FLORIDA HOSPITAL ASSOCIATION
An Association of Hospitals & Health Systems

February 19, 2007

Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: (CMS-2238-P) Medicaid Program: Prescription Drugs (71 *Federal Register* 77173), December 22, 2006

Dear Ms. Norwalk:

The Florida Hospital Association, on behalf of its member hospitals and health systems, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule related to Medicaid prescription drugs, as published in the *Federal Register* dated December 22, 2006. We are most concerned about the provisions related to physician-administered drugs as addressed in the Deficit Reduction Act of 2005 (DRA), section 6002. This provision, as interpreted by CMS, would require hospitals to include an accompanying National Drug Code (NDC) for outpatient claims beginning with a service date of January 1, 2007.

Medicaid fiscal agents in numerous states have moved forward with implementation of this provision based on the requirements of the DRA, while other states have yet to even address this issue with their hospitals. Some are perhaps waiting for the release of a final rule while others are concerned with the impact of this change on their internal processing systems.

The FHA is concerned with the implementation of this regulation from two perspectives. First, while the DRA provision was intended to enhance the ability of state Medicaid programs to secure rebates from drug manufacturers related to physician-administered drugs, we do not believe that Congress intended application of this section to hospital outpatient services. The current law, at Section 1927(j)(2), exempts hospital outpatient clinics and departments from Medicaid rebate program obligations and there was not a provision in the DRA to eliminate the existing exemption.

The DRA provision was enacted to address a problem with rebate collection on drugs administered in physician offices, in direct response to a report from the Office of Inspector General. That report projected that states were losing millions of dollars in Medicaid rebate payments due to their failure to collect rebates on physician-

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administered drugs, defined in that report as "drugs that a medical professional administers to a patient in a *physician's office.*" [Emphasis added.]

The second issue associated with implementation of this regulation is one of administrative burden required for hospitals to be in compliance with NDC reporting. Hospital patient accounting systems capture HCPCS codes for pharmaceuticals, not NDC codes. To report the NDC, hospitals across the country would be required to make major revisions to their chargemasters. The American Hospital Association estimates that these changes will take between 500 and 1,500 work hours to design, build, and test a short-term work around for NDC reporting, without certainty of compliance because of the needed crosswalk from the hospital's pharmacy system. At this time, many of the pharmacy systems capture only a primary NDC for a particular drug and do not have the ability to include multiple secondary sources for similar drugs that would be required under the Medicaid rebate program.

The FHA urges CMS to revise its interpretation of Section 6002 of the DRA and to continue to exempt hospitals from the reporting of NDCs for physician-administered drugs in the outpatient hospital setting under for purposes of the Medicaid rebate program. If you have questions on these comments, please do not hesitate to contact me at (407) 841-6230 or via email at kathyr@fha.org.

Sincerely,

Kathy Reep

Kathy Reep
Vice President/Financial Services

Zydus Pharmaceuticals (USA) Inc.

ZyPharma

A US Generic Pharmaceutical Company

ZyGenerics

Center for Medicare and Medicaid Services
Department of Health and Human Services,
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

February 16, 2007

Re: Concerns regarding the proposed AMP regulations

Enclosed, please find the comments from Zydus Pharmaceuticals USA Inc, a US Generic Company, regarding the proposed AMP calculations.

1. Individual company product AMP's are confidential, especially in the case of a small company that may only have one customer. AMP's are internal competitive strategic information and under no circumstance should they be published by company – the AMP published by product should be just the one number blinded as to the company referenced.

2. In regards to CMS's request for comments around the nine versus eleven digit NDC (pages 78 – 80), we feel AMP's are needed for all product SKU's as package sizes have a significant issue on pricing. The eleven digit NDC should be the reference rather than the nine digit proposal due to the large pricing per tab variances that can occur based upon bottle size. For example, the price per pill would be higher for a bottle of 30 count at retail vs. 1000 count bottle due to the additional manufacturing and packaging costs.

3. CMS asked the question or asked for suggestions around outliers in the market place (page 82). The AMP should exclude suppliers that are not commercially available in the marketplace or on a long term backorder, sales of short dated product (product with less than 12 month dating), products supplied as a "one time deal" prior to a market discontinuation / NDC change, or manufacturers that may be leaving the marketplace. One additional idea around this would be to exclude the AMP of manufacturers that have a limited or small market share (eg. less than 10%). These AMP's or transactions could be marked accordingly and excluded from AMP.

4. The report it states that customers could obtain product from the lowest AMP to be competitive. Within the generic market, especially one that has multiple players, a manufacturer may not have the inventory available to supply the entire market or the capacity (including API, excipients, etc.) within their manufacturing site to meet this demand.

5. Data should be provided by manufacturers quarterly rather than monthly. This way smoothing could take effect around any adjustments, returns, and ordering patterns of our customers. (Note: Some customers may order every other month or even quarterly.)

6. In regards to CMS's request for public comment on mail-orders and PBM's, the AMP should be established for each channel separately (e.g.: Retail, Mail, Hospital etc). This is especially true if an organization has only one customer and it is a PBM or mail-order. All other classes of trade could be severely affected (in reference to page 26), especially the independent retailers.

7. It is still not clear as to how the calculation of AMP will be handled for the following:

   - Free goods, upfront funding etc that benefit future periods (current period vs. future period AMP).
   - How do handle the differences between accruals and actual AMP post a reporting quarter. E.g. Prior period financial adjustments? What if this actually should have been a higher AMP than reported?

8. On initial product launches, additional fees may be paid for marketing or stocking expenses. We feel these would be one type of "bona fide" service fees reference on page 54. These should not be included in the AMP as it is not a true representation of product costs. Will there be a list of "bona fide" services provided by CMS?

9. In the event that product costs would rise, especially in the case of older generic products or products where raw material shortages may occur, there is no protection for the marketplace. It would be a loss to dispense a generic, thus driving higher costs as pharmacies would dispense the brand instead given the time delay of AMP publication.

10. There is still confusion around whether cash discounts will be part of the AMP calculation. It is reference twice within the document and it's treated differently in each reference.

We look forward to your comments and please feel free to call if you need any further clarity on our remarks. In conclusion we offer two final thoughts:

1. We could recommend that reconsideration of an AMP "average" be used as a benchmark vs. the lowest AMP.

2. We strongly feel that the implementation of AMP be delayed until the above issues could be resolved.

Best regards,

Mike Keenley
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February 5, 2007

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

Re: CMS-2238-P

Dear Director,

I am referencing File Code # CMS-2238-P. Implementation of a manual system to provide each NDC number for claims submission would be highly impractical, inefficient, and may create potential safety issues if such a process was established within a hospital.

The only feasible method for a hospital to support such a request is to have an electronic Bar-coding Application at the point of Medication Administration (BCMA) so all administered medications can be tracked and recorded. Even with BCMA application in place additional software costs would have to be expended to get the NDC # on a reporting document for claims submission. The cost for BCMA software and hardware systems is approximately $500,000 to $600,000 with an additional $35,000 to $60,000 in annual support fees.

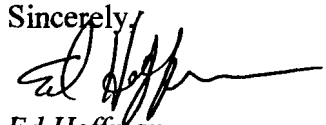
- Currently our hospital information system will not yield an 11-digit unique NDC number to submit to the State Medicaid agency. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication. These medication NDC numbers may change from month to month, week-to-week and day-to-day based upon medication ordering practices due to contract pricing, back-orders and stock outs. This causes frequent switching of NDC numbers in order to supply a patient's medication needs during their hospital experience.

- The impact on workflow, staffing, financial resources and patient safety issues to the hospital is unrealistic and not justifiable given current fiscal and workforce constraints.

I urge you to reconsider implementation of the adoption of the proposed rule in the Federal Register December 22, 2006, which would force hospitals to provide NDC information on a billing submission to the State Medicaid agencies to enable them to bill manufactures for rebates under the Medicaid program. The reporting of the 11-digit unique NDC number of the outpatient drug administered to the patient would create an undue hardship on all institutions.

Thank you for considering this request.

Sincerely,



Ed Hoffman

Ed Hoffman,
Director of Pharmacy

EH: kdr

KERR DRUG

ANTHONY N. CIVELLO
President & CEO

February 16, 2007

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS 2238-P
Post Office Box 8015
Baltimore, Maryland 21244-8015

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

Kerr Drug operates 102 pharmacies in North and South Carolina. Kerr Drug in conjunction with NACDS is pleased to submit the attached comments to the Centers for Medicare and Medicaid Services (CMS) regarding our views on the proposed regulation published on Friday, December 22, 2006 in the *Federal Register.* That proposed regulation would provide a regulatory definition of AMP, as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

We ask that CMS address the following critical issues for our industry, both through modifications to the proposed regulation, as well as through changes to the proposed timeline for the release of AMP data.

Public Release and Use of AMP Data Should be Delayed

CMS should not post any AMP data on a public website before CMS finalizes its regulation with a clear, validated definition of AMP that accurately reflects the prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies.

AMP Definition Should be Revised to Reflect Retail Pharmacy Purchasing Costs

CMS' proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the approximate prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs distributed to traditional community retail pharmacies should be included in the AMP definition.

Sales to mail order pharmacy, nursing home pharmacy, hospital outpatient, clinic sales, and manufacturers' coupons must be excluded because these are not sales to traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of

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trade. In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP because those discounts and rebates do not affect prices paid by wholesalers.

CMS must also address how to account for the potential lag between the time the manufacturer calculates the AMP data and the time it is posted on a website. Without an adjustment to AMP, the posted AMPs may be outdated and may not reflect the existing prices at which retail pharmacies purchase medications.

New Generic FULs Should be Suspended

The new FULs for generic drugs proposed in the regulation – calculated as 250percent of the lowest average AMP for all versions of a generic drug – will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas.

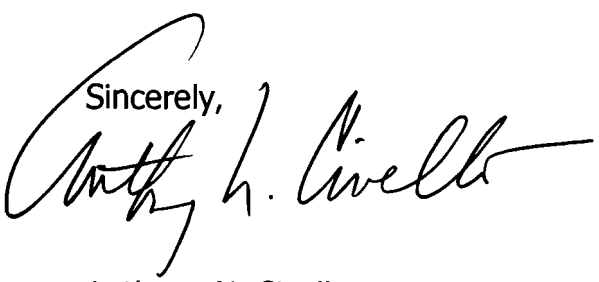
We ask that the implementation of these FULs be suspended because these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office (GAO) found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

States Need to Increase Pharmacy Dispensing Fees:

CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset anticipated losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

We appreciate your consideration of these attached comments and ask that you please contact us with any questions. Thank you.

Sincerely,



Anthony N. Civello
President & CEO

NATIONAL ASSOCIATION OF CHAIN DRUG STORES (NACDS)
Comments on Medicaid Program: Prescription Drugs
CMS 2238-P RIN 0938-AO20
February 20, 2007

I. Section 447.504 – Determination of AMP

This section defines the sales that manufacturers must include and the price concessions that they must omit when calculating their Average Manufacturers Price (AMP). Appropriate calculation of the AMP depends upon several factors, including an accurate definition of the retail class of trade, an accurate identification of manufacturers' prices paid by wholesalers for drugs distributed to retail pharmacies, and an appropriate definition of wholesaler. CMS proposed definition of AMP is problematic in all three areas.

a. The Law Requires that AMP Must Include Only Prices Paid by Wholesalers

Since 1990, federal law has defined AMP, with respect to a covered outpatient drug, as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1). A change made by DRA requires manufacturers to calculate AMP without regard to customary prompt pay discounts extended to wholesalers beginning on January 1, 2007. *Id.*

The law clearly limits AMP calculations to prices paid by wholesalers and discounts received by wholesalers. Yet, CMS proposes to require that manufacturers include in the AMP calculation prices that are not paid by wholesalers, as well as discounts on drugs that are not received by wholesalers. Only payments to manufacturers by wholesalers, for drugs that are subsequently distributed to the retail class trade, can by law be included in the AMP. Any other payments must be as a matter of law, excluded from the calculation of AMP.

The proposed rule would include many payments that have nothing to do with payments by wholesalers to manufacturers. As examples, the proposed rule would include in AMP calculation the following payments, regardless of whether the entities involved are acting as wholesalers making payments to manufacturers:

- 447.504(g)(3): Direct sales to hospitals
- 447.504(g)(4): Nominal sales to "any entity" (with a few enumerated exceptions)
- 447.504(g)(5): Sales to retail pharmacies
- 447.504(g)(6): Rebates, discounts and other price concessions paid to PBMs
- 447.504(g)(7): Direct sales to patients
- 447.504(g)(8): Sales to outpatient clinics
- 447.504(g)(9): Sales to mail order pharmacies
- 447.504(g)(10): Rebates, discounts and other price concessions "associated with" sales of drugs that are "provided to" the retail pharmacy class of trade
- 447.504(g)(11): Coupons redeemed by "any entity other than the consumer" that are "associated with" sales of drugs that are "provided to" the retail pharmacy class of trade

- 447.504(g)(12): Sales under Medicare Part D, SCHIP, SPAPs and Medicaid that are "associated with" sales of drugs that are "provided to" the retail pharmacy class of trade.
- 447.504(i): Discounts, incentives, contingent free goods, fees and "any other discounts or price reductions" that reduce the income received by a manufacturer

Because the law is clear, CMS must revise the final rule to exclude all of these sales from calculations of AMP. AMP must only reflect payments by wholesalers to manufacturers for drugs that are distributed to retail pharmacies.

