methodology results on a de facto basis to government imposed price controls on generic or multi source pharmaceuticals.

Another consequence of AMP based FULs is that State Medicaid Programs will view the FUL value of each multi-source drug as ceiling for a that particular and as is the present custom and not in the aggregate, with no individual drug exceeding FUL. There is nothing in place to require State Medicaid programs to come within a degree of closeness to aggregate FULs.

PAAS believes that the new FULs will also continue to be the maximum value that any commercial drug plan would reimburse a retail pharmacy on a multi-source drug. Any effect on a State Medicaid Programs will trickle down to all commercial managed care prescription plans. The magnitude and responsibility resting upon CMS in establishing New FUL calculations is huge. The impact of this decision will determine the continued access of patients to prescription services and the future of retail pharmacy in the United States.

DEFINITION OF RETAIL PHARMACY CLASS OF TRADE AND DETERMINATION OF AMP (PAGES 25 – 43)

Comments—Inclusion of Mail Order in Retail Pharmacy Definition

If mail order pharmacies are in the same class of trade as retail pharmacies, why did the Medicare Modernization Act that established Medicare Part D separate retail pharmacy, nursing home pharmacy and mail order pharmacy? Obviously, there is a large enough difference that each of the three was addressed on its own. PBMs view their mail order business as so important that they segregate their reporting and accounting of retail prescriptions and mail order prescriptions in their quarterly and annual reports.

We agree that CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade. Hospital and nursing home pharmacies have long been recognized as a

separate class of trade and on some products extended lower prices not available to retail pharmacy. The definition of retail pharmacy that CMS is looking at includes "publicly accessible;" nursing homes and hospitals are not publicly accessible.

Mail order pharmacies are not accessible to the public. Their sole purpose is to service the managed care prescription benefit plans that they contract with. PBM-owned mail order pharmacies dominate nearly 100% of the mail order segment of pharmacy. When a plan sponsor aligns their prescription benefit with a PBM, the sponsor is only offered the PBM's own mail order pharmacy. There isn't competitive bidding between mail order pharmacies to gain a sponsor's business. This results in a *de facto* closed pharmacy environment with the plan sponsor and individual patients not having any freedom of choice from one mail order pharmacy to another.

PBM's can design guidelines that can be much different for their mail order pharmacy versus retail pharmacies. They may employ different generic substitution parameters, different preferred drugs or formulary drugs and different refill limitations and controls. PBMs can allow their mail order pharmacy to use different NDC numbers that they do not make available to retail pharmacy and can dispense brand drugs instead of generics (Nexium). PBMs have advantaged themselves when a brand drug loses market exclusivity by negotiating generic pricing on the brand—and then employing a weighted brand-generic mix to heighten their profits.

The PBMs also control the estimated acquisition cost they reimburse a retail pharmacy and it could be at a rate less than they pay their mail-order operation. The PBM also controls the prices they charge to a plan sponsor and can manipulate those prices between prescriptions filled at retail versus mail order to push spreads the most favorable for the PBM.

PBM owned mail order pharmacies have an inherent flaw in that their interests do not always align with the plan sponsor or patient. They are not required to adhere to any fiduciary standard. It is possible for PMBs to make money at the expense of the plan sponsor. This business model is akin to a consulting entity who acts as a purchasing agent for a company and the consulting entity also manufacturers a line of products that would be competing to win the business of the company. The conflict is obvious. The consulting entity cannot serve their manufacturing sales and establish a purchasing relationship best for their company client.

Including mail order pharmacies in the definition of retail pharmacy only advantages the largest businesses at the disadvantage of smaller retail pharmacies.

Comments—Determination of AMP

CMS is correct to include PBM price concessions in manufacturer's calculations for Best Price. However, PBM price concessions should not be considered by CMS in the determination of AMP.

PBM discounts paid by manufacturers for steering transactions should not be included in AMP calculations for the same reason that CMS excludes rebates paid to the States under the Medicaid

Drug Rebate Program. As CMS states on page 36 of the Proposed Rule, "As a general matter, Medicaid does not directly purchase drugs from manufacturers or wholesalers but instead reimburses pharmacies for these drugs. Therefore, Medicaid sales are determined by the entities that are actually in the sales chain and because Medicaid reimburses pharmacies for drugs for Medicaid beneficiaries, integrated into the chain of sales otherwise included in AMP." CMS goes on to state, "rebates paid to States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that price concession associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included."

