**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

Attach # 1556

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

ATTACH # 1550

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

Attach # 1357

**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)

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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

Attach # 1360

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

**Amylin Pharmaceuticals, Inc.**
9360 Towne Centre Drive
San Diego, CA 92121 USA

Tel (858) 552 2200
Fax (858) 552 2212
www.amylin.com

***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

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.