CMS appears to recognize that it is not following its prior practices regarding this issue. In the preamble to the proposed rule, CMS acknowledges that for years "our position has been that PBMs have no affect on the AMP calculations unless the PBM is acting as a wholesaler...." 71 Fed. Reg. at 77179. Now, however, CMS proposes to change this longstanding position and instead include "any" price adjustments or discounts provided by manufacturers, regardless of whether those price adjustments or discounts have anything to do with the prices paid by wholesalers. *Id.* This represents a complete reversal of CMS' longstanding interpretation of the statute, which clearly defines AMP as the prices paid by wholesalers.

CMS also appears to understand that it is not following the plain language of the statute by including payments by non-wholesalers in calculations of AMP. CMS says that "we recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade...." Id. Nevertheless, CMS goes on to state that "however, in light of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such adjustments are provided directly or indirectly by the manufacturer." This newfound "Congressional intent" is not reflected in statute, and is completely inconsistent with CMS's longstanding interpretation of the statute.

This is not just an academic issue of statutory construction. CMS's new position on this issue is problematic because the it will cause AMP to have little or no relation to the prices actually paid by wholesalers, much less the prices paid by retail community pharmacies that CMS relies upon to dispense covered drugs to Medicaid recipients. Retail pharmacies do not realize many of these so-called price adjustments. This was confirmed by a recent CBO report, when referring to manufacturer rebates paid to plans, which said: "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies." (*See* CBO, Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.)

We provide additional explanations as to why these other manufacturer sales should be excluded from the AMP calculation.

Mail Order Sales and Nursing Homes: When calculating AMP, manufacturers should omit sales of pharmaceuticals to wholesalers that are eventually sold to mail order pharmacies and nursing home pharmacies. Proposed section 447.504(9) would require manufacturers to

include sales to mail order pharmacies in the calculation of the AMP. We believe that CMS has made the correct decision in the proposed regulation to remove "sales to nursing facilities, including long term care pharmacies" from the calculation of AMP.

In justifying this action, CMS correctly indicates that because long term care pharmacies do not generally dispense prescriptions to the general public – but rather only patients of the facility – their sales should be excluded from the calculation of the AMP. We agree. This same logic, however, applies to mail order pharmacies. These pharmacies are not generally "open to the public" like most traditional retail pharmacies. Individuals cannot "walk into" a mail order pharmacy to obtain a prescription, and there is limited ability for patients to obtain a prescription from a mail order pharmacy unless they belong to a health care plan that includes mail order as part of its benefit design. Moreover, given that there is extremely limited distribution of prescription drugs to Medicaid recipients through the mail, it makes little sense to include these prices, or associated rebates, in the calculation of AMP.

CMS indicates in the proposed rule that, in directing manufacturers in the calculation of AMP, it "considered limiting mail order pharmacy prices to only those prices that are offered to all pharmacies under the same terms and conditions." 71 Fed Reg at 77179. Through this statement, CMS explicitly recognizes that there are different prices available to different purchasers in the marketplace. In general, the discounts for brand name drugs provided to mail order pharmacies are not available to retail pharmacies.

However, CMS says that it considers mail order "simply another form of how drugs enter into the retail pharmacy class of trade." Yet CMS also recognizes that retail pharmacies may be disadvantaged by inclusion of these sales in the calculation of AMP because "retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for manufacturer price concessions." CMS itself makes the argument as to why sales to mail order pharmacies should be excluded from the calculation of the AMP.

Inclusion of these sales and rebates – which are not available to traditional retail pharmacies – would result in an AMP that is not reflective of the prices paid by traditional retail pharmacies. This is confirmed by the CBO report which says that mail order pharmacies tend to get lower prices than conventional pharmacies for single source drugs. The report provides an example of how excluding mail order sales from the AMP calculation would increase the AMP. This confirms that including mail order sales would lower the AMP and not approximate the prices at which conventional retail pharmacies purchase medications.

Moreover, given that there is relatively no distribution of Medicaid prescriptions through mail order, including these sales and rebates would create a benchmark that would be of little use to state Medicaid directors to set reimbursement rates for retail pharmacies.

Sales to Other Outpatient Channels: Sales to hospitals and outpatient clinics should be omitted given that these entities do not fall within the definition of a traditional retail pharmacy, even if these drugs are dispensed at outpatient clinics. Direct sales to patients through entities such as specialty pharmacies should also not be included in AMP because the entities that arrange for these sales do not conform to a traditional definition of wholesaler. Only sales to

wholesalers for drugs distributed to traditional retail pharmacies can be included in the definition.

Patient Assistance Programs: The proposed regulation would include in the AMP, "manufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail class of trade." These coupons might refer to manufacturer promotional programs where the manufacturer provides a certain discount off the price of the medication to a patient. If the coupon is used by the patient but redeemed by the pharmacy, CMS would require manufacturers to include those sales in AMP.

Similarly, there are many patient assistance programs where the pharmacy fills a prescription based on a coupon that the manufacturer provides to the physician, where the patient redeems these coupons at the pharmacy. The manufacturer reimburses the pharmacy for the drug that was dispensed, so in theory the manufacturer receives no net revenue from the sales of those drugs. Deducting these sales from the AMP (essentially recording a $0 sales for these drugs), but including the units sold in the AMP, would further lower the per-unit amount received by the manufacturer.

However including these sales has nothing to do with the price paid by the wholesaler or the pharmacy, and would inappropriately lower the AMP. For this reason, drugs provided to patients through manufacturer assistance programs should not be included in the AMP. These items cannot be law be included in the AMP because they do not reflect priced paid by wholesalers to manufacturers for drugs distributed to the retail class of trade.

PBM Rebates: There is wide documentation in government agency reports (OIG and GAO) that manufacturers have not been consistent in how they have handled PBM rebates in the calculation of the AMP. According to these reports, some have included, excluded or only partially included rebates paid by them to PBMs and health plans. (*See* GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States; February 2005). CMS issued a Medicaid drug rebate program labeler release in April 1997 that attempted to clarify how these PBM rebates should be handled both in the calculation of a drug's "best price" as well as it's AMP. (*See* CMS Manufacturer Labeler Release #28, April 1997.) That release said that "Drug prices to PBMs have no effect on the AMP calculation unless the PBM is acting as a wholesaler."

The proposed regulation would suddenly change the policy that has been in effect for many years by requiring that drug prices to PBMs, which heretofore have only been included where the PBM was acting as a wholesaler, be included in the calculation of the AMP. Most disturbing is the proposed inclusion of "discounts rebates or other price concessions to PBMs associated with the sales for drugs provided to the retail pharmacy class of trade". Manufacturers can only include prices paid by wholesalers in the calculation of AMP.

Today most prescriptions are paid for through a third party entity – such as a PBM – that receives rebates and discounts from pharmaceutical companies. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts. These

discounts are either retained by the PBM, or passed through in whole or part by the PBM to the payer. Manufacturers should not deduct these amounts when calculating the AMP because PBM price concessions are not payments by wholesalers, and retail pharmacies do not receive these price concessions.

Including PBMs' sales and discounts unfairly lowers the AMP, making it unreflective of sales to retail pharmacies. This fact was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies." (*See* CBO, Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.) The report also said that "...conventional retail outlets generally do not receive rebates for single source drugs." Therefore, including these rebates would lower the AMP for traditional retail pharmacies below their approximate acquisition costs. It is immaterial whether the PBM that receives the rebates passes through some or all of these rebates to the plan sponsor. These rebates ultimately do not affect the prices paid by retail pharmacies for prescription medications.

To demonstrate how dramatic the impact of the inclusion of PBM rebates would have on deflating the AMP, a recent CBO report indicated that, in terms of the financial transactions in the pharmacy supply chain, "the manufacturer keeps the amount paid to it by the wholesaler (roughly the AMP) minus any rebates paid to the PBM." According to a 2005 Federal Trade Commission (FTC) report on the PBM industry, the average payment made by manufacturers to PBMs is about $6 per prescription (*See* Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies*, August 2005.) So, using this average payment, a product with an AMP of $80 (the price paid by the manufacturer to the wholesaler) would be reduced by $6 under the CMS definition to $74. The AMP would be $74 under the CMS definition, but should in reality be $80.

Proposed §447.504 (g)(12) would require manufacturers to include sales and associated rebates, discounts and other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program, SCHIP program, SPAP programs and Medicaid programs (other than rebates provided under Section 1927.) Manufacturers don't sell drugs to these programs directly. They sell drugs to wholesalers and retail pharmacies that dispense these drugs to enrollees of these programs. Retail pharmacies are then paid by these entities for the drugs they dispense.

Thus, in theory, manufacturers' sales of drugs to wholesalers who sell to retail pharmacies would already include drugs that are dispensed to enrollees of these programs. However, including the rebates and discounts manufacturers provide to these programs would be inappropriate because federal law provides that only payments by wholesalers to manufacturers can be included in AMP calculations. Moreover, there are several different types of MA-PD programs including staff model HMOs and regional PPOs. Including sales of drugs to HMOs is explicitly proposed to be excluded from the calculation of AMP under proposed §447.504(h)(5).

b. The Proposed Rule Incorrectly Defines "Retail Class of Trade"

In proposed §447.504(e), CMS attempts to define the retail class of trade. In the proposed regulation, CMS has adopted an overly expansive definition of "retail class of trade". The definition proposes to include "...any outlet that purchases or arranges for the purchase of drugs from a manufacturer, wholesalers, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public." Overall, the proposed regulatory definition of AMP does not achieve the goal of giving Medicaid and other payers a benchmark that approximates the "true market price for prescription drugs" paid for by the real provider of Medicaid outpatient drugs: retail community pharmacies.

State Medicaid programs pay traditional retail community pharmacies for the overwhelming majority of covered outpatient drugs provided to Medicaid recipients. Therefore, it stands to reason that AMP data, which will be used to calculate reimbursement rates for those retail community pharmacies, should be based only on sales of drugs dispensed by those retail community pharmacies. It is illogical and counterproductive to based Medicaid reimbursement rates for community pharmacies on sales of drugs that are not dispensed by community pharmacies.

Therefore, the "retail class of trade" should be defined as including only traditional community retail pharmacies. Only the community pharmacies that dispense outpatient drugs to Medicaid recipients - traditional chain pharmacies, independent pharmacies, mass merchandise pharmacies, and supermarket pharmacies – should be considered the "retail class of trade." Given that AMP will be used to calculate reimbursement rates for Medicaid outpatient drugs, and given that virtually all of those drugs are dispensed by retail community pharmacies, it makes sense that the "retail class of trade" should be defined to include only retail community pharmacies.

CMS's definition of retail pharmacy in this proposed regulation is inconsistent with that used in the Medicare Part D prescription drug program final rule. (*See* 42 CFR 423.100). In the final rule implementing the Medicare Part D prescription drug benefit program, the agency defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy."[1] Thus, it would be consistent with CMS' current Part D definition of "retail pharmacy" for the agency to indicate that only sales to true retail community pharmacies represent the "retail class of trade" for the purpose of calculating the AMP.

Moreover, in conducting an audit of the Medicaid rebate program in 1997, OIG defined the retail pharmacy class of trade as only independent and chain pharmacies that sold drugs directly to the public. OIG had recommended that CMS ask the manufacturer to exclude from the calculation of AMP transactions that OIG determined were to non-retail entities such as mail order pharmacies, nursing home pharmacies, independent practice associations, and clinics. It is

clear that OIG has recognized that the definition of retail class of trade should not be as expansive as proposed by CMS.

c. Scope of Discounts Included in AMP Must be Narrowed

Manufacturers are, by law, required to calculate AMP without regard to customary prompt pay discounts extended to wholesalers. Prompt pay discounts are generally considered to be a form of cash discounts. However, manufacturers are required to include cash discounts when calculating AMP. It is important for CMS to clarify in the final regulation that these type of cash discounts – that is customary prompt pay discounts – can not be deducted by the manufacturer from AMP. For that reason, we recommend that CMS include a definition of "cash discounts" that would be defined as not including "any discount off the purchase price of a drug offered by the manufacturer to a wholesaler for prompt payment of purchased drugs."

In addition, there are certain payments made by manufacturers to pharmacies that should not be deducted from the AMP because they reflect concessions relating to the "time value of money" or payments for services performed by the pharmacy on behalf of the manufacturer. These payments are not discounts or rebates off the actual drug product. In addition to customary prompt pay discounts, these include bona fide service fees, payments for pharmaceutical returns, and payments for patient care programs.

Likewise, only incentive-based discounts, rebates or other price concessions that are ultimately passed through to retail community pharmacies through wholesalers should be deducted by the manufacturer in calculating the AMP. Manufacturers should at most be allowed to deduct chargebacks only to the extent that they know that these were provided by the manufacturer to wholesalers for products that are distributed by the wholesalers to retail community pharmacies.

c. Definition of Wholesaler Must be Narrowed

Proposed §447.504(f) attempts to define wholesaler. Wholesaler is defined as "any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug." The proposed definition of wholesaler is overly broad and inconsistent with Federal and state statutes and regulations that define wholesalers.

For example, according to the National Association of Boards of Pharmacy (NABP), "Wholesale Distribution":

> *"... means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer of Prescription Drugs by a Pharmacy to another Pharmacy if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period.* "

NABP goes on to say further that "Wholesale Distribution" does not include:

- The sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;
- The sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;
- Intracompany Transactions, unless in violation of own use provisions;
- The sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;
- The sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;
- The transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;
- The sale, purchase, or trade of blood and blood components intended for transfusion;
- The return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations; or
- The sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations.