The same statement replacing PBMs for Medicaid is every bit as valid.

"As a general matter, a PBM does not directly purchase drugs from manufacturers or wholesalers but instead reimburses pharmacies for these drugs. Therefore, PBM sales are determined by the entities that are actually in the sales chain and because a PBM reimburses pharmacies for drugs for PBM beneficiaries, integrated into the chain of sales otherwise included in AMP." Moving on to state, "rebates paid to PBM under the PBM's Drug Rebate Program should be excluded from AMP calculations but that price concession associated with the sales of drugs in the retail pharmacy class of trade which are provided to PBM patients should be included."

PBMs exert every bit as much force and control over drug transactions as Medicaid in general and much greater control when compared to individual State Medicaid Programs. The equalizer for Best Price to State Medicaid Programs is the Medicaid Drug Rebate Program and the similar equalizer for PBMs "Best Price," is their Manufacturer Rebate Programs.

Although the dollar values of rebates may vary to a degree from one PBM to the other, the net effective is that these are administrative/transactional rebates/discounts that a retail pharmacy has no control, has no direct knowledge and is not a stakeholder. In as much that retail pharmacies are not held responsible for the rebates in the Medicaid Drug Rebate Program, they cannot be held responsible for PBM rebates.

PBMs receive payments from manufacturers as administrators for the transactions they steer and influence, and not necessarily a drug they ever own, take possession of, or dispense to patients. In fact PBMs do not shoulder any risk for the cost of these drugs. PMBs add language to pharmacy contracts absolving the PMB of any payment liability to a provider pharmacy if the plan sponsor fails to pay the PBM. These payments are proprietary, not accretive of a retail pharmacy's knowledge or awareness. Additionally, these rebates do not impact on the price that PBMs reimburse pharmacies for drugs and have no impact on the price a drug wholesaler may charge a pharmacy. Unless these PMB discounts would start passing through to retail pharmacies—it is competitively unfair to hold retail pharmacy to an AMP value that includes them.

Because PBMs own mail order pharmacies, they have the ability to move a myriad of discounts to advantage themselves in a competitive sense. Discounts shifted to a PBM's mail order pharmacy may be in effect, *defacto* payments from manufacturers to administer drug

transactions. The PBM decides what pocket to take money out of and which pocket to put it in. The clear danger is the formation of a government created monopoly where a PBM could push administrative discounts paid by manufacturers into the cost of a drug dispensed in their mail order facility—resulting in an artificially deflated AMP value. If the PBM would be careful enough to avoid being tagged as an outlier, the net effect would be to drive competitors out of business who could not steer transactions in a PBM sense, and therefore receive similar discounts.

This unfair advantage is heightened by the fact that PBMs, as benefits administrators, determine the Maximum Allowable Cost (MAC) they will reimburse retail pharmacies for multi source prescription claims. PBMs would have the ability to use artificially deflated AMPs to establish MACs values well below the acquisition cost of retail pharmacies. PBMs unilaterally set MAC values, change them as they please and refuse to negotiate their values with their retail pharmacy providers. In many instances, PBMs refuse to publish or reveal MAC pricing schedules to provider pharmacies.

Outliers

CMS has requested input on how to define and remove outlier AMPs "as a safeguard to ensure that a drug is nationally available at the FUL price." CMS proposes to set the AMP "on the lowest AMP that is not less than 30 percent of the next higher AMP for that drug."

PAAS sees this proposed action as an arbitrary percentage selection as to what CMS views as fair, rather than a value calculated with some statistical significance. The amount of the difference could actually vary to a greater or lesser degree and remain within a range of fairness that would allow retail pharmacies to purchase the multi source drug at or below the FUL.

PAAS suggests that CMS use a statistical calculation of a standard deviation for each group of therapeutically equivalent therapeutic products. Any manufacturer AMP falling below one standard deviation would be removed as an outlier. The AMP would be based upon the lowest value within one standard deviation.

V. B. 2. Effects on State Medicaid Programs
Comments

Multi-source prescriptions represent a significant savings for Medicaid programs over brand name, single source prescription drugs. Brand drug prescriptions typically average five to eight times the cost of the average multi-source drug prescription. It is important for CMS to recognize the significance of generic drugs on overall costs. Any disincentive to generic dispensing will produce devastating results; inflating program drug spends out of control. A one percent decrease in generic dispensing rate inflates a plan's overall costs by 1.5%.