Based on this NABP definition, PBMs do not perform wholesaling functions either. In fact, most PBMs are administrative service organizations that contract with health plans and other entities to provide prescription drug benefits. Pharmacies do not buy drugs from PBMs like they buy them from wholesalers. PBMs that own mail order operations may obtain their drugs from wholesalers or may obtain them directly from manufacturers, but they do not perform traditional wholesaling functions in either case. Only prices paid to manufacturers by wholesalers can by law be included in AMP. PBMs should not be considered wholesalers.

We urge CMS to adopt a more limited, realistic definition of pharmaceutical wholesaler that is more consistent with the intent of the law by drawing on existing Federal and state definitions of wholesaler:

- The Federal Food, Drug and Cosmetic Act defines wholesale distributor as any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

- Under the PDMA regulations, wholesale distributor means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

Chains pharmacy distribution centers are generally licensed as wholesalers in the states in which they are located. This is important because manufacturers are, by law, allowed to calculate AMP without regard to customary prompt pay discounts extended to wholesalers. Chain pharmacy distribution centers should be eligible for the same customary prompt pay discounts as traditional pharmaceutical wholesalers.

f. Smooth AMP Data

CMS should require manufacturers to "smooth" any discounts or rebates that are passed through by wholesalers to retail pharmacies over a rolling 12-month period. This will help reduce the potential for any significant fluctuations in AMP from quarterly and monthly calculations, and maintain some consistency in reimbursement levels. Such a process was developed by CMS for manufacturers' calculations of the Average Selling Price (ASP), which is used as the basis for Medicare Part B drug reimbursement. Without such smoothing, it is very possible that upper limits for generics could be based on AMPs that are simply not reflective of the approximate current market prices for drugs, further reducing generic dispensing incentives.

A recent General Accountability Office report confirmed that AMPs for generics can fluctuate widely from quarter to quarter. (*See* GAO: Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, December 22, 2006. GAO-07-239R). The study calls into question the credibility and reliability of AMP as a benchmark for generic reimbursement. That is because GAO found 66 of the 77 drugs (almost 85 percent) had significant variation in their lowest AMP between first and second quarters of 2006. For example, 30 of the 77 drugs – or almost 40 percent of the drugs – had a decrease in their lowest AMP, averaging 33 percent. Fluctuations in AMP are concerning to pharmacies because their reimbursement would similarly fluctuate, which may not reflect similar variation in their own acquisition costs.

In the proposed rule, CMS is allowing manufacturers to "estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period." We believe that a much better process would be to require manufacturers to calculate the impact of these discounts based on a rolling 12-month average, rather than allowing manufacturers to simply estimate what these discounts might be in order to

make its monthly AMP calculation. The process described in the regulation seems arbitrary as compared to the smoothing process used by manufacturers to determine the impact of their discounts when calculating ASP.

g. Clarify Terms Relative to Sales, Rebates Discounts and Other Price Concessions Excluded from the Calculation of the AMP

Bona Fide Service Fees: NACDS strongly supports the proposal that bona fide service fees should be excluded from the calculation of AMP, especially where these fees are not ultimately passed through to the product's ultimate purchaser. A bona fide service fee pays for a bona fide service, so it does not reduce its cost of purchasing the drug. However, if these price concessions are deducted from the AMP, it could reduce the AMP further below the purchaser's costs for the drugs. Therefore, price concessions or discounts that do not decrease the actual purchaser's market price for the drug should not be deducted from the AMP.

NACDS does not support an attempt to list specific bona fide service fees, but believes that additional direction should be provided as the proposed regulation is ambiguous and leaves significant room for inconsistent interpretations. The market should be allowed to evolve regarding the services needed to assure that manufacturers can get their drugs to the market. This will allow for future flexibility and innovations to occur in a highly competitive marketplace. Manufacturers rely on wholesalers and others to perform various functions to allow their products to come to market in a safe and effective manner. A significant number of new biological products are likely to come to market over the next few years. For that reason, it is unclear as to what types of new services will be needed to be performed by wholesalers and chain pharmacy warehouses on behalf of manufacturers to assure that their products get to the ultimate purchaser for dispensing or administration to the ultimate user.

In this regard, we urge that the preamble to the final rule (but not the rule itself) provide an overview (but not an exclusive list, such as using the phrase "include, but are not limited to...") of the types of payments for bona fide service fees that would be acceptable for exclusion from the AMP calculation at this time, but allow for manufacturers and contracting entities to make future interpretations based on the needs of the marketplace. We do not believe that future guidance or rulemaking should be required for the purpose of adding to this list. Use of an "updated list" may actually reduce the level of innovation and could actually impede the delivery of new products to patients.

As an example of legitimate bona fide service fees, we would urge that payments made by manufacturers to entities such as wholesalers and pharmacies acting as wholesalers for inventory management agreements or distribution service agreements should not be deducted from a manufacturer's sales when calculating AMP. These payments do not lower the cost of purchasing prescription drugs. Moreover, not all purchasers are able to participate in these agreements, so deducting them when calculating ASP would be unfair to some smaller purchasers.

In addition, pharmacies sometimes receive payments from manufacturers for performing certain patient care programs, such as patient education and compliance and persistency

programs. These payments should be omitted from the AMP calculation because they do not reflect prices paid by wholesalers for drug products. These services provide valuable benefits to patients and the health care system because they improve patients' understanding of their medications and enhance patient compliance. They do not reduce the retail pharmacy's cost of purchasing the drugs. If these payments are included in AMP, pharmacies would not have incentives to do these programs because it would reduce the value of the AMP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, since not all pharmacies participate in these programs, it would be unfair to include these payments in the AMP.

Definition of "Return Goods": Proposed §447.504(h)(13) would allow manufacturers to omit from the AMP "returned goods when returned in good faith." Although we applaud CMS's willingness to exclude returned goods from the calculation of AMP when returned in good faith, the additional condition that the return must be made "pursuant to manufacturer policies" does not take into consideration that negotiated return goods policies exist between manufacturers and retail pharmacies.

We urge that CMS adopt the following policy regarding returned goods in the calculation of the AMP: "a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, which is designed to reimburse pharmacies for the replacement cost of product as well as the associated return related expenses and not designed to manipulate or artificially inflate or deflate the AMP"

These negotiated return goods policies take into consideration the unique burdens which retail pharmacies must absorb in order to effectuate the efficient return of expired pharmaceutical products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from the calculation of AMP, CMS could be voiding by default these negotiated return goods policies (which were negotiated in good faith between manufacturers and retailers) and are forcing retailers to accept manufacturers' policies and their inherent deficiencies.

Such action ignores the fact that retailers absorb considerable cost through: replacement value of returns, inventory carrying cost, reverse logistics cost, and administrative expense. In order to remedy this imbalance, returned goods made in good faith and pursuant to a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, must also be excluded from the calculation of AMP.

Definition of Manufacturer: NACDS recommends that the definition of manufacturer, found at proposed §447.502, be narrowed such that entities that repackage drugs simply for distribution to retail pharmacies – also known as retail pharmacy service repackagers – not be considered manufacturers. These entities should not be responsible for signing rebate agreements with the Secretary of HHS, or paying the rebates to Medicaid because these repackagers simply perform a function for thousands of retail pharmacies (i.e. preparing dispensing quantities in a highly efficient manner), that would otherwise have to be performed individually by retail pharmacies.

This repackaging has allowed manufacturers to continue to use the original manufacturers' NDC number on the repackaged drug, rather than that of the repackager. In many cases, the wholesale repackager may not even have its own NDC, necessitating that the originator's number be used. Retail pharmacy service repackaging is performed in a central location by wholesalers on behalf of retail pharmacy operators.

This type of repackaging is done so that the repackaging of thousands of "unit of use" quantities for distribution to patients does not have to occur in thousands of individual retail pharmacies. This increases the efficiencies of prescription dispensing for retail pharmacies, and reduces the chance for misfiling of prescriptions that might occur as a result of a pharmacist having to repackage additional unit of use quantities of drugs. For that reason, we urge that a wholesaler be permitted to repackage or relabel a drug, without being defined as a manufacturer, when it is acting as a retail pharmacy service repackager.

Requiring that these entities act like manufacturers, obtain NDC numbers, and sign rebate agreements would likely result in their elimination. That is because these repackagers are low-margin businesses, who could not afford to pay the rebates. Thus, the proposed definition of manufacturer should be revised to reflect an exemption for "retail pharmacy service repackagers" who purchase drugs from the manufacturer solely for the purpose of repackaging in unit of use quantities for dispensing by community retail pharmacies.

II. Section 447.506 – Authorized Generic Drugs

Proposed §447.506 describes new DRA requirements relating to authorized generics. Specifically, proposed §447.506(b) would require a manufacturer holding title to the original NDA of the authorized generic to include the direct and indirect sales of this drug in its AMP. The inclusion of the AMP of the authorized generic in the calculation of the originator manufacturer's AMP may be required under DRA. However, manufacturers should be required to report separate AMPs for the originator product and the authorized generic version, and these are the AMPs that should be posted on the public website.

If the AMP for the originator brand name product and authorized generic are averaged together, the AMP value for the originator brand may be lower than the pharmacy's acquisition cost for the product. While CMS may allow the manufacturer of the originator drug to pay its rebate based on the blended AMP, it is not fair to use this blended AMP to potentially underpay pharmacies for the dispensing of the originator drug when prescribed by the physician. We urge that any AMP website include a specific AMP value for the originator brand and the authorized generic.

III. Section 447.510 – Requirements for Manufacturers

This section proposes specifications for how manufacturers will provide quarterly and monthly AMP reports to CMS, the time frame for these reports, and other record keeping requirements.

a. Prohibit Restatements of Monthly AMP

The proposed rule at §447.510(d) implements DRA requirements relating to new monthly reporting of AMP by manufacturers. Specifically, manufacturers must report AMP not later than 30 days after each month, including an estimate of rebates or other price concessions that should be included in that month's AMP calculation. In calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary. We support the prohibition on the ability of manufacturers to restate monthly AMP data, but are concerned that incorrect estimates of potential liabilities (i.e. chargebacks, rebates) could inappropriately reduce AMP.

Under proposed §447.510(b), "a manufacturer must report to CMS revisions to AMP...for a period not to exceed 12 quarters from the quarter in which the data were due." We understand that the regulation would continue to require that manufacturers calculate AMPs on a quarterly basis for rebate purposes, and that these retroactive adjustments only apply to quarterly AMPs reported for rebate purposes, not monthly AMPs. Monthly AMPs will be used for reimbursement purposes.

We are concerned about whether a manufacturer's restatement of AMP could affect the reimbursement amounts already paid to pharmacies by Medicaid. If an AMP value is recalculated by a manufacturer after the time that it is reported to the states by CMS, these restatements should not be used as the basis for reducing the reimbursements already paid. Restating AMPs could cause significant disruption to pharmacies, as recoupment activities are generally extremely time consuming, labor intensive, and frankly unfair. We believe that CMS should only allow restatements for quarterly-reported AMPs rather than monthly-reported AMPs.

The proposed rule at section 447.510 (d)(3) indicates that "in calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary." This appears confusing, given that it sounds like a manufacturer still has the ability to revise its monthly AMP 30 days after reporting its monthly AMP. This should not be the case and needs to be clarified.

We are concerned that proposed §447.510(d)(2) would allow manufacturers, when calculating monthly AMP, to "estimate the impact of its end of quarter discounts and allocate these discounts in the monthly AMPs reported to CMS." This seems like an arbitrary way for manufacturers to calculate its monthly AMPs, and could be subject to manipulation. Manufacturers have a vested interested in maintaining low AMPs, while retail pharmacies want these AMPs to approximate pharmacy acquisition costs.

Moreover, this approach would not appear to be as auditable as a process that would require that the manufacturers smooth their data in a 12-month rolling average of all discounts and rebates given. This approach is similar to that used for Medicare Part B ASP calculation, although it is done on a quarterly basis for ASP. Nevertheless, the proposed rule seems to develop an arbitrary manner for manufacturers to determine the amount of rebates and discounts

that should be deducted from their monthly AMPs, given that there exist other more credible and auditable approaches that would result in potentially more accurate AMPs.

b. Adjust AMPs to Reflect Lag in Data Reported

We are concerned that, even though AMPs will be reported monthly by manufacturers, the AMPs will still be inaccurate compared to current retail pharmacy purchasing costs because of the reporting delay. Manufacturers have 30 days after the end of each month to report their AMPs. Currently, changes in AWP and WAC – the existing reimbursement benchmarks – are passed through from the manufacturer to the ultimate payer within 24 hours, as a result of electronic feeds that re-adjust all pricing when a manufacturer price increase occurs. This assures that pharmacies are being paid consistent with their current purchasing costs for medications.

Under the proposed rule, the monthly AMP reported to CMS is already 30 days old, and this AMP must then still be reported by CMS to States and posted on a public web site. Thus, by the time AMP is posted publicly and available to be used for reimbursement purposes, it will be outdated by at least 60 days. This is of particular concern when manufacturer price changes are announced and implemented immediately. There may be various ways to try to mitigate this impact, such as building in a cushion for price increases and inflation generally, since the impact on a drug-by-drug basis could be significant.

We are concerned that this timing issue has not yet been addressed or even sufficiently recognized and appreciated, and believe that CMS should address it directly and in detail before states and others are encouraged to use AMP as a reimbursement benchmark. One way to do this is to compare the AMPs for brand name drugs to the WACs, given that this published benchmark does approximate retail pharmacy acquisition costs for brand name drugs. This was recently confirmed by a CBO study that study said that "...for single source brand name drugs, WAC approximates what retail pharmacies pay wholesalers." CMS should not publish any AMP that does not approximate the WAC for a brand name drug.

c. Only Publish Last Month's Data for the Quarter on Public Website

In the preamble to the proposed regulation, CMS indicates that it will publish both monthly and quarterly AMP data on the public website because "the statute does not specify that this exception applies only to monthly AMP; therefore we also propose to make the quarterly AMP publicly available." CMS goes on to say further that "We note that the quarterly AMP data would not necessarily be identical to the monthly AMP data due to the differences in AMP from one timeframe to the next." 71 Fed. Reg. 77186.

Publishing both the monthly AMP data and the quarterly AMP data will add more confusion to what is likely already going to be a confusing situation. The DRA requires that CMS update the public website on a quarterly basis. Does CMS intend to publish on the website the AMP values for the last month of the quarter or each month of the quarter that just ended? Moreover, CMS indicates that it will also be publishing a quarterly AMP value. Does CMS intend to publish each monthly AMP value for a quarter as well as the quarterly AMP, or just the last monthly AMP for the quarter and the quarterly AMP? The quarterly AMP is likely to be

lower than the monthly AMP, so how will CMS (and providers) explain to the public why these AMP values differ? If the AMP website is supposed to give the public a general idea of the current prices paid by retail pharmacies for medications (assuming that CMS fixes all the fundamentally flawed definitions in this proposed regulation), then releasing the last month's AMP data for the quarter would appear to be sufficient.

Moreover, CMS must include special disclaimers and instructions on this website so that individuals viewing the data on this website clearly know how to interpret these data. We believe that release of inaccurate AMP data or AMP data that do not reflect retail pharmacy purchasing costs could cause irreparable harm to community retail pharmacies.

d. Continue to Delay Public Release and Use of the AMP Data

The preamble to the proposed regulation indicates that CMS will release AMP data sometime this spring. CMS should not post any AMP data on a public website until such time as a final AMP definition reflects the approximate prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies, and that these prices have been validated to be accurate. The release and use of flawed AMP data could have a negative impact on patient access, if the resulting reimbursement rates are so inadequate that pharmacies are forced to close, or individually decide that they can no longer afford to participate in Medicaid or other programs. It is in the interests of all relevant parties – patients, payers and providers – to postpone use and disclosure of AMPs until such time as CMS finalizes a regulatory definition of AMPs, and that definition approximate retail pharmacies purchasing costs.

In the recent past, CMS prudently recognized that AMPs should not be disclosed until they are properly defined. In announcing that CMS would postpone the AMP website last May, the CMS Administrator McClellan stated that "CMS will not publicly release the current AMP figures. They just aren't the right numbers to use." The Administrator added that "Instead, we are focusing our efforts on developing a proposed regulation that will assure an accurate and effective AMP calculation ahead of implementation of the drug payment reforms." *(See* Remarks of Mark B. McClellan, NCPA 38th Legislation and Government Conference (May 22, 2006). CMS should not now reverse course and use AMPs before they are properly defined and determined to be accurate.

The AMP data that CMS would propose to release this spring are no better than the AMP data that CMS promised not to release. While DRA made some modest changes to the calculation of the AMP, there would still be wide-ranging documented inconsistencies in that data which would render them useless to states and potentially damaging to retail pharmacies.

OIG recently reported to CMS that "Existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent." OIG added that "Because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors." (*See* OIG, *Determining Average Manufacturer Prices For*

Prescription Drugs Under The Deficit Reduction Act of 2005, Report No. A-06-06-00063 (May 2006). We concur with the OIG's findings.

CMS should not underestimate the impact that faulty AMP data could have on the generic marketplace and the pharmaceutical marketplace in general. FULs act as a price control on generics. Given that dollar margins on generics are slim, inappropriately low FULs may force generic manufacturers to exit the market, resulting in less competition and ultimately higher prices. That would have dramatic consequences for the entire marketplace. Disclosing current AMPs could also create confusion with respect to the negotiated prices that Part D plans publish on the CMS website, as well as the prices that cash-paying consumers pay for drugs.

With respect to generic drugs, CMS should only publish an AMP value for a particular dosage form and strength of a generic drug that represents the weighted average of all the AMPs for the manufacturers' 100-count retail package sizes of that particular dosage form and strength of the drug (or the one that is most commonly dispensed by retail pharmacies) that are widely and nationally available for purchase by community retail pharmacies. This would eliminate the need to report potentially dozens of AMP values for the same dosage form and strength of a particular generic drug.

Publication of all these data could create confusion in the market and lead states and others to set reimbursement rates that would not be reflective of widely-available market prices. Reporting this "average" AMP number – rather than individual AMP numbers – would also limit the extent to which manufacturers' individual proprietary pricing information is introduced into the marketplace, which could limit competition and reduce incentives for pharmacies to negotiate for lower generic prices.

e. Limit Release of AMP Data to Assess Validity

Finally, when AMPs are first publicly reported by CMS, only a limited number should be reported to allow the marketplace to assess the validity of the data. Given the potential for AMP data to have implications throughout the supply chain, it behooves CMS to be cautious in how it releases any data. Irreparable harm could be done to many industries in the pharmacy distribution supply chain. We urge that CMS interact with the affected industries first before publishing any AMP data.

As an example, the MMA required CMS to use ASP as the basis for Part B drug reimbursement beginning in January 2005. However, CMS required manufacturers to report several quarters of ASP data and published some of these data before implementing the ASP approach. This allowed for necessary public comment on this new and unknown approach for reimbursing physicians and pharmacies for Part B medications.

Before publishing AMP data, CMS must also determine how it will account for the lag from the time that the manufacturers report AMP data to the time that it is reported by CMS. Without such an update, the AMP values that are reported will not reflect the approximate prices at which retail pharmacies purchase medications.

IV. Section 447.512 – Drugs: Aggregate Upper Limits of Payment

Proposed Section 447.512 would specify that states could not exceed the FULs in the aggregate, and would specify when an FUL would not apply relative to the dispensing and payment of an innovator multiple source drug. CMS indicates that it will set FULs based on the AMP data reported by manufacturers after January 1, 2007 because it will reflect DRA changes such as the omission of prompt pay discounts by manufacturers. However, these AMP data lack consistency in how they are being calculated and reported by manufacturers. They may likely be no more accurate or appropriate to use than the generic reimbursement benchmarks that are in public use.

a. Suspend Implementation of AMP-Based FULs

In general, NACDS believes that the FUL reforms mandated under the DRA be suspended until Congress is given the chance to revisit the use of AMP as a benchmark to set these FULs. That is because a recent GAO study basically confirmed that retail pharmacies will be significantly underpaid for multiple source drugs if 250 percent of the lowest AMP is used to set FULs for multiple source drugs.

Suspension of the FULs would be consistent with a "Dear Colleague" letter that then House Speaker Dennis Hastert sent to Members of the House in February 2006. In that letter, he indicates that a DRA technical corrections bill would include a provision that would "permit the Secretary of HHS to delay the implementation of the new payment rates if the Secretary determines, based on information in the new GAO report, that the new payment rates do not reflect pharmacy acquisition costs."

In fact, that GAO report found that for a select market basket of high expenditure, high volume multiple source drugs, using 250 percent of the lowest AMP to set the upper limits would significantly underpay pharmacies. Under this new formula, the GAO report found that retail pharmacies will be reimbursed on average 36 percent lower than their costs to purchase these generic medications. This analysis provides credible, independent evidence that DRA changes to pharmacy reimbursement will be inadequate to cover the pharmacy's costs of purchasing generic medications. The GAO study, which compared the new AMP-based FULs for 77 generic drugs compared to retail pharmacies' average acquisition costs for these drugs during the first quarter of 2006, found:

- Pharmacies acquisition costs for 59 of the 77 (76 percent) generic drugs in study were higher as compared to the new FULs;
- For the 26 of the 27 high expenditure Medicaid generic drugs studied, the FULs were on average 65 percent lower than the average retail pharmacy's acquisition costs;
- For the 17 of the 27 drugs that are frequently used Medicaid generic drugs, the FULs were on average 15 percent lower than retail pharmacies' acquisition costs;
- For the 16 of the 23 drugs that were both high expenditure and frequently used, the FULs were on average 28 percent lower than the average pharmacy's acquisition costs. For 11

of these drugs, the FULs were below the lowest acquisition cost available to retail pharmacies.

Another report to the Minnesota Medicaid program found that, under the DRA's new definition of multiple source drug, the number of generic drugs with FULs will increase from about 500 to 3,000 products. In addition, the DRA will reduce payment for generics by approximately 35 percent in 2007, 51 percent in 2008 and 67 percent less in 2009 to 2011.*(See* Implementation of Pharmacy Payment Reform in the Minnesota Medicaid Program, January 15, 2007, prepared by the University of Minnesota PRIME Institute.)

Generic drug dispensing by pharmacies is helping to reduce the rate of growth of Medicaid drug spending. It makes no sense to underpay pharmacies for dispensing generic drugs – essentially forcing them to dispense these prescriptions at significantly reduced margins – when multiple source drugs are helping to keep Medicaid drug spending growth in check.

b. Allow for Electronic Certification of Brand Name Drugs

NACDS asks that CMS clarify proposed §447.512(c)(1) such that a physician has the option to override the dispensing of a generic drug if the physician certifies through electronic means that a brand is medically necessary. This authority would be provided in addition to the current policy that allows a physician to override the dispensing of a generic through "his or her own handwriting." There is a significant increase in the number of prescriptions that are being transmitted to pharmacies electronically. For that reason, it is critical that the state be permitted to be able to obtain Federal matching funds for a brand drug prescription where the physician has certified through a credible electronically-transmitted prescription that a brand is medically necessary.

We also ask that CMS clarify that the physician can indicate in various ways that a brand product is medically necessary, not just through the use of the term "brand medically necessary." States have various laws and regulations relating to how a physician can block generic substitution and require the dispensing of a brand name drug. Some states use "brand medically necessary", others use "no generic substitution", while others use different phrases. CMS should allow states to use their own distinct phrases on written or electronic prescriptions to block generic substitution.

Pharmacies should not be penalized for dispensing a brand name drug to Medicaid recipients where it was the clear intent of the physician to do so, even if the physician did not use the exact term "brand medically necessary." This option appears to be available to states given that the proposed regulation indicates that "...a notation like brand medically necessary is allowable" However, we ask that it be clarified in the final regulation.

c. Dispensing Fees Should Cover All Pharmacy Costs and Provide Reasonable Return

Proposed §447.512(b) specifies that the state agency establishes a 'reasonable' dispensing fee that would be paid to pharmacies for dispensing Medicaid prescriptions. We believe that CMS should give states additional guidance in the final regulation on how to determine the

professional fees that are paid to pharmacies for providing Medicaid prescriptions. That is, the states should be required to set the fees such that they cover all pharmacy's costs of dispensing. It is well documented that one of the major Congressional goals of Medicaid pharmacy payment reform was to pay pharmacies more accurately for the cost of the drug they dispense as well as more accurately for their cost of dispensing.

For example in his May 12th letter to Secretary Leavitt, then Senate Finance Chairman Grassley said that, "CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs." Similarly, we appreciate the strong statements that he made in a November 3, 2005 colloquy with Senator Jack Reed when the Senate was considering the Deficit Reduction Act.

In that colloquy, Senator Grassley indicated "states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions."[2] Former CMS Administrator Mark McClellan, in remarks made at the NCPA conference on May 22nd, indicated that "If states do not maintain the right incentives for generic utilization, any savings will be lost due to higher brand name utilization...CMS guidance encourages states to align incentives for generic utilization and consider paying pharmacies more in dispensing fees to support state savings from greater use of generics."

The need to increase pharmacy fees was discussed in the context of paying pharmacies more accurately for their drug product acquisition costs by former House Energy and Commerce Committee Chairman Joe Barton (R-TX). In his opening statement at a December 2004 hearing, Chairman Barton said, "I believe we should pay providers fairly for their services. I have got absolutely no problem with increasing dispensing fees if that is what we need to do..." *(See* Hearing of the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, December 7, 2004, opening statement of Chairman Joe Barton)

When new Federal Upper Limits (FULs) are phased in this spring, most states are likely to realize significant savings from reduced payments for generic drug products. As Senator Grassley further stated in his colloquy regarding the Medicaid section of the DRA, "The overall assumption made in the bill is that states will increase their fees to account for the fact that states would probably be paying pharmacists a lower amount for the drug product that more accurately reflects the cost of the drug product being dispensed."[3] (See Congressional Record, Senate, November 3, 2005, p. S12326). Yet, CMS gives little guidance to states about their obligations, consistent with Congressional intent, to increase their dispensing fees.

Today, Medicaid pharmacy dispensing fee payments are lower than the average pharmacy's cost to dispense a prescription. Recent state-specific studies have shown that the average cost of dispensing a Medicaid prescription is anywhere from $9 to $11, while the average current dispensing fee is only about $4.25.[4] A recent national cost of dispensing study conducted by Grant Thornton and released on January 31 found that the average cost to dispense a

prescription, weighted by prescriptions, is about $10.50.[5] (*See* Grant Thornton LLP, "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies" (January 2007). The full report can be obtained from the Coalition for Community Pharmacy Action (CCPA) at www.rxaction.org). This amount is higher when weighted by stores. These amounts vary by state. Therefore, while the Medicaid program will be paying pharmacies less for the generic drug ingredient cost when these new FULs take effect, we believe that CMS should mandate states to make sure that the dispensing fee is adequate and accurate for all pharmacies. This would be consistent with Congressional intent.