In their latest report, the GAO voices the same concern in reporting their findings:
"The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006." -GAO-07-239R

II. Aggregate Upper Limits of Payment—Section 447.512
Comments
CMS is proposing to reduce the number of therapeutically equivalent drugs to establish a FUL from three to two. This definition includes repackagers in the count and could mean that a drug of more limited availability could fall under the FUL provisions because of repackager duplications of the ANDAs.

In addition, CMS proposes to include sub-standard B-rated generic drugs which do not meet the FDA standard of equivalence for the purpose of generic drug interchange could. It is possible that the B-rated drug would establish the AMP and therefore the FUL value or a multi-source entity. The net effect is that a retail pharmacy would be required to dispense a more expense "A" rated equivalent or contact the prescriber to see if a new prescription could be generated for the "B-rated" version.

V. B. 1. Effects on Manufacturers
Comments
PAAS believes that multi source drug manufacturers, especially the larger plays could manipulate their pricing on drugs to generate artificially low AMPs and eventually drive weaker competition from the marketplace. Once this occurs the remaining manufacturer(s) would gain a competitive advantage and raise prices well beyond their present levels.

V. B. 3. Effects on Retail Pharmacies
Comments

CMS states that, "pharmacies have the ability to mitigate the effect of the proposed rule by changing purchasing practices. . . Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss."

CMS makes an incorrect assumption that the same manufacturer, multi source drug that establishes AMP, is available through many wholesalers at similar price to retail pharmacies. The reality is that one wholesaler may have a business relationship and preferred position with a manufactuer that another would not. The lowest price and the manufacturer offered by a wholesaler on a particular therapeutically equivalent multi source drug varies from wholesale to wholesaler.

As an example, last December when Simvastatin passed the 180-day period of generic exclusivity, it was launched and distributed by a number of manufacturers. Wholesalers postured to offer their best price to their retail customers on Simvastatin. A December 28, 2006 competitive price shop of the following wholesalers: Dik Drug, Masters Rx, McKesson, Bellco, Kinray, Pharmacal, Cardinal revealed a myriad of manufacturers in the lowest priced position.

WHOLESALER

SIMVASTATIN	PKG.	A	B	C	D	E	F	G
10 mg	30	Auro-bindo	Cobalt	Dr. Reddy	**Cobalt**	Dr. Reddy	Auro-bindo	TEVA
10 mg	90	**Auro-bindo**	Cobalt	Dr. Reddy	Cobalt	Dr. Reddy	Auro-bindo	TEVA
10 mg	1,000	**Auro-bindo**	Cobalt	Dr. Reddy	Dr. Reddy	Dr. Reddy	Auro-bindo	TEVA
20mg	30	Auro-bindo	Cobalt	Lupon	**Cobalt**	Dr. Reddy	Auro-bindo	TEVA
20mg	90	Auro-bindo	Cobalt	Lupon	**Cobalt**	Dr. Reddy	Auro-bindo	TEVA
20mg	1,000	Auro-bindo	Cobalt	**Lupon**	Cobalt	Dr. Reddy	Auro-bindo	TEVA
40mg	30	Auro-bindo	**Cobalt**	Dr. Reddy	Cobalt	Dr. Reddy	Auro-bindo	TEVA
40mg	90	Auro-bindo	**Cobalt**	Dr. Reddy	Cobalt	Dr. Reddy	Auro-bindo	TEVA
40mg	1,000	Auro-bindo	Cobalt	**Lupon**	Cobalt	Dr. Reddy	Auro-bindo	TEVA
80mg	30	Auro-bindo	**Cobalt**	Dr. Reddy	Cobalt	Dr. Reddy	Auro-bindo	TEVA
80mg	90	Auro-bindo	Cobalt	**Dr. Reddy**	Cobalt	Dr. Reddy	Auro-bindo	TEVA
80mg	1,000	Auro-bindo	**Cobalt**	Dr. Reddy	Cobalt	Dr. Reddy	Auro-bindo	TEVA

The bolded manufacturer in the wholesaler column represents the lowest invoice price to retail pharmacies that we found in the marketplace on December 28, 2006. Five different manufacturers at various strengths and package sizes earned the lowest price position.