We believe that CMS needs to direct states to conduct (and update annually) a comprehensive pharmacy professional fee study, which would include the components relating to the costs of dispensing Medicaid prescriptions, as well as providing a reasonable return to pharmacies. It is important for these fees to be updated frequently – using a benchmark such as the BLS pharmacist wage index – because pharmacy labor costs, which account for about 75 to 80 percent of the average pharmacy's cost of dispensing, are increasing each year.

Increasing dispensing fees will not threaten the budget savings forecasted by the Congressional Budget Office (CBO) for DRA. On the contrary, CBO's budget savings projections are based on the "expectation" that states will increase dispensing fees in response to decreased reimbursement for drug acquisition costs *See* CBO, *Cost Estimate: S. 1932 Deficit Reduction Act of 2005,* at p. 37 (Jan. 27, 2006) (savings estimates of $3.6 billion and $11.8 billion "reflect CBO's expectation that states would raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid.")

In fact, failing to ensure that dispensing fees cover the full cost of dispensing may actually *increase* overall Medicaid expenditures. Decreasing generic drug reimbursement rates without increasing dispensing fees to cover dispensing costs is likely to create a perverse incentive for pharmacies to dispense more expensive brand name drugs. In 2005, the average brand was $101.71 per prescription and the average generic was $29.82 per prescription. (See NACDS Industry Profile) Conversely, government spending can be reduced if dispensing fees are set at levels which encourage pharmacists to dispense less expensive generic drugs.

We also ask that CMS expeditiously approve state plan amendments that would increase pharmacies' professional fees that are closer to their actual cost of dispensing, providing for a reasonable return. CMS should also reject those SPAs that simply decrease payment for the reimbursement paid to pharmacies for the ingredient cost component without making increases to the dispensing fee.

With respect to the definition of "dispensing fee, found at proposed §447.502, NACDS believes that the definition of "dispensing fee" in the proposed regulation is overly restrictive. To accommodate any future costs that pharmacies might incur in dispensing prescriptions to Medicaid recipients, we agree that the terminology "includes, are not limited to" should remain in the final definition. However, it should be made clear to states that they can provide a reasonable margin or profit to pharmacies when determining a reasonable dispensing fee.

Pharmacies can not be expected to dispense Medicaid prescriptions solely based on their costs. Some margin has to be built in so that pharmacies can remain in business, especially those that do a significant volume of Medicaid prescriptions.

We also urge that the state be allowed to provide payment for medication therapy management services (MTMS) in the overall dispensing fee if they so choose, or as a separate payment. Many states have CMS approved demonstrations programs that pay pharmacies for a wide range of MTM services. States should not be discouraged from paying for these services because of an overly restrictive definition of dispensing fee as proposed in the regulation.

d. Eliminate Ability for States to Promote Brands rather than Generics

We are concerned that some states are promoting the use of brand versions of generically-available drugs because they are receiving rebates from branded manufacturers that lower the net cost of the brand to that of the generic. While this may be viewed by some as "pro competitive", the growth of this practice has potential negative implications for generic drug use in Medicaid. We encourage CMS to prohibit states from engaging in this practice because it can discourage the overall availability of generic drugs in the marketplace.

If generic manufacturers cannot gain access to the Medicaid market in states because of these brand name manufacturers' practices, it could discourage generic manufacturers from legally challenging the patents on brand name drugs. This could reduce the availability of generics in the marketplace in general, and for the Medicaid market in particular. Whatever short term gain this might bring to states, it could end up increasing long term Medicaid prescription drug costs.

V. Section 447.514 – Upper Limits for Multiple Source Drugs

Proposed §447.514 would specify the procedures by which CMS would establish and issue a list of FULs for multiple source drugs, specify the upper limits, and assure that a drug is available for sale nationally when determining such FULs.

a. Identify Reference Product Used to Set FUL

Proposed section 447.514(a) describes the criteria by which CMS would determine whether a multiple source drug product should have a FUL. The DRA changed the definition of multiple source drug from a covered outpatient drug for which there is at least two other drug products that are AB rated in the FDA *Orange Book* to a covered outpatient drug for which there is at least one other drug product that is AB rated in the *Orange Book*. In this regard, CMS proposes that two criteria have to be met before an FUL can be established. First, at least two or more AB rated products have to be listed in the *Orange Book*. Second, at least two suppliers list the drug in the nationally-available pricing compendia.

If a particular product is on the market and is available from two different brand name manufacturers under two different trade names, it may not necessarily be the case that these products are AB rated to each other. Generic manufacturers may conduct bioequivalence studies

using one or the other branded product as the reference product. In these cases, CMS cannot establish an FUL for all the drugs in these categories by considering all these drugs bioequivalent to each other. It should establish subcategories of these products according to the products that are determined to be bioequivalent to each other, and then apply the criteria above to determine whether an FUL should be set.

If CMS does not use a "weighted average" of AMPs to calculate the FUL, we urge that the agency publish in its listing of drugs subject to an FUL, the identity of the manufacturer whose product was used to set the FUL. This would be known as the reference product. Publication of the reference product would provide an important "check and balance" in the setting of the FULs, and help assure the integrity of the process used to set the FULs. Identifying the reference product would help pharmacies and generic manufacturers identify for CMS cases in which the reference product used to set the FUL may not be appropriate because it is in short supply or is no longer being produced and distributed.

b. Establishment of Specific Upper Limits

Proposed §447.514(b) would specify how CMS would set the FULs for multiple source drugs. The FULs are proposed to be set by applying for each drug entity 250 percent of the average manufacturers' price..."for the least costly therapeutic agent." However, DRA does not specify that the FUL must be set at 250 percent of the lowest AMP, as the rule would propose. DRA merely changes a section of the current regulation found at section 447.332(b) which indicates that "250 percent of the average manufacturers price (as computed without regard to customary prompt pay discounts extended to wholesalers)" shall be substituted for "150 percent of the published price."

Because Congress did not expressly state that the FUL had to be set based on the lowest AMP, we encourage CMS to base the FUL on 250 percent of the weighted average 11-digit AMPs for all the 100 package sizes (or most commonly dispensed package size by retail pharmacies) of all the nationally and widely available therapeutically equivalent products, weighted by sales. This would require that manufacturers report sales volume of their generics, as is done in the calculation of the ASP under Medicare Part B.

This is particularly important given that a recent GAO report found that using the lowest AMP would underpay pharmacies on average for generic drugs by 36 percent. Even when GAO examined AMP-based FUL rates for the lowest AMP which had the highest value among several quarters of AMP data, it found that reimbursement rates were lower than pharmacy acquisition costs. This argues for an approach that would use, at a minimum, 250 percent of the weighted average AMPs (based on 11-digit NDCs) for the 100 package sizes or the package sizes most frequently dispensed by community retail pharmacies.

c. Use 11-Digit NDC Rather than 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, but then rejects its own arguments by saying that

"the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." As CMS knows, there are many items that Congress fails to specify in passing legislation, leaving the particulars to the implementing agency to develop the best possible approach. There is no evidence that Congress didn't intend that the AMPs be calculated at the 11-digit level for generic drugs in order to determine the FULs.

We believe that CMS should use an 11-digit weighted average 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, not the 9-digit weighted average AMP for the product. FULs are being set for generic drugs dispensed by retail pharmacies. Thus, 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. There is no legislative history to suggest that Congress intended to change this methodology in the existing regulation.

In fact, had Congress intended to change this, it would have amended the existing regulation through statute as it did to change the basis on which the FUL is calculated. Including the prices paid by other purchasers in a weighted average AMP, some of which may buy in volumes larger than the traditional retail pharmacy can buy, can drive down the AMP below the prices traditionally available to retail pharmacies. According to a recent GAO report, the current AMPs are already well below retail pharmacies' acquisition costs for generic drugs. CMS needs to do all it can to assure that the basis of the AMP is high enough to assure that pharmacies will continue to encourage the use of generic drugs in Medicaid.

d. Base the Reference AMP on Nationally-Available Products Only

In proposed §447.514(c) CMS attempts to ensure that only drugs that are available for sale nationally are used to determine the FUL. In order to encourage continued generic drug dispensing in Medicaid, it is critical that the FUL be based on prices for products that are currently nationally and widely available in the marketplace.

For example, we believe that only generic products that are AB-rated in the FDA *Orange Book*, and are widely and nationally available to pharmacies for purchase from the three major national wholesalers in adequate and consistent supplies, should be used in the calculation of the reference AMP. Unit dose products, larger bulk package sizes (drum sizes, which are generally custom packed for a few select customers), and products that are limited and in short supply, should be excluded from the weighted average AMP calculation used to set the FUL. CMS has an obligation to proactively determine whether products are in fact nationally available and in consistent supplies by contacting the manufacturers of these products on a regular basis, or the national wholesalers that stock them.

We concur with the agency's proposal to not use a terminated NDC to set the FUL beginning with the first day of the month after the actual termination date is reported to the

manufacturer by CMS. The terminated NDC issue needs to be further clarified as drugs can remain on the market for years after a manufacturer ships their last lot. The "termination date" must be based on the last shipment date and not the expiration date of the product as community pharmacy will dispense the product long after the final shipment into the market as wholesalers and retailers deplete their stock. It would be inappropriate to set the FUL based on a product that is no longer being distributed in the marketplace.

As CMS notes in its proposed regulation, eliminating AMPs that are outliers would also reduce the chance that FULs would not be set based on products that are not widely and nationally available. CMS goes to great lengths to describe a process that would eliminate an outlier AMP that is 70 percent lower than the second highest AMP. This outlier AMP would not be used to set the FUL, even though it might be the lowest. It also discusses the option of eliminating an AMP that is 60 percent lower. It asks for comment on whether these percentages are appropriate to use.

CMS should have offered AMP data to entities to make informed judgments about what appropriate outlier policy might be. However, CMS did not do that, so it is difficult for any entity to offer a percentage within this so-called "outlier" policy that makes sense in the context of the current AMP data. In fact, CMS itself offers no data to suggest why it chose these percentages. Given that CMS is one of the few entities that has access to and can analyze AMP data across generic drugs, it is in the best position to offer a reasonable percentage that might eliminate outliers.

However, to minimize the possibility that an FUL would be set based on a product that is in limited or in short supply, the use of a percentage relationship between AMPs to determine outlier policies seems arbitrary. We believe that "outlier" policies could be avoided if CMS assures that the product used to set the FUL is nationally and widely available in the marketplace, and that the monthly AMP data for multiple source drugs are subject to a 12-month rolling average smoothing process. Without this smoothing process, there is no way to know whether the so-called "outlier" AMP is actually the AMP of a widely available product whose AMP just happens to be artificially low in that month. That is because all or many of the rebates and discounts provided for that drug might just happen to be reported in a particular monthly AMP calculation period.

Moreover, we believe that a process that allows a manufacturer to estimate a certain amount of discounts and rebates for a month and subtract them from their AMP calculation for the month is an arbitrary way of determining AMP. CMS should not be inconsistent and require manufacturers to calculate a reimbursement metric in one manner under one CMS-administered program – that is the Medicare Part B ASP program – and specify that it be done in another manner for a different CMS administered program. AMP calculations should be subject to the same 12-month rolling average smoothing process as are ASP calculations. We urge that CMS rethink this issue of an outlier AMP in favor of a more rational approach to determining the reference AMP used to set the FUL.

e. Provide Appeal Mechanism for Published FULs

Providers and states should have a formal mechanism to appeal (and expeditiously receive a response from CMS) on a questionable FUL established for a particular product. CMS has generally been responsive to cases in which pharmacies have identified problems or issues with a FUL. However, we believe that there should be a formal appeals process for a FUL if one of the following situations exist: 1) the product does not meet the criteria for a FUL because the product is in short supply or there are no longer an adequate number of suppliers to meet the criteria for an FUL; 2) there have been price changes in the market due to raw ingredient shortages or market consolidation; or 3) the product is generally unavailable at the AMP used to generate the FUL.

VI. Regulatory Impact Analysis

The regulatory impact analysis of the proposed rule suggests that the proposed generic drug payment reductions will have a small impact on the "great majority" of retail pharmacies. The main conclusion is that the anticipated effect on retail pharmacies will be less than one percent of revenue, on average, and that this impact is potentially even smaller when potential increases in non-prescription sales are considered. The analysis also concludes that the proposed rule may have a significant impact on "small" pharmacies, particularly those in low-income areas, but fails to quantify the impact on pharmacies. This analysis demonstrates a lack of understanding of the pharmaceutical and pharmacy marketplace on many different levels, and the likely reaction of the entities that comprise the pharmacy supply chain.

a. Analysis Substantially Underestimates Financial Impact to All Retail Pharmacies

We believe this analysis seriously understates the potential financial impact on retail pharmacies. Fully $8 billion out of the $8.4 billion in the proposed regulation's budgeted Medicaid savings (2007-2011), or 95 percent, comes from cuts in generic drug reimbursement to retail pharmacies. While CMS measures the economic impact to retail pharmacies in terms of a reduction in gross revenues, it is more appropriate to measure the impact in terms of a reduction in margins or profits.

As CMS points out, the analysis also does not take into account the additional impact to pharmacies from a decrease in state payments for drugs which are not on the FUL list, and the impact on pharmacies if states start to use AMP as a reimbursement mechanism for brand name drugs. Because of the time lag in the calculation and reporting of AMP, brand name drug prices will likely always be higher than AMP, meaning that pharmacies will be underpaid if AMP is used. Moreover, the analysis fails to account for the fact that CMS proposed definition of AMP, if adopted, would not even approximate retail pharmacy acquisition costs. The proposed definition includes prices and discounts that are not available to retail pharmacies.

We are concerned that these inaccuracies and omissions in doing this regulatory analysis have led CMS to the erroneous conclusion that the impact on retail pharmacies will generally be

insignificant. For these reasons, we believe that CMS must substantially revise the Impact Analysis to reflect: (i) the projected impact of the use of AMP as a reimbursement benchmark instead of AWP in the Medicaid and commercial marketplace for brand name and generic drugs other than those subject to the FUL; (ii) the projected impact of the lack of currency of the AMP benchmark and the fact that AMP as proposed would understate pharmacy purchasing costs; and, (iii) the distinction between the impact on pharmacy profits versus pharmacy revenue, so that the impact on the latter is not understated.

In conducting its analysis, CMS cites NACDS statistics estimating that there were sales of $230 billion in pharmaceuticals at retail pharmacies in 2005. It then trends forward this amount to over $300 billion in sales by 2011 by assuming five percent annual growth. Comparing this amount to the estimated $2.1 billion savings in 2011 arising from the planned cuts in retail pharmacy reimbursement for multiple source drugs, CMS concludes that the economic impact on pharmacies of the proposed rule is "less than one percent of total revenues".

One problem with this measure is that $230 billion in 2005 is not the appropriate baseline for these calculations. This amount includes mail order sales, but there is almost no mail order use in Medicaid. The baseline should reflect only sales at *community-based* retail pharmacies. The NACDS data cited by CMS indicate that mail order sales were 19.1 percent of the $230.3 billion in total retail sales in 2005. Community-based retail sales were $186.3 billion in 2005. Projecting to 2011 using five percent annual growth, total community-based retail pharmacy sales would be about $250 billion in 2011.

In addition, while CMS measures the impact in terms of a loss of pharmacy revenue, the actual impact on pharmacies falls directly to the bottom line – that is, margins or profits. Cuts to reimbursement paid to pharmacies do not change the prices that pharmacies must pay to wholesalers or manufacturers to acquire products, nor do they change the costs that pharmacies incur to staff and operate stores convenient to patients. A significant percentage of a pharmacy's revenue is needed to cover these costs of purchasing, maintaining, and dispensing its pharmaceutical inventory. As a result, the $800 million decrease in 2007 and $2 billion decrease annually by 2011 will be decreases in profits, not revenues.

The 2005 NCPA-Pfizer Digest reports that independent pharmacy owner's discretionary profit was 7.4 percent in 2004. Taking out owner compensation, net profits were about 3.6 percent. Similarly, NACDS estimates that the average retail pharmacy net profit per prescription is about 2.8 percent. Assuming a net profit margin of 5 percent, a $2.1 billion decrease in annual profits in 2011 actually translates to a $42 billion decrease in revenue. Considering that total pharmaceutical sales are estimated to be $250 billion, this would equate to a nearly 17 percent decrease in revenues – by no means an insignificant change.

A key shortcoming of the proposed rule is that it fails to account for additional changes to pharmacy reimbursement by states and other payers once AMP data are published on a public Web site. Such changes are clearly the government's intent in providing AMP data to states on a monthly basis, posting it on a public Web site, and producing reports that will compare pricing among states. Therefore, the impact analysis omits what may be a far more significant and

profound financial impact on pharmacies due to this proposed rule, rendering the impact analysis misleading at best.

If new AMP-based pricing were to decrease reimbursement to pharmacies by 1 percent overall, that would be a loss of over $3 billion in 2011 alone based on CMS projection of more than $300 billion in total drug sales at retail pharmacies. Using the lower NACDS-estimated figure of $250 billion in total drug sales at community-based retail pharmacies (i.e., excluding mail order), the impact would be $2.5 billion in 2011 and more than $9.2 billion from 2008-2011.

CMS also fails to estimate the impact of lost rebate revenues to states as a result of the proposed definition of AMP. The proposed definition of AMP – which would make it a standard practice for manufacturers to include PBM rebates in their AMP calculations – will invariably lower AMP for many drugs. This will reduce the rebates paid by manufacturers for these drugs to the extent that other changes in the "best price" calculation do not affect these manufacturer rebate liabilities.

b. Analysis Fails to Estimate Impact on Generic Drug Use

The economic impact analysis indicates that the $8.4 billion in savings from Medicaid's pharmacy benefit represents 5.6 percent of projected drug spending. Based on these data, it can be derived that CMS projects roughly $150 billion in total Medicaid pharmacy expenditures over the 2007-2011 budget period before these cuts.

However, the $8 billion in savings comes from cuts in reimbursement for multiple-source (generic) drugs. Dispensing of off-patent brands is relatively rare in Medicaid programs. When these products are dispensed to Medicaid beneficiaries, they are likely to be paid above the FUL due to a "dispense as written" designation. Therefore, the $8 billion in savings is likely to be taken entirely from reimbursements for generic drugs.

In 2006, generics accounted for about 18 percent of Medicaid spending for prescription drugs. Carrying this percentage forward, Medicaid would spend about $27 billion for generics over the entire 2007-2011 budget period (18 percent of $150 million). Savings of $8 billion out of $27 billion in spending for generic drugs equates to a 30 percent reduction in reimbursement for generic drugs.

A reduction of this proportion will have a considerable impact on incentives to dispense generic medications where pharmacies have a choice. Rather than a system where pharmacies gain equal or greater revenue from dispensing a generic instead of a brand-name drug, the pharmacy will receive far less revenue from a generic. CMS cannot ignore the perverse incentives that it is establishing in this program that could discourage the dispensing of generic drugs.

c. Rule Will Adversely Affect Many Retail Pharmacies

Requirements for federal rulemaking stipulate that agencies report on the potential effects on "small business." For the purposes of the rule, a small pharmacy is defined as one that receives less than $6.5 million in average annual receipts. The rule indicates that roughly 18,000 pharmacies meet this definition. CMS concludes that the proposed rule may have a significant impact on some small, independent pharmacies.

The proposed rule will have a significant impact on many more pharmacies than this statement suggests. A large number of pharmacies – even those that are part of retail chains – operate much like small businesses. Like an independent pharmacy, each pharmacy in a multiple-location company must generate enough revenue to cover its costs of purchasing, maintaining, and dispensing its pharmaceutical inventory. A chain pharmacy that does not cover its own costs is not likely to remain open for long. The average total sales in traditional pharmacies are about $4.5 million per year. Chain-operated stores have a higher average per store ($6.2 million) compared to independent stores ($2.4 million), but overall many small chain-operated stores are not significantly different at an individual store level than independent pharmacies.

All pharmacies have some percentage of Medicaid business, averaging about 8 to 9 percent. Many in urban and rural areas have a much higher percentage of Medicaid, some with half of their prescriptions paid for by Medicaid. The use of AMP, however, by payers other than Medicaid could have a significant negative economic impact on all retail pharmacies, given that third party prescription sales represent over 90 percent of the average retail pharmacy's business. If these payers use a government-sponsored benchmark that is inaccurate and outdated, it could irreparable economic harm to many pharmacies, maybe forcing many to close.

Rural pharmacies may be particularly hard hit by this rulemaking. Data from a recent nationwide survey found that Medicaid accounted for approximately 12 percent of all prescriptions filled by rural pharmacies.[6] A reduction in beneficiary access to prescriptions in rural areas could result in higher costs for other Medicaid services, such as hospitalizations, physician office visits and emergency room visits.

d. Pharmacies Cannot Compensate for Lost Revenues with Non-Prescription Sales

With regards to the impact of the proposed regulation on pharmacy revenues, CMS claims that "actual revenue losses would be even smaller" than their projections. One reason cited is that sales of other merchandise ("front end" sales) help offset these losses. CMS states that, "almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as pharmacy sales." This statement is false. The data cited by CMS and posted on the NACDS Web site (www.nacds.org) show that pharmacy sales are, on average, 78 percent of total retail sales in traditional chain and independent drug stores. In 2005, total

pharmacy sales in these stores were $136.3 billion, including $94.4 billion for traditional chain drug stores and $41.8 billion for independent pharmacies, while their combined total retail sales were $174.2 billion. For traditional chain drug stores alone (that is, excluding independent pharmacies) pharmacy sales average 72 percent of total retail sales ($94.4 billion in pharmacy sales divided by $131.7 billion total retail sales). Clearly, front-end sales are a *minority* of total sales in most retail pharmacies, not "twice as much" as pharmacy sales as CMS claims.

Although not shown on that Web page, NACDS has also determined that:

- Pharmacy sales average 62 percent of total retail sales across all types of pharmacies when weighted by the number of pharmacies of each type. This measurement is the only credible way to compare pharmacy sales to retail sales regardless of the type of store.
- For independent drug stores, pharmacy sales average 98 percent of total retail sales.
- Pharmacy sales are a smaller percentage of sales at grocery (13 percent) and mass merchandise stores (7 percent), but these types of stores account for less than one-quarter of all community-based retail pharmacies in the United States.

It is unlikely that most retail pharmacies can make up pharmacy sales losses with front end sales. The marketplace for the products sold in pharmacy front ends is much more competitive and margins on these can be particularly small. Pharmacies cannot simply force consumers to purchase more front end items. Fortune Magazine reports that profits as a share of total revenues average less than 2 percent among the largest food and drug stores in the country, reflecting these smaller margins.

In addition, selling more items would require significant investments in larger front end areas, locating stores in high visibility, high traffic commercial locations, more staffing, and other changes that many pharmacy retailers may not be able to afford or may not have interest in providing. In essence, the impact analysis treats prescription drugs as simple commodities rather than medical products that require proper training on behalf of suppliers and consumers concerning their handling and use.

e. <u>Changes to Purchasing Practices Are Not Certain</u>

CMS also claims that pharmacies have the ability to mitigate the effects of the proposed rule and that they will *<u>often</u>* be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs. NACDS does not share this optimistic opinion.

CMS claims that the 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. However, a January 2007 report by the U.S. General Accounting Office estimated that retail pharmacies will be reimbursed on average 36 percent lower than their costs to purchase generic medications dispensed to Medicaid recipients. The study also indicated that pharmacies' would lose money on 59 of 77 generic drugs examined (76 percent). CMS to date has provided no evidence publicly to refute the GAO's research.

We do not agree that pharmacies *will* be able to purchase at lower costs. Today, pharmacies can negotiate lower prices for generics because they can move market share to that product. If all purchasers shift to the lowest cost manufacturer, that manufacturer has no incentive to offer lower costs. In fact, manufacturers may raise prices to larger buyers if they have to reduce prices to other purchasers, otherwise their revenues could be reduced considerably.

Manufacturers may compete on price initially, but if all manufacturers' prices are public, then pressures from purchasers should drive pricing towards comparable if not identical prices. At that point, manufacturers' incentives to hold down prices are reduced as any price increase would provide more revenues to them and higher reimbursements to retail pharmacies. We also are concerned that the lowest-cost manufacturer or manufacturers may not be able to produce sufficient supplies to serve large numbers of new buyers. They also may not be able to increase capacity to produce more supplies quickly. However, pharmacies literally pay the price when the manufacturer is unable to provide adequate supplies.

f. Pharmacies have other costs beyond simply purchasing drugs that must be covered

A recent national study determined that the average cost of dispensing a prescription in a retail pharmacy is $10.50 per prescription. Conducted by the accounting firm Grant Thornton, LLP, the study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.[7]

The report measures costs including prescription department salaries and benefits, other prescription department costs (e.g., containers and pharmacy supplies), and facilities and other costs (e.g., rent, utilities, computer systems). State-specific averages range from $8.50 in Rhode Island to $13.08 in California.

All of these averages give more weight to higher volume pharmacies that fill larger numbers of prescriptions and which tend to have lower costs per prescription as a result of that volume. The nationwide average increases to more than $12 per prescription when all pharmacies are given equal weight in computing the average. Nevertheless, CMS does not require nor even suggest in the proposed rule that states should consider increasing their dispensing fees. Medicaid dispensing fees are, on average, about $4.50 nationally, far below pharmacies' actual costs of providing services.

[7] The full report is available from CCPA at www.rxaction.org.

Planned Parenthood® of Georgia, Inc.

February 16, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I writing about the proposed rule published by the Centers for Medicare and Medicaid Services ("CMS") on December 22, 2006, to implement section 6001(d) of the Deficit Reduction Act of 2005 ("DRA") which preserves the ability of three kinds of providers - 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes - to purchase drugs at best price nominal pricing.

As the Chief Executive Officer of Planned Parenthood of Georgia (PPG), with non-profit health centers, I am concerned that we are leaving out safety net providers such as ours will adversely affect women in need in Georgia. PPG serves over 20,000 of patients each year in Georgia, many of whom could not otherwise afford the health services and contraceptives methods that we provide. Three of our centers do not qualify under the new DRA ruling, thus leaving 8,000 low income women at these centers at risk of losing their health care provider. Most of these women do not have insurance and cannot afford the high cost of private practice and retail pharmacies.