CMS also makes an assumption that retail pharmacies are able to set-up accounts with many wholesalers and 'jump' to the wholesaler who has the product at price under the FUL. In the above example, six wholesalers were shopped, resulting in four of offering the lowest price depending upon strength and package size. It is not feasible to shop a myriad of wholesalers every time a pharmacy purchases a generic drug. Wholesalers place requirements on retail pharmacies for minimum order amounts and monthly purchase volumes to open accounts. Additionally, retail pharmacies are dependent upon value-added services provided by their wholesaler that are tools retail pharmacies use to assist them in operating their businesses. Retail pharmacies are very concerned with patient safety and attempt to avoid switching the manufacturer on refills of the multi-source drug dispensed. Multi source drug manufacturers vary tablet (capsule) sizes, colors and markings. Switching manufacturers on a multi source generic by a retail pharmacy requires extra patient consultation and care.

FULs set below the acquisition cost of retail pharmacies will push some of them toward purchasing drugs from gray market, and secondary handlers of drugs. These types of wholesalers have a tainted history with problems of diversion and counterfeit drugs.

CMS states that even though, "The savings to the Medicaid program would largely be realized through lower payments to pharmacies," they can mitigate the loss as "almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales."

This inference by CMS is incorrect as prescription drug sales represent a much higher percent of a retail pharmacy's business. In the case of the over 24,000 independent retail pharmacies in the United States, the 2006 edition of the "NCPA-Pfizer Digest" reports that 91.2% of total business is prescriptions. Even pharmacy chains refute the supposition that overall sales average twice as much as prescriptions. The three largest pharmacy chains in the country, Walgreeen, CVS and Rite Aid collectively own about 15,000 pharmacies. Walgreen in their 2006 Annual Report state that 64% or nearly two-thirds of their business is prescriptions. CVS in their 2005 Annual Report states pharmacy sales at 70.5% of their total. And, Rite Aid in their 2006 Annual Report state that prescriptions are 63.4% of their total business. Prescription drug sales are the most critical element in determining the success or failure of a retail pharmacy.

CONCLUSION

On behalf of PAAS National, Inc. I thank CMS for their diligence in reviewing our comments.

Sincerely,

H. Edward Heckman, R.Ph.
President

Submitter : **Mr. Paul Tirotto** **Date: 02/20/2007**

Organization : **Broad Street Apothecary**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1360-Attach-1.DOC

Regarding the changes that will occur with the Deficit Reduction Act of 2005, I feel the studies were flawed from the very beginning. Everyone in the industry knows retail pharmacies pay much more for their drugs than anyone else in the industry. Therefore, to reimburse retail pharmacies the same price as you will mail order is totally outrageous. Retail pharmacies will be closing down on a daily basis and patient choice will be at a minimum. Every business in the United States is allowed to make a reasonable profit, except for retail pharmacy.

This one paragraph should enlighten each of you who read this letter. When I opened my pharmacy on January 15, 1990, my reimbursement rates were full AWP (average wholesale price) + 3.00. Fast-forward today the average reimbursement rate is AWP-16% +1.50. So What? You say. Well, this should show retail pharmacies are not the culprit. You should be going after PBMs (pharmacy benefit managers) and brand name drug manufacturers. First, the pbms are forcing their clients to use more expensive brand name drugs instead of generics or less expensive brand name drugs, because of the rebate factor. Second, drug manufacturers keep raising their prices for their products. Third, brand name companies are now using delay tactics to stop generic drugs to come to market.

Thank You,
Paul V. Tirotto

Submitter : **Date: 02/20/2007**

Organization : **Amylin Pharmaceuticals, Inc.**

Category : **Private Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1361-Attach-1.PDF

1361

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SUBMITTED ELECTRONICALLY

February 20, 2007

The Honorable Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Ms. Norwalk,

I am writing on behalf of Amylin Pharmaceuticals, Inc. ("Amylin") to submit comments on the recently published proposed rule on the treatment of prescription drugs under the Medicaid program ("Proposed Rule").[1] Amylin is a biopharmaceutical company dedicated to improving patient lives through the discovery, development and commercialization of innovative medicines. Amylin appreciates the opportunity to comment on the issues related to prescription drug reimbursement under the Medicaid program, and looks forward to working with the Centers for Medicare and Medicaid Services ("CMS") to implement appropriate policies that ensure appropriate access, use, and reimbursement for Amylin products.

Amylin applauds CMS for its efforts to improve the Medicaid program and enhance care to the nation's most vulnerable populations. The task of accurately calculating the Average Manufacturer Price ("AMP") for purposes of the Medicaid program is a complex and difficult undertaking, and Amylin appreciates CMS' willingness to work with parties impacted by the issue to reach an acceptable methodology. As a member of both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO), Amylin, in general, supports the broader comments submitted by those groups. In addition, Amylin would also like to specifically address a few issues that are particularly important in the mission to provide quality medicines to all patients. These issues include:

- Exclusion of product returns from the AMP formula;
- Use of eleven digit NDC numbers for purposes of calculating AMP;
- Creation of separate AMP calculations for the Medicaid program and 340B drug discount program; and

[1] 71 Fed. Reg. 77174 (Dec. 22, 2006).

- Inclusion of manufacturer coupons redeemed by entities other than patients in the AMP formula.

1. Amylin Pharmaceuticals, Inc. Supports Excluding Returns Made in Good Faith from the AMP Calculation.

First, Amylin would like to commend CMS for its recognition that product returns should be excluded from the calculation of AMP when returned in good faith. The current CMS policy that requires inclusion of such returns in a manufacturer's AMP calculation can make it difficult for the manufacturers to accurately determine the AMP for its products, particularly where a product has been returned after the close of the quarter in which it was sold. Amylin agrees with CMS's assessment that the proposed policy of excluding good faith returns will enhance the accuracy of AMP calculations as well as reduce the administrative burden on manufacturers when determining the appropriate AMP for any given month or quarter.

2. CMS Should Revise the Proposed Rule To Use Eleven-Digit NDCs in the AMP Calculation.

Amylin is concerned with CMS' decision to move forward with product reporting using a nine-digit NDC number rather than an eleven-digit NDC number to calculate AMP. In the Proposed Rule, CMS explains that while it considered the use of an eleven-digit NDC for purposes of AMP calculations, it ultimately decided to maintain its current policy of using a nine-digit NDC. As the Proposed Rule explains, the nine-digit NDC number currently used is specific only to the product code for a drug and combines all package sizes of the drug into the computation of the AMP. However, as CMS also explains, use of the eleven-digit NDC would allow pricing data to distinguish between various product package sizes and may ultimately lead to increased transparency in pricing, enhanced ability to track specific package sizes more closely and a more accurate calculation of AMP. Nonetheless, CMS concludes that Congress did not intend to change the NDC level at which manufacturers are to report AMP and that to make such a change would require manufacturers to change their data reporting systems.

Amylin urges CMS to consider implementation of an eleven digit system. Under the provisions of the Deficit Reduction Act, manufacturers will already be required to change their data reporting systems.. Reporting AMP at the eleven-digit NDC level will ultimately alleviate the administrative burden on manufacturers by eliminating the need to calculate a weighted average for product families. Furthermore, Best Price (BP) is currently calculated at the eleven-digit NDC level, and transitioning the AMP calculation to this same eleven-digit standard will enhance consistency between both calculations in the future and allow for more accurate determination of Medicaid drug rebates. However, it is also important to note that should CMS choose to move forward with an eleven-digit NDC reporting system for AMP, it will need to alter the BP portions of the Proposed Rule so that BP calculations incorporate this change as well (i.e., the use of the lowest BP for all package sizes would no longer be the appropriate method of calculating the Unit Rebate Amount for an entire product family). Implementing a one to one NDC relationship in the calculation of the AMP and BP will allow for more consistent, transparent and accurate calculations.

3. CMS Should Clarify the AMP Calculation for 340B Purposes.

Amylin is also concerned with the administrative burdens posed by CMS' apparent policy to develop two separate methods of the AMP calculation: one for use with the 340B drug discount program and another for all other federal health care programs. AMP plays a critical role in the calculation of two main categories of drug prices under federal statute: the price for products used for the Medicaid population and the price for products purchased by the 340B drug discount program. Because 340B is modeled after the formula used to calculate reimbursement under the Medicaid drug rebate program, changes to the calculation of AMP for Medicaid program purposes also has a direct impact on prices under the 340B program.

However, in the Proposed Rule, CMS sets forth potential policies that are not consistent with current policies under the 340B program, creating the possibility that calculation of AMP under Medicaid and other federal programs would not be consistent with calculation of AMP for purposes of establishing 340B prices. Using this methodology would be extremely difficult for manufacturers to accurately determine the appropriate price for products under each program. Moreover, it will require a manufacturer to track and report product prices using two separate program mechanisms that will ultimately end in the manufacturer's preparing two different calculations, further causing confusion and inconsistency in the Medicaid drug rebate and 340B drug discount programs. Requiring a manufacturer to accurately distinguish between product prices under the Medicaid AMP and the 340B AMP is complex and confusing, and it creates significant administrative and cost burdens.

Given the complexity of the AMP formula, the administrative burden would be significantly increased if manufacturers would be required to calculate more than one AMP each quarter for each of its retail products. A method that requires manufacturers to calculate multiple variations of this formula for individual health care programs is unreasonable, and such an approach would create an unnecessary burden for manufacturers participating in the 340B program. Considering the significant number of data and reporting obligations manufacturers already face, Amylin asks that CMS be cautious about creating reporting requirements that could potentially impact data quality and accuracy.

Moreover, the 340B program depends on CMS to supply them with the AMP information, yet the CMS Drug Data Reporting (DDR) system does not include a field to enter a separate AMP to be used for the 340B program. Under the current proposal, it is unclear how this information will be communicated to the 340B program.

4. CMS Should Revise the Proposed Rule to Exclude All Coupons from the AMP and Best Price Calculations.

Under the Proposed Rule, CMS seeks to include manufacturer coupons redeemed by entities other than patients in the calculation of AMP. Amylin is concerned that this proposed policy may impact the ability to obtain lower cost pharmaceuticals for patients in need while providing little benefit in terms of AMP accuracy. As noted by the Senate Committee of Finance in its January 31, 2007 letter to CMS discussing the nominal pricing provisions in the

Proposed Rule, Congress has historically emphasized the importance of patient access to pharmaceuticals, and it strives to develop policies that protect the integrity of the Medicare and Medicaid programs without having an adverse impact on beneficiaries.[2] Manufacturer coupons redeemed by non-patient purchasers typically provide a benefit to patients that is similar to the savings patients receive when directly redeeming a manufacturer coupon themselves. The savings realized from these coupons, even when redeemed by an entity other than the patient, are most often used to provide expanded access to a pharmaceutical product for an individual who may otherwise be unable to obtain the medicine. Conversely, Amylin believes the risk that manufacturers would use such coupons to manipulate AMP should CMS exempt such coupons redeemed by entities other than patients would be minimal or non-existent. As such, the threat to patient access to pharmaceuticals posed by the proposed policy does not appear to be outweighed by a significant benefit to AMP accuracy, and CMS should reconsider its decision to include such manufacturer coupons in the calculation of AMP. The broader price reduction that could be seen by inclusion of such coupons could produce a negative effect on manufacturers' ability to offer such arrangements and limit patients' ability to realize the benefits of these coupons.

In light of the administrative burdens that will result from implementation of this rule, Amylin respectfully asks CMS to delay implementation of the rule to consider the comments presented by the public and revise the policies proposed in the rule as appropriate.

Once again, Amylin appreciates the opportunity to offer comments on the Proposed Rule and looks forward to working with CMS to ensure fair and accurate reimbursement of prescription drugs under the Medicaid program to assure access to innovative therapies. Please do not hesitate to contact us if you have questions or need additional information. We look forward to working with you on these very important issues.

Sincerely,

Marcea Bland Lloyd
Senior Vice President, Legal & Corporate Affairs
And General Counsel

Amylin Pharmaceuticals, Inc.

[2] Letter to Leslie V. Norwalk from Senators Max Baucus and Charles Grassley, January 31, 2007.

Submitter : **Date: 02/20/2007**

Organization : **Planned Parenthood of Metropolitan Washington**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Having a non-340B clinic in Falls Church, Virginia, we have found that we are no longer making a profit off of selling pills, and have had to resort to raising the cost of other services we provide to keep the clinic running. We are unable to offer our patients the latest birth control options because we are unable to afford them ourselves.