Currently, there are approximately 1 million women who are in need of contraceptive services and supplies in Georgia. Approximately half of these women are in need of publicly supported health care and services. Even with a strong public health system, our public health clinics are only able to provide contraceptive care to 41% of all women in need and 37% of teenagers. **Thus, 59% of women and 63% of teenagers have unmet need in Georgia.**

PPG has been providing low cost quality services to the women for over 42 years and helps to supplement the public health system to meet this unmet need in Georgia. We do this by providing health services, including physical exams, STD testing and treatment, and contraceptives, at a cost lower than the private sector. We are able to keep our costs low because we have been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. If we not able to continue to purchase these medications at a nominal price, we would not be able to continue to operate and may even have to close our doors, thus leaving low income women without services in the community we serve. Currently this would impact over 8,000 women we serve.

As a key safety net provider in our communities, our ability to provide low cost services depends on our ability to purchase contraceptive drugs at a nominal price. Unfortunately, like many other small safety net providers, we do not qualify for the three categories listed. Leaving out safety net providers from the ruling puts not only our center, but other non-profit providers, at risk of closing their doors.

Our hope is that the Centers for Medicare and Medicaid Services will reconsider the ruling and name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. Planned Parenthood is clearly a safety net provider and we strongly urge CMS to include in its definition of safety net providers nonprofit, health center such as ours.

Please reconsider and help us meet the need of low income women of Georgia.

Respectfully,

Kay Scott
CEO
Planned Parenthood of Georgia, Inc.

Washington D.C.Pharmacy Assn
Herbert Kwash Pres.and Exec.Director
908 Caddington Ave
Silver Spring, Maryland 20901

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-AO 20

I would like to submit comments to CMS regarding proposed regulation that would provide a true definition of AMP (average manufacturers price) to be used for payment to Community Pharmacies in the Medicaid drug program ; and also implement the new Medicaid Federal upper limit program for generic drugs. I will also submit my personal comments on this issue.

1. Remove PBM and Mail Order Pharmacies from the regulation since they are able by negotiation with Drug Manufacturers directly to receive much lower costs for the same drugs as Community Pharmacies who can not negotiate with these same companies.

2. Address draconian price fluctuations (currently these changes can take months to address and correct. Both increases and decreases)

3. Use of the 11 digit NDC identification of drugs rather than the 9 digit NDC . The 11 digit NDC is the label on most package drugs used in Community Pharmacy.

These are the most needed changes I hope you at CMS will consider and change before all the new regulations are implemented.

The following are my personal comments on the issue.

President Bush for many years has emphasized how entrepreneurial spirit is one of the most needed parts to spur the economy of the United States. These regulations (as part of the Deficit Reduction Act) will cause irreparable damage to many of these needed entrepreneurs ; namely Independent Pharmacies participating in the Federal Medicaid Program. Most of these Pharmacies have worked together with their State Medicaid programs for many years . They have supported these programs through many years of budget deficits that caused financial problems for these businesses but they still continued supplying their patients with their much needed drugs. The GAO ,your own government agency has researched this issue and determined that most generic prescriptions dispensed by Pharmacies in the program will be reimbursed at a loss level of approximately 30%. My feeling is that little consideration was given to the impact of this

regulation to Community Pharmacy. Much more investigation in depth would have been done if this was a conservation issue.

Community Pharmacy welcomes regulation to improve our profession but this regulation will do much more harm than good as it is proposed now.

I appreciate this opportunity to comment on this issue.

Herbert Kwash Rph

908 Caddington Ave

Silver Spring, Md 20901

118

1314 South Davis Road
Ashland, OH 44805
lux627on@yahoo.com
419/281-0027

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

Dear Sirs:

I am deeply concerned about CMS-2238-P. If nothing changes, I will not be able to fill prescriptions for my Medicaid clients. CMS-2238-P contains a definition of AMP (Average Manaufacturers Price) that would not even cover my ingredient costs for prescriptions.

As it stands, CMS-2238-P is a death knell for retail pharmacy. Pharmacies can not stay in business if they are expected to sell items at a loss. Besides the negative effect on our store, our clients will suffer extreme inconvenience, as the establishments they trust & prefer may not survive this blow.

I do not know who proposed this definition of AMP, but it does not reflect real life finances in the retail setting. While I am glad CMS is exploring options to get the most benefit for our tax dollars, I hope you will reexamine the current proposal. Surely there is a formula that would be fair for CMS and Retail Pharmacies both, so our Medicare patients can continue to benefit from our services.

Thank you for addressing this matter and listening to people who will be affected.

Sincerely,

JoAnn Seaman, RPh

Knisley Pharmacy, Inc.

2647 Falls Road
Bainbridge, Ohio
45612

Phone: 740 634-3233
Email: jknisley@horizonview.net

John N. Knisley
RPh

February 14, 2007

Leslie Norwalk
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: Proposed AMP Rule

Leslie,

I have recently been made aware of the proposal CMS-2238-P Prescription Drugs with AMP reimbursement. Since I sold my community Pharmacy in 2003, I have nothing to gain or lose by writing this letter. I understand that this plan will have the potential to reimburse retail pharmacies below what it actually costs them. I strongly urge CMS to redefine AMP so it reflects what pharmacies actually pay for the product. If they are reimbursed less than the product costs, they will be forced to turn the patient away or have their doctor change to a similar brand name product where they can show a profit. If the latter happens, it will end up costing Medicare/Medicaid programs much more.

If instated, this program will have a devastating effect on our small community Pharmacies – perhaps making them close their doors. In turn, this will be detrimental to the health and welfare of patients who depend on these pharmacies for many different services far beyond retail sales. Our community pharmacies are a vital link in today's healthcare system. If you take this link away, just like any other vital link, the system will suffer drastically.

As a former small community pharmacy owner for 25 years, I ask that you look beyond the monetary savings before you make your final decision. Please issue a clear definition of Average Manufacturer's price that covers our community pharmacies' acquisition costs. This definition should be issued as soon as possible, before AMP takes effect.

In closing, I have one question for you and all others that are implementing this rule: Would you be in favor of paying your employer each week so you could work for him? In reality, this is what you are asking retail pharmacies to do.

Professionally,

John N. Knisley, RPh

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February 14, 2007

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Department of Health and Human Services
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Professionally,

John N. Knisley, RPh

IRO

SCRIPTSHOP PHARMACY
4894 ERIE SW
NAVARRE, OHIO 44662
Phone: 330-879-5626 **FAX: 330-879-5666**

RE: The proposed AMP definition under CMS 2238 P

PROBLEM:

We ask that CMS seriously reconsider this proposal. A proper definition of AMP is needed. I understand the Secretary of DHS has been given a wide leeway in writing this definintion and it has been estimated that the AMP will result in a reimbursement that is below our costs (approximatly 36% below our costs).

No business can exist with negative reimbursements.

CONSEQUENCES :

Many pharmacies, especially small independents, will have to close their doors, or will have to turn away Medicaid and Medicare Part D patients.

These are the very people that CMS is supposed to help.

The closing of small pharmacies will interrupt patient access to care in a significant way, especially in rural areas.

As things are being set up right now, the impact of AMP would be felt on mostly generic drug purchases. That might force the pharmacies to dispense more brand names, ultimately increasing the cost to CMS.

We care about our patients. We do not want to turn anyone away or have to charge more because of inadequate reimbursements.

SOLUTION

I respectfully request that the AMP be revised to reflect what we actually pay for the medication. Please issue a clear definition of AMP that covers community pharmacy acquistion costs in a realistic manner. This definition needs to be issues as soon as possible, before AMP takes effect.

Sincerely

John Kinzer RPh.
Kathleen Heinzerling CPhT
Charlotte Angeres PT

Nuway Pharmacy
1627 Haines Rd
Levittown,Pa.19055
Dennis Mitnick

To whom it may concern:

Thank you for the opportunity to comment on these proposed rule changes Of the deficit Reduction Act for 2005.

The reimbursements based on AMP is a devastating effect on retail Pharmacy. No business whether independent or chain can sustain a profitable financial bottom line and many stores will eventually opt out of the program or even worse close it"s doors forever. Pharmacy is an integral part of the health care system and it is being targeted to help mend the rising cost of medicine today. It has been shown in all studies that it is cheaper to fill prescriptions in a neighborhood Pharmacy as opposed to Mail Order but no one takes the initiative to follow up and really save on dispensed drugs. The services of retail Pharmacy Are undermined but if you tabulate the cost of these services then you realize that they have to be eliminated just to break even under this proposed plan. Overhead goes up every year: vials and bottles and labels go up every year: Transmission fees add up to sizeable monthly payments; delivery when applicable time on phone with doctors, pbms patients; patient counseling; blister packaging for home bound facilities and many other hidden expenses.

The last study showed that it cost $10.50 to fill a prescription. That covers just the overhead expenses. Then how can your proposed reimbursement rate based On the Manufacturers cost be able to keep any Pharmacy afloat financially? Answer: it can't. The latest study showed your formula to be 36% below the actual acquisition cost of the drugs. To keep Pharmacy as an integral part of the health care system these rates would have to be calculated on a realistic figure so that Pharmacy owners would be able to stay in these programs and stay in business and be able to serve the public in a professional and caring manner. Your formula should only include retail Pharmacies and not mail order pricing because that pricing is not available to any of us. Your proposal as is will cause many to close down or opt out of the program. I'm sure this is not your intention But surely it will happen. Retail Pharmacies made lots of monetary sacrifices on the implementation of the medicare d program and kept the program from Becoming a debacle in the opening months.

A fair and justifiable reimbursement should be established along with a reasonable fee schedule to assure the public they will have reasonable access to the stores they have patronized and trusted for many years.

Thank you for this opportunity and I hope your results would be favorable to Pharmacy so I could continue to serve my community as I have in the past

Thank you

Dennis Mitnick rph.

FRIENDSHIP PHARMACY INC
3300 COTTMAN AVENUE
PHILADELPHIA,PA 19149
215-624-0440

2-18-07

CENTERS FOR MEDICARE AND MEDICAID SERVICES
DEPT. OF HEALTH AND HUMAN SERVICES
ATTN; CMS-2238-P
PO BOX 8015
BALTIMORE, MD 21244-8015

ATTN; LESLIE NORWALK - ACTING ADMINISTRATOR

DEAR MS. NORWALK

ENCLOSED PLEASE FIND COMMENTS FROM OUR NATIONAL ASSOCIATION WHICH COMPLETELY STATES MY FEELINGS OF WHY AMP WOULD BE DISASTEROUS TO MY PHARMACY.
I AM NOT TAKING THE TIME TO RE-WRITE WHAT THEY HAVE ALREADY STATED, BUT I CANNOT EMPHASIZE ENOUGH WHAT A TERRIBLE EFFECT IT WOULD HAVE ON MY BUSINESS. I WOULD NOT BE ABLE TO SERVICE MY MEDICAID PATIENTS. THANK YOU FOR YOUR CONSIDERSTION

SINCERELY,

FRANK A RUBINO BS, RPH

CMS-2238-P: Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005

As promised, NCPA is providing an outline of our position regarding CMS-2238-P, the agency rule which will redefine Average Manufacturers Price (AMP) for use as a Federal Upper Limit (FUL) in the Medicaid program. The move to AMP will result in a significant reduction in Medicaid reimbursement for multiple source generic medications. NCPA will be submitting a comprehensive set of comments on behalf of community pharmacy, however it is our desire for the Centers for Medicare & Medicaid Services (CMS), the agency that runs the Medicaid program, to receive a significant number of comments from the pharmacy community.

This outline is provided so that community pharmacy's comments will have a more unified theme in order to magnify their impact. Please review the rule and these suggested comments and then submit your own comments to CMS from your perspective.

Comments can be submitted electronically, by mail, by express mail and by hand or courier. Full details are outlined on pages 2-4 of the proposed rule. The proposed rule can be found on the CMS website at: http://www.cms.hhs.gov/MedicaidGenInfo/downloads/AMP2238P.pdf.

NCPA suggests you submit your comments electronically by visiting http://www.cms.hhs.gov/eRulemaking. **PLEASE REMEMBER: Your comments must be received by CMS no later than 5 p.m. on February 20, 2007.** Comments should also be addressed to Acting Administrator Leslie Norwalk.

NCPA comments reference the recently released Government Accountability Office (GAO) report on Medicaid Federal Upper Limits (GAO-07-239R) which can be found at http://www.gao.gov/new.items/d07239r.pdf.

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:

> "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 p.4

This finding validates community pharmacy's contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates

AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. **AMP was never intended to serve as a baseline for reimbursement,** and may not have been an effective measure for manufacturer rebates as outlined in the report "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States" (GAO-05-102).

However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in "Best Price" but should not be included in AMP.

An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

The following is a summary of NCPA's suggested comments to CMS. Specific CMS requests for comment (in bold, with page reference) are followed by an NCPA response.

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.—pg. 29

Public Access Defines Retail Pharmacy Class of Trade

CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be "publicly accessible." Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in AMP.

NCPA recommends "retail pharmacy class of trade" include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.—pg. 31-33

Inclusion in Best Price of PBM rebates, discounts and other price concessions—pg. 53

Treatment of Manufacturer coupons with regard to Best Price—pg. 55

Inclusion of Direct-to-Patient Sales with regard to AMP—pg. 41

AMP Must Differ From Best Price

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the

market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.

For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.

How PBM price concessions should be reported to CMS.—pg. 33

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.—pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP—pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110

CMS discusses impact on pharmacy:

- On independents: potential "significant impact on small, independent pharmacies."—pg. 101
- On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 ("a small fraction of pharmacy revenues").—pg. 108
- "We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

Summary of Key Points:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.

2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*

3. Reporting AMP at the 11-digit NDC level to ensure accuracy

123

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-2238-P
PO Box 8015
Baltimore, MD 21244-8015

2-18-07

Dear Ms. Leslie V Norwalk, ESQ:

I thank you for the opportunity to comment on the proposed rule changes that will implement the provisions of the Deficit Reduction Act of 2005 (DRA).

My first comments, after reading the 150 pages are that there seems to be some problems with the assumptions that influenced the final rulings. Also, many of these rules use a flawed GAO report, "*Medicaid Drug Rebate Program – "Inadequate Oversight Raises Concerns about Rebates Paid to States"* (GAO-05-102), dated February 2005 as its basis for many parts of this ruling.

In press releases, after the implementation of Medicare Part D, you personally praised the efforts of Community Pharmacy (Chain Store & Independent) for the help they provided during these troubled times. Billions of dollars have already been saved by the Federal Government, and most importantly, the "senior" consumer has much better access to its pharmaceutical needs. Now you are asking Community Pharmacy to give up another $8.4 Billion dollars over the next 5 years. This is not the "Thank You" we expected.

This ruling only pertains to multiple source drugs (generics), which is within itself a very complicated and time sensitive part of Pharmacy. Prices change on a daily basis, some increased & others decreased due to market place availability and the number of manufacturers supplying the product. Updating pricing monthly, with a 30 day window for the manufactures to supply pricing means that pricing will always be 60 days behind the market place pricing; while invoicing to Community Pharmacy changes daily.

While everyone agrees that Average Wholesale Price (AWP) is no longer an accurate basis for pricing, all I can say at this point about Average Manufacturer's Price (AMP) is that AMP could also be an acronym for **"Ain't My Price"**. The one major flaw I see in your calculation for determining Federal Upper Limit (FUL) using AMP is that distribution costs added to this price by Wholesalers & Distributors is not calculated in your formula. While your people may feel that this is a minimal mark-up (like with Brand Name Products), in reality this figure ranges at a low of 15% to a high of about 35%. With Independents, 95% of their purchases of generics are through Wholesalers & Distributors. Chain store purchases of generics through Wholesalers & Distributors are lower, but their net price after warehousing and distribution of products purchased direct from the manufacturers are very similar to the Independents invoice pricing.

Wholesalers in the United States are very important in the day-to-day operation of a pharmacy and only because of them are drugs available to the consumer in a timely manner. Maybe the authors of these rulings should spend a day at a wholesaler's distribution center and see the technology involved in this process. Without the wholesalers, distribution of product to the end user would be in chaos.

Now let's get into your specific requests for comments:

Including mail-order pricing into the pricing formula to calculate FUL's –
The fact that manufacturers have instituted different prices for different categories is discriminatory and has been in Federal Court for the past 11 years. That being said, including mail-order pricing in the formula is wrong and in its stead there should be a Retail Average Manufacturers Price (RAMP) and a Mail-Order Average Manufacturers Price (MAMP), and reimbursement to these two entities should use the RAMP price or the MAMP price. Better yet, the Federal Government should mandate a "One Price Policy" by all manufacturers to all categories, thereby lowering the price to the consumer, leveling the playing field and ending discriminatory pricing. It seems to work in Europe and Canada – but PHRMA spends millions to prevent this from occurring in the United States

Including rebates to PBM's in the calculation of AMP –
You state in your rulings that you have no way of knowing what portion of these rebates are passed onto Community Pharmacy or the consumer. Allow me to simplify this matter for you – ***NONE OF THESE DOLLARS ARE PASSED ONTO COMMUNITY PHARMACY OR THE CONSUMER*** – The present day PBM's (no longer just an administrator) is big business and their profits are astronomical and at the point where they are unconscionably increasing the costs of health care. There are multiple reports showing this that are available to you by our national organizations and the business pages of every newspaper report "settlements" made by PBM's to the States, HMO's, etc. quite often.

Effect of these new proposed rulings on the growth of dispensing of generics in the future, and to what extent PBM's act as wholesalers.
Over the past few years generic utilization has greatly increased saving the government billions of dollars. This utilization has increased from about 30% ten years ago to approximately 55% now. Decreasing reimbursement for generics will reverse this increase in utilization very quickly and more than make up the proposed $8.4 Billion in savings. As for the PBM's acting as wholesalers, they own the Mail-Order houses, mandate the use of the mail-order by consumers using unfair business practices (co-pay differentials) and take advantage of their mail-order category to obtain discriminatory pricing which they do not pass on to consumer or the end payor. They do not actually act as a wholesaler, but use the "charge-back system" developed by the wholesalers and manufacturers to greatly increase their profits. They also spend millions of

dollars fighting "transparency" law suits throughout the country, rather than allowing any one the ability to see "the money trail".

Allowing each State to set Professional Fees:
Many cost surveys have been published over the past few years showing that the actual costs by the Pharmacy Community to dispense a prescription are in the range of $9.50. With each State having its own budgetary problems, these surveys have been ignored and there is no reason to think that the States will mandate a fair reimbursement. This would be an excellent opportunity for CMS to mandate a $10.00 professional Fee for Brand products and a $15.00 Professional Fee for generics. This would assure that generic utilization increases and access by the consumer of their prescription needs would not be seriously affected. Also at the same time, rather than instituting a complicated method of calculating AMP by manufacturers, why not use the present Wholesale Acquisition Cost (WAC) which is a much better picture of a stores acquisition cost and is already readily available and published by the pricing guides. Of course, the above mandated Professional Fees must also be included in the formula.

Including in the AMP calculation, rebates paid to SCHIP, Medicare Part D Plans, and SPAP Plans.
You are excluding rebates to Medicaid, DoD, HIS, and DVA because prices to these entities are not available to the Retail Pharmacy Trade. What makes you think that rebates offered to SCHIP, Medicare Part D Plans, and SPAP Plans are available to the Retail Pharmacy Trade? All your assumptions in this portion of the proposed rules are definitely flawed and should be revisited.

Initiation of the Definition of Fair Market Value:
In this section, you mention Medicare Part B initiating a Fair Market Value for their limited number of drugs and whether this method should be instituted in these rulings.
First, in many cases Part B drugs can not be bought by the Pharmacy Community at the prices set. Initiating this method would transform Chain Pharmacy Stores into variety stores and Independent Pharmacy would cease to exist. Access to Prescription drugs would cease to exist and hospital emergency rooms would become understaffed clinics.
Secondly, let me just say **NO**.

Pricing for new generic Products entering the Market-Place:
Over the past few years when a brand name product nears the end of their patent, the manufacturer works out a deal with just one generic manufacturer to have exclusive rights for a period of about 6 months. In many cases, the Brand manufacturer has an equity ownership in the generic manufacturer or the Brand Name manufacturer shares in the profits during this period through a licensing agreement. Invoice pricing is not generally decreased by more than 20 – 25% than the Branded product during this period. Therefore, an FUL price should not be

permitted until at least 2, or preferably 3 manufacturers make it available and affect market-place pricing.

Inclusion of Administration Fees or Service Fees paid to Wholesalers, PBM's or HMO's:
These fees are not available to the Retail Pharmacy Trade and should be excluded from the calculation. They are kept by the above entities and have no affect to invoice pricing to Retail Pharmacy. If you actually feel that these fees are more than nominal, then further legislation in the future should address this. It should not be even considered at this time.

Nominal Pricing:
This pricing is also not available to the Retail Pharmacy Trade and should be excluded from any calculations.

Use of pricing services in any way to determine FUL's:
We have seen over the past 3 years when most manufacturers stopped supplying AWP's to the pricing services because of multiple lawsuits that all pricing services are not the same. We have seen some able to update prices in a timely manner, while others take 60 – 90 days to update price changes. Using the "lowest price" from these pricing services would just mean that you would be using outdated information in many cases. This should be done internally in a timely manner and the "slow poke" should be excluded entirely.

Use of 9 digits NDC versus the 11 digits NDC:
Every stores inventory of a product is determined by actual usage of a product. In these times, proper control of inventory is very important to a stores bottom line. Therefore, since you agree that keeping the 11 digits NDC is no more work than keeping the 9 digits, I would suggest that the 11 digits be used to allow for the difference in the popularity of a drug in different areas of the country.

Outlier Price:
Because a manufacturer stops manufacturing a product does not mean that the pricing services remove the product. In fact, it remains for quite some time. There are many instances where many manufacturers decide to stop manufacturing a drug and the price from the remaining manufacturers increase sharply in price. Your guidelines do not consider this, and this has become a very common practice. Under your guidelines, it could take well over 90 days for you to catch up while stores would lose money filling these prescriptions.
What must be done is for your department to set up a process whereby pharmacies can fill out a form showing that a product is not available from their distributors at the price you are paying. This information can be verified quickly and pricing changed in a timely manner. We presently have a program in affect in Pennsylvania with most of the Third Party Plans, including Medicaid Programs and Part D Programs, and have had great success.

Savings Estimates developed by the Office of the Actuary in CMS:
In this section you mention the impact on just 3 types of small businesses, & they are (1) small pharmaceutical companies participating in the Medicaid Drug Rebate Program, (2) small retail pharmacies & (3) physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician administered drugs.
It should be noted that while these proposed rules will affect all of Pharmacy, including the large Chains, no consideration is given to these small retail pharmacies that have increased their generic utilization to over 55% and whose business is much more dependent on prescription sales than the larger chains.
In the summary of this section, your people say this will only result in an overall 1% decrease. From what I have seen and heard from others with much more information in hand, AMP pricing will decrease reimbursement by $3.00 to $4.00 per prescription which will decrease gross profits by approximately 15 – 20% for an industry that is seeing its profits decreasing yearly.
The loss of access by the consumer when more Independents close their doors CANNOT be picked up by the Chains or mail-order who do not offer the personal services provided by Independent Pharmacy (counseling, pick-up & delivery, house charges, third party administrative help, and the knowledge of their patient needs to name just a few).

Summary:
It seems that Pharmacy is the easiest group to attack and from which to take money back. Federal Antitrust laws prevent us from working together so what can a "small" Independent do to fight back with any success? Medicare Part D has placed such a burden on Pharmacy that only a very few have the time to read over these 150 pages & express their concerns. I hope my comments and suggestions are considered.

Suggestions:
Include the Pharmacy Profession in your meetings and allow our National Groups to sit in and express their feelings at your meetings before a proposed ruling is sent out for just a 60 day comment period. Include managers of Chain Stores & owners of Independent Stores that "live" the day-to-day operations of a pharmacy.

Do your "Cost of filling an Rx" surveys and abide by their results. Include input from the Pharmacy Community & I am sure your results will not differ from those surveys already completed by CPA's, Schools of Pharmacy & State Agencies.

With Gross Profits so low in this industry, a fair Federally Mandated Profession Fee must be included in your final rulings if you now expect to receive acquisition costs. Do the calculation on a drug where a 30 day supply may cost 50 cents, $5, $10 etc. One price does not fit in Pharmacy, never did & never will. At least a Minimum Professional Fee must be mandated that will allow stores some type of Return on Investment.

Include Wholesaler & Distributors Mark-Ups in your calculations.

Insist that your employees spend a full day in a Pharmacy before they write up the final rules.

Members of PHRMA are not affected by these rulings while their products still account for **85%** of your drug costs. Have them explain the much lower pricing they offer other countries. Have them explain why they spend more on TV advertising than they do on Research & Development.

A 5% decrease in pricing from PHRMA will save much more than $8.4 Billion.

Finally:

It is time someone in the government gets the courage to go after the real money to be found in the huge profit margins of big PHRMA and the PBM's. Take any more from Community Pharmacy and there will be no next generation of patient and service oriented independent pharmacist/owners since they will no longer be able to make a decent living. That would indeed be a tragedy and very short sighted on CMS's part. Pharmacists are the most respected and easily accessible health care professionals. The patient medication counseling they now provide saves CMS million, if not billions of dollars annually in hospital and related expenses that do NOT occur due to the influence they have on patients taking medication correctly. These CMS proposals will put many independent pharmacy owners out of business and the positive influence they have on patient outcomes will disappear. Any savings CMS thinks it will gain will be far outweighed amid skyrocketing costs in other areas of healthcare.
This administration has targeted community pharmacy for 90% of the Medicaid cuts-although those expenses account for only 2% of the Medicaid budget- in the form of reduced payments for generics.

I thank you for this opportunity to express my concerns:

FRANK A RUBINO BS, RPH
FRIENDSHIP PHARMACY INC.
FRIENDSHIP PHARMACY LTC
3300 COTTMAN AVENUE
PHILADELPHIA, PA 19149

February 18, 2007

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

Subject-Medicaid Program: Prescription Drugs:AMP Regulation
CMS-2338-P RIN 0938-AO20Acting Administrator Leslie Norwalk

Dear Ms.Norwalk

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 (FUL) program for generic drugs. My pharmacy is located at 400 W. Spruce St. Shamokin, Pa. 17872. We are a major provider of pharmacy services in the community and your consideration of these comments is essential my comments are attached to my letter.

In conclusion, I support the more extensive comments that are being files by Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments.

Sincerely,

Janice E. Miner, RPh

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

We agree with the more extensive comments submitted by Pennsylvania Pharmacists Association addressing differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP-Removal of Rebates, Concessions to PBM's And Mail Order Pharmacies.

AMP should reflect prices paid by retail pharmacies. Please make pricing a fair and equal to all.

3. Removal of Medicaid Data

Medicaid pricing is heavily regulated by the state and federal governments.

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

In order to address these concerns, Pennsylvania Pharmacists Association proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS/

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 to retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug.