

Submitter : john clay  
Organization : ncpa  
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

**Background**

Background

GAO was questioning the validity of old pricing structure based on AWP(average wholesale price) was giving rise to so called AMP(average manufacturers price) for use as FUL(federal upper limit) in hope of saving a lot of money for CMS

**GENERAL**

GENERAL

Unlike what president Bush stated in Feb 2006, Pharmacies are not 'overcharging the system'. They are barely making a razor-thin profit(in some cases as low as 5% to cover their professional expenses & financing the expensive medicines to stock on their shelves) & service american citizens.

AMP or any other pricing formulas should not dip below what pharmacies are paying their suppliers for the medicines!!

average manufacturers price has nothing to do with the price pharmacists are paying the suppliers.

If this AMP gets approved as our new basis for reimbursements on medicines...it will irreversibly destroy the network of little & big corner apothecaries & cripple even big outfits that fills community prescriptions in urban areas.

AMP is definitely not the way to measure cost of filling a prescription. Medicines cost way more than \$4.00 (as advertised by WAL-MART which is only a gimmicky ploy to lure uninsured cash paying customers). By the way an average cost of filling a prescription is \$ 9.85 in USA !!

A sure way to close the fiscal gap is to go after manufacturers who play all kind of games in raising cost of brand name drugs & extending & manipulating patent laws.

Another way to be fair is to include several community health professionals(esp.pharmacists) to help reformulate pricing structures instead of other vested interest groups who are eager to see little retail-pharmacies disappear & they can have a field day with their monopoly on rx-supply !!

I know you legislatures are wonderful human beings & care for not just the citizens who voted you in but also for supposedly most respected professionals-PHARMACISTS !!

Submitter :

Date: 02/19/2007

Organization : San Juan Pharmacy

Category : Pharmacist

Issue Areas/Comments

**GENERAL**

**GENERAL**

**UphA PERSPECTIVE**

The proposed rule does not address national and state pharmacy associations concerns for adequate reimbursement under an Average Manufacturer s Price (AMP) based reimbursement formula or our concerns regarding payment for pharmacist services (dispensing fee):

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics. These pharmacies may have access to rebates and price concerns that are not accessible to traditional community pharmacy. All major mail order pharmacies in the U.S.A. are owned by PBM s. The alignment of the PBM, its customers and their mail order division permits them to leverage manufacturers for substantial rebates which are not available to retail pharmacies. If the final rule permits the inclusion of mail order pricing in the calculation of AMP then mail order pharmacies will have an unfair competitive advantage over retail pharmacy where 80% of consumers currently access these products. Consequently, AMP will be set at a rate lower than what community pharmacy can purchase multi-source generics.

The proposal does not address dispensing fees and continues to let States determine the reasonable dispensing fee they are required to pay pharmacists. UphA is concerned that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. In Utah, the Medicaid dispensing fee is \$3.90, while a recent study indicated that the average cost to dispense a medication in the state of Utah is \$12.39. It is unlikely that the State of Utah would set the Medicaid dispensing fee high enough to cover the cut in drug cost reimbursement that will result from AMP based pricing.

One Utah pharmacy owner estimates that if the proposed AMP based reimbursement is implemented, this would result in a net loss of \$117,000 in net profit in his two small independent pharmacies!

CMS-2238-P-1050

Submitter : Bob Hager, Jr  
Organization : Quality Discount Drugs  
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

February 19, 2007

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

Ms. Norwalk,

The purpose of this letter is to comment on the proposed rule (CMS-2238-P) regarding the reimbursement of pharmacy providers based on the AMP model as set forth in the Deficit Reduction Act of 2005.

As I am sure you are well aware, pharmacy services are an integral part of the health care of all Americans, but especially important to the health care of the poor, indigent, or others who qualify for state Medicaid assistance. This population may be at an increased risk of poor health care due to various influences, and often, pharmacy services, such as prescriptions, may be one of the most efficient and influential accesses for the recipient.

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medication. This does not consider the recently released report from the accounting firm Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies in which it is reported that the median cost of dispensing a prescription for a pharmacy is \$10.51.

My concerns are further supported by the GAO's report that states that community pharmacies, such as mine, will lose an average of 36% on each generic prescription filled for Medicaid recipients. My pharmacy will not be able to fill Medicaid prescriptions under such an environment.

Pharmacists save money for state Medicaid agencies, CMS, and this country. If the AMP is not defined fairly, from a retail pharmacy perspective, and if the GAO report is accurate, many pharmacies, including my pharmacy, will be unable to fill Medicaid prescriptions or will cease to exist. This in turn will decrease access for the Medicaid recipient and will increase the costs for Medicaid and this country far above any savings that are to be realized through AMP pricing for generic prescriptions.

Sincerely,

Robert Hager, Jr., RPh.  
Quality Discount Drugs  
4109 Eva Road  
P.O. Box 98  
Eva, Alabama 35621

**Submitter :** Mr. Patrick Hilger  
**Organization :** Gregwire Drug Store  
**Category :** Pbarmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

**Background**

Legislation passed changing the reimbursement of generic drugs under Kansas Medicaid. The move to a proposed AMP formula. This new formula would force thousands of patients to experience access issues and would cause many pharmacies to go out of business, furthering the problem of access to quality health care.

**Collection of Information Requirements**

**Collection of Information Requirements**

These provisions if implemented would require pharmacists like myself to sell prescriptions on average 36% below our actual acquisition costs.

**GENERAL**

**GENERAL**

It would be extremely detrimental to the patient, to the community pharmacy and to the delivery of health care to let this legislation continue and be implemented. This is absurd to expect pharmacists to dispense medication 36% below what it cost them. Please stop this before it has a chance to be implemented.

Submitter : Mr. Glenn Newsome

Date: 02/19/2007

Organization : Mr. Glenn Newsome

Category : Individual

Issue Areas/Comments

**GENERAL**

**GENERAL**

I live in a small community that depends greatly on the pharmacist in our local drugstore for advice and counsel regarding proper use of prescribed drugs. Our pharmacist normally recommends generic drugs to reduce cost to the customer. It is my understanding that proposed changes in the Medicaid program will discourage our local pharmacist from using generic drugs. I believe this will ultimately cost the consumer and our government more.

I do not have an answer for the current health care crisis in our country but I believe our government must do everything possible through law and regulation to encourage preventive care and healthy life styles and at the same time reduce the cost of medication.

I encourage you to carefully consider the long term impact of the rule change on small town local pharmacies that are struggling against the ever increasing "walmart" drug stores. It is my understanding that generic drugs cost less to produce and distribute. Any regulation that will reduce the use of generic drugs is not in the best interest of our country.

Thank you for the opportunity to share my comments.

**Submitter :** Dr. David Fong  
**Organization :** United Pharmacists Network, Inc.  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

**Background**

My name is David Fong and I currently serve as the Vice President of Development for the United Pharmacists Network, Inc. (UPNI). We represent the interests of 700 independent community pharmacies throughout the Riverside/San Bernardino, Los Angeles, Orange and San Diego Counties. I also serve as the Chief of Operations for Cathay Medical Industries, which is owned by my parents. Cathay Medical Industries operates two independent community pharmacies in Los Angeles and I currently practice in one of the pharmacies on Saturdays. I am a graduate of the USC School of Pharmacy and have been in practice as an independent community pharmacist for over 24 years.

**Collection of Information Requirements**

**Collection of Information Requirements**

This proposed rule would implement the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid Program. The DRA would amend section 1927(e) to revise the formula CMS uses to set the Federal Upper Limits (FULs) for multiple source drugs in the Medicaid Program.

**GENERAL**

**GENERAL**

It is our feeling that the Pharmacy Community was not included at the table when the DRA was being developed. In addition, a study by the Government Accounting Office (GAO-07-239R) which looked at what would happen to 77 drugs if AMP-based FULs were implemented. The study found that for the entire sample of 77 multiple source outpatient drugs, AMP-based FULs were, on the average, 36% lower than the average retail pharmacy acquisition cost.

In particular, the estimated AMP-based FUL were, on average 65% lower than average retail pharmacy acquisition cost for the 27 high expenditure drugs and 15% lower for the 27 frequently used drugs in the sample.

The results of the GAO study was based on 250% of AMP. There is no assurance that states and/or pharmacies will be reimbursed at 250% of AMP.

In addition, one may find an increase in the utilization of higher cost brand medications. General wisdom encourages the use of generic drugs because they are cheaper than brand drugs and they save the system money. The DRA actually encourages the use of brand medications and higher costs for State Medicaid Programs.

**Regulatory Impact Analysis**

**Regulatory Impact Analysis**

Currently, the Medicaid program will reimburse independent community pharmacies for prescriptions for Medicaid beneficiaries at a discount off of Average Wholesale Price (AWP) plus a dispensing fee. Payments for most generic or multi-source drugs are subject to aggregate federal upper limits (FULs) that are usually 150% of the Wholesaler Acquisition Cost or WAC of the lowest published price for equivalent drugs.

The Deficit Reduction Act would change the way in which State Medicaid Programs would pay independent community pharmacies for prescriptions for their beneficiaries from AWP to Average Manufacturer Price (AMP). The DRA would then set the FUL at 250% of AMP for multiple source drugs.

AMP was created thru OBRA '90 as a benchmark for rebate payments by manufacturers to State Medicaid Programs. The fundamental problem in creating, using and monitoring the use of AMP is that each manufacturer defines AMP differently. CMS has not provided clear guidelines on how to calculate AMP nor has it resolved price determination problems.

For example: Sales to mail order pharmacies and nursing homes when calculating AMP, because mail order and nursing homes pay lower prices than retail pharmacies, because they are different classes of trade, i.e. one is a closed door pharmacy that does not see any walk in patients and the other is open to the public. Although they are both retail pharmacies, because they are in different classes of trade, the pharmaceutical manufacturers provide different pricing strategies for the products that they purchase. Including mail order and nursing home pharmacies in the calculation would lower the AMP below the price a traditional retail pharmacy pays.

Another example would be that rebates paid to health plans and pharmacy benefits managers when calculating AMP would also result in a lower value for AMP. This is because PBMs are not distributors of drugs to retail pharmacies. PBMs do not purchase, warehouse nor do they deliver pharmaceuticals to retail pharmacies. PBMs mainly provide pharmacy network management services. The only instance where they would purchase drugs would be if they owned a closed door pharmacy/mail order house, which would process prescriptions and mail the medications to their patients. However, this type of activity is different from the activities of the PBM where price concessions and rebates are based on placement on their formulary and movement of market share for particular products. Independent community pharmacies do not share in these types of rebates, discounts or any other price concessions that PBMs negotiate.

Other issues regarding AMP include:

1. AMP was created as a way to determine the amount of rebates that pharmaceutical manufacturers would pay to stay on State Medicaid Programs. As such, there is an incentive to report the lowest number possible.
2. The 11-digit National Drug Code (NDC) for the drug should be used to calculate AMP as it will offer the most accurate number according to package size.
3. Clarification of the AMP reporting period to a time frame that

CMS-2238-P-1053

is available in the private sector.

4. Direct the States to utilize monthly Retail Survey Price date.  
These payment amounts represent the weighted average reimbursement received by independent community pharmacies for each drug, reflecting a blend of cash and third party payments.
5. Rebates paid by the manufacturer for state sponsored assistance programs should not be included in the calculation of AMP as these rebates do not affect the price paid by independent community pharmacies nor are the rebates shared with the pharmacy.
6. Coupons redeemed by a pharmacy on behalf of the consumer should not be included in the calculation of AMP because manufacturer coupons are essentially cash discounts and in no way affect the price paid by the independent community pharmacy for the drug product.

CMS-2238-P-1054

**Submitter :** Ms. Tom Smallwood  
**Organization :** Buena Vista Drug, INC.  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

If proposed AMP rules go into effect I will probably have NO CHOICE but to stop serving Medicaid patients because I will be LOSING MONEY on every prescription that I dispense on this program.

**CMS-2238-P-1055**

**Submitter :** Mr. Christopher Howes  
**Organization :** Colorado Retail Council  
**Category :** Other Association

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1055-Attach-1.DOC



Colorado Retail Council / 1580 Lincoln Street, Suite 1125 / Denver, CO 80202  
www.coloradoretail.org / Phone (303) 297-0657

February 19, 2007

Leslie Norwalk, Esq.  
Acting Administrator  
The Centers for Medicare & Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201  
(via email)

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

Dear Administrator Norwalk:

The Colorado Retail Council appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). We are quite concerned about the impact of the proposed rule on our chain pharmacies. We represent over 500 pharmacies here in Colorado and employ more than 75,000 Coloradans and worry that the proposed rule may do real damage to our operations.

The Colorado Retail Council works with the Food Marketing Institute (FMI), and fully supports the comments filed by FMI and incorporates FMI's comments herein. In addition, we specifically wish to call your attention to the following issues.

As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Although we understand the challenge the dual use of AMP presents to CMS, we believe that several aspects of the proposed rule would unduly reduce AMP, thereby jeopardizing our member companies' ability to continue to serve Medicaid beneficiaries.

In this regard, we urge CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Supermarket pharmacy profit margins are in the range of approximately 2 to 3 percent of total revenues. Recent studies suggest that the Federal Upper Limits (FULs) based on AMP may result in ingredient

cost reimbursement that is below pharmacy acquisition cost.<sup>1</sup> In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. To the extent that FULs are below pharmacy acquisition costs for generic drugs, many companies may find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts in the states in which we operate that are far below the costs we incur to dispense prescription drugs to Medicaid patients.

Accordingly, although we do not believe that this situation can be fully addressed through the regulatory process and we are joining with FMI and others to seek a change in the underlying law, we believe that CMS should take the steps discussed below to mitigate the problem in the interim.

First, CMS should revise the proposed AMP regulation so that it will align more closely with the underlying statute and provide a more realistic and accurate benchmark for pharmaceutical reimbursement to pharmacies. Specifically, the statute defines AMP as “the average price paid to the manufacturer for the drug in the United States by wholesales for drugs distributed to the retail pharmacy class of trade.” Accordingly, only those sales that are to entities that are truly within the “retail class of trade” should be included in the calculation. PBM’s, mail order pharmacies and other non-retail entities should be removed. Similarly, purchases by entities other than wholesalers should also be excluded. Likewise, the FUL should be based on the weighted average AMP of therapeutic alternatives, not the lowest cost alternative.

Second, CMS should delay publication of the AMP information to ensure that the consequences of publishing the data are fully understood. Publication of the AMP data will result in an immediate impact on the pricing of generic drugs that will create a floor on the price discounts that generic manufacturers are willing to offer, thereby reducing the level of competition between generic manufacturers with potentially significant negative effects on neighborhood pharmacists and the Medicaid program alike.

Third, state dispensing fees must be reviewed in light of the changes imposed by the federal drug reimbursement scheme. Accordingly, CMS should ensure that all pharmacy costs are included in the federal dispensing fee definition and require states to update their Medicaid dispensing fees to ensure appropriate utilization of generic drugs.

We respectfully request that you address our concerns on the record. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to contact me at 303-355-1066 or at [chris@chrishowes.com](mailto:chris@chrishowes.com).

Sincerely,

Christopher D. Howes  
President

---

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

Submitter : Ms. Bobbi Jo Long  
Organization : Zeigler Pharmacy  
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services  
Attn: CMS 2238-P mail stop C4-26-05  
7500 Security Blvd  
Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation  
CMS 2238-P RIN 0938-Ao20

The Long Rx Corporation is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid FUL program for generic drugs.

Our Corp. operates a pharmacy in Ohio. We are a major provider of pharmacy services in the community we are located.

This proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy. It could jeopardize my ability to provide pharmacy services to Medicaid beneficiaries and the general public. This regulation should not move forward unless substantial revisions are made. Incentives need to be retained for pharmacies to dispense low-cost generic medications. I ask that CMS please do the following:

\*Delay Public Release of AMP Data: The Centers for Medicare and Medicaid Services should not make AMP data public until a final regulatory definition of AMP is released. This definition should reflect the prices at which traditional retail pharmacies purchase medications. CMS indicates that it will start putting these data on a public website this spring. However, release of flawed AMP data could adversely affect community retail pharmacies if used for reimbursement purposes. CMS has already delayed release of these data, and we urge that release of these data be delayed again.

\*Define AMP to Reflect Retail Pharmacy Purchasing Cost: CMS' proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires.

Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade.

In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating AMP. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.

\*Delay New Generic Rates that would Significantly Underpay Pharmacies: The new FULs for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This 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 it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability office 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.

\*Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential 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.

I support the more extensive comments that are being filed by the NACDS regarding this proposed regulation. We appreciate your consideration of these comments. Thank you.

Sincerely,  
Bobbi

CMS-2238-P-1057

**Submitter :** Mr. Kelcey Diemert

**Date:** 02/19/2007

**Organization :** WESTERN DRUG

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I'm afraid that the Proposed Rule will make it impossible for us to continue to provide pharmacy services to our Medicaid patients. We are in rural Montana and have a high Medicaid population. This Rule will force many Montana pharmacies to stop serving Medicaid patients, causing a serious hardship for that population. Thank you for considering the potential impact on rural pharmacies and our patients.

Kelcey Diemert, RPh

**CMS-2238-P-1058**

**Submitter :** Mr. Kelcey and Nancy Diemert

**Date:** 02/19/2007

**Organization :** Chinook Pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

The Proposed Rule by CMS will cut our reimbursement for Medicaid prescriptions to a level which is below our cost of dispensing. We will be forced to stop filling prescriptions for this population, leaving many Medicaid patients without pharmacy services. Rural pharmacies provide a valuable service to Medicaid beneficiaries.

We are the only pharmacy available in Blaine County. If we cannot fill these prescriptions, many people will have to travel 50 to 100 miles round-trip to get their medications.

CMS-2238-P-1059

**Submitter :** Becky Claiborne

**Date:** 02/19/2007

**Organization :** Four Way Prescription Shop

**Category :** Other Technician

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

By passing the AMP Rule, you will be ending the life of the Independent Pharmacies thru out the state of Tennessee. I have had the privilege of working in 4 of these pharmacies in our area in the past 18 years. Yes I did have to find work at another independent when my first employer was put out of business by TennCare. I have seen the poor hard working Independent Pharmacies struggle thru all the changes in Tennessee's health care. WE MADE IT.....BUT will not be able to endure if this passed. We love our customers and hate to see them have to go elsewhere, as well as ourselves. IT IS NOT FAIR, chain stores have all the breaks due to size. I beg you to please help us. Blessings to you all and please pray for our troops.

Submitter : Dr. clive fuller  
Organization : Bascom Pharmacy  
Category : Pharmacist

Date: 02/19/2007

**Issue Areas/Comments**

**Collection of Information  
Requirements**

**Collection of Information Requirements**

AMP, average manufacturers price as a basis for medication cost

**GENERAL**

**GENERAL**

To :Leslie Norwalk, Acting Administrator

From :Clive Fuller, PharmD;

I am writing this letter in opposition to CMS using the Average Manufacturers Price (AMP) as the basis for reimbursement for Medicaid and Medicare patients for the following reasons.

1. The formula for AMP based Federal Upper Limit (FULs) in the proposal will not cover pharmacy acquisition cost for multiple source generic medication.
2. Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement
3. To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy.
4. The true cost will only be reflected by the following
  - a. Excluding all rebates and price concessions made by Manufacturers which are not available to retail pharmacies.
  - b. Excluding all Mail Order facilities and PBM pricing from AMP calculation. Mail order and PBM are extended special pricing from manufacturers, and they are not publicly accessible as is a community retail pharmacy.
  - c. Reporting AMP at the 11-digit NDC level to ensure accuracy.

Submitter : Mr. Douglas Heidbreder

Date: 02/19/2007

Organization : Addison Pharmacy

Category : Pharmacist

**Issue Areas/Comments**

**Background**

**Background**

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

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

I am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer's price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Addison, Michigan. Addison Pharmacy is a major provider of pharmacy services in the community and your consideration of these comments is essential to ensure that we can continue to meet the needs of our area.

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

CMS should exclude pharmacy benefits managers (PBMs) and mail order pharmacies from the definition of retail pharmacy class of trade. PBMs and mail order pharmacies are not community pharmacies, which is where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the general public. The definition of retail pharmacy class of trade should include independent pharmacies, independent pharmacy franchises, independent chains, chain pharmacies, mass merchandisers and supermarket pharmacies.

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

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. Nursing home pharmacies, PBMs and mail order pharmacies receive discounts, rebates, and price concessions that are not available to the community retail pharmacies, making them a fundamentally different class of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacy for medications. Including these elements is counter to Congressional intent.

**3. Removal of Medicaid Data**

Including Medicaid data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. Medicaid, like the PBMs, does not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Inclusion of Medicaid data would have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs and, therefore, be excluded from AMP calculations in the proposed regulation.

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

Reporting of AMP data by the manufacturers on a quarterly basis versus a monthly or weekly basis does not address the issue of price fluctuations when they occur. CMS needs to address this concern and create an exceptions and appeals process, similar to Medicare Part D, which would allow any provider, including a pharmacy, a mechanism to request a redetermination process for a FUL. The redetermination process should include a toll-free number that would be monitored by CMS and include a specific timeframe in which the redetermination process must occur and a procedure by which a redetermined FUL would be updated. This process would mitigate the risk of pricing lag and create a fair reimbursement mechanism for community pharmacy that is timely.

**GENERAL**

**GENERAL**

**5. Use of 11-Digit NDC Versus Nine-Digit NDC**

We believe that CMS should use the 11-digit NDC in the calculation of AMP since this is package size most commonly dispensed by retail pharmacies. The prices used to set the FUL should be based on the most common package size dispensed by retail pharmacies, not quantity sizes that would not be purchased routinely by a community pharmacy. 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.

I appreciate your consideration of these comments and support the more extensive comments that are being filed by the Michigan Pharmacists Association

**CMS-2238-P-1061**

regarding this proposed regulation. Please feel free to contact me with any questions.

Sincerely,

**Douglas Heidbreder**  
Addison Pharmacy

Copy: Members of Congress

CMS-2238-P-1062

**Submitter :** Mr. Hunter Baird  
**Organization :** Medical Arts Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**CMS-2238-P-1063**

**Submitter :** Mr. Jimmy Nuckolls

**Date:** 02/19/2007

**Organization :** Hudson Drug Store

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

CMS-2238-P-1064

**Submitter :** Dr. Marc Summerfield  
**Organization :** University of MD Medical Center  
**Category :** Hospital

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

**Background**

I am writing for a major urban DSH Hospital in Baltimore Maryland.

**Collection of Information Requirements**

**Collection of Information Requirements**

The requirement to submit NDC numbers for physician administered drugs in our outpatient treatment areas is onerous.

**GENERAL**

**GENERAL**

See attachment

CMS-2238-P-1064-Attach-1.DOC

#1064

University Of Maryland Medical Center  
Pharmacy Services  
29 South Greene Street, Room 400  
(410) 328-5650 FAX: (410) 328-8984



February 19, 2007

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

To Whom It May Concern:

On behalf of the University of Maryland Medical Center (UMMC), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 as published in the Federal Register on December 22, 2006. UMMC is a 700-bed Disproportional Share Hospital (DSH) under the Medicare program located in Baltimore, Maryland. UMMC also qualifies and is enrolled as a covered entity under the federal 340b drug discount program. Our primary concerns about the proposed regulations are as follows.

The proposed regulations would create enormous administrative, financial, and computerized systems burdens for our hospital by requiring the reporting of NDC information on drugs administered in our hospital outpatient locations. At present, NDC numbers are neither captured in our billing system charge master, nor transmitted/interfaced from our pharmacy dispensing system. This regulation would require us to negotiate software modifications necessary to accommodate this change with our billing software vendor. It would also require both billing and dispensing vendors to establish a new interface of data. HCPCS J-Codes are presently provided through UMMC's hospital billing system, and we are hard pressed to understand why the switch to NDC numbers is being suggested.

The pharmacy dispensing and billing system are not "brand" based, but, in fact, based on generic medications designations. At any time there could be multiple manufacturers of the same drug and strength in inventory and placed in any of the scores of outpatient treatment areas. This inventory is not managed as part of a perpetual inventory system. Once dispensed to the treatment area as floor stock or in unit-based cabinets, it is impossible to tell which manufacturer's drug is dispensed to which patient. Furthermore, in some cases, we actually repackage medications in pre-filled unit doses. In this case the manufacturer's barcode is not currently replicated and included on the new hospital packaging.

Because there are no currently available automated technology systems in place, or even designed as yet, to accommodate these regulations, the only alternative would be to regress to a contrived manual paperwork system. This would require the health care professionals treating the patient to manually record the drug's NDC being administered. Besides transcription errors and additional audits

to make sure the drug dispensed corresponds to the NDC manually entered, UMMC will also face a cadre of process issues on how to collect, reconcile, and record these manual transcriptions. This would have to occur at the same time the hospital is currently implementing CPMOE or Computerized Physician Medication Order Entry in the hospital to eliminate paper processing and more safely and accurately communicate the patient medication order.

Finally, from an administrative viewpoint, not all unit-dose medications are bar coded from the manufacturer. The FDA has in fact loosened the requirement for single or unit-dose bar coding. Therefore, any automated solution in the future would require the hospital to barcode these drugs with manufacturer-specific bar codes before deploying these to the outpatient treatment areas. UMMC is considering the future implementation of bedside scanning of medications, but this potential implementation is not currently budgeted or projected for the next 3-5 years.

We respectfully request that the concerns raised in this letter be given serious consideration as the proposed regulations are revisited during this open comment period.

Sincerely,

Marc Summerfield  
Director of Pharmacy Services  
University of Maryland Medical Center

**CMS-2238-P-1065**

**Submitter :** Mrs. Karol Heidbreder

**Date:** 02/19/2007

**Organization :** Addison Pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

My husband and I own Addison Pharmacy in Addison, Michigan. The proposed legislation in its current form would have a tremendously damaging effect on our business and the customers we serve.

It's crucial that the definition of AMP include and reflect prices that retail pharmacies like ours have access to. It must not include rebates and discounts that PBM's and mail order pharmacies receive because these are NOT available to us.

Pharmacies like ours throughout the U.S. have been financially hammered by the Medicare D program over the past year. To ask us to bear the brunt of Medicaid cuts and reimburse us at levels of 36% below our acquisition cost would effectively put us out of business.

Dispensing fees have not kept up with inflation over the past 30 years. Fairness dictates that professionals like us be properly reimbursed for the important services we provide. The current proposed AMP would not result in proper reimbursement and must be changed.

Sincerely,

Karol Heidbreder  
Addison Pharmacy

CMS-2238-P-1066

**Submitter :** Mr. JAMES MARMAR  
**Organization :** WOODSTOCK PHARMACY  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

Background  
see the attached document

**GENERAL**

GENERAL  
My letter is in the form of an attachment

CMS-2238-P-1066-Attach-1.DOC

CMS-2238-P-1066-Attach-2.PDF

CMS-2238-P-1066-Attach-3.DOC

#1066#1

**MODEL COMMENTS FOR "INVOLVED" MEMBERS**

go to : <http://www.cms.hhs.gov/eRulemaking/>

choose Submit electronic comments on CMS regulations with an open comment period

choose CMS-2238-P

March 3, 2007

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

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

I am pleased to 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. [REDACTED] We are a major provider of pharmacy services in [REDACTED] and your consideration of these comments is [REDACTED]

- 1. Remove PBM and Mail Order from Retail Class of Trade**
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
- 2. Implement a Trigger Mechanism**
  - (i) Addresses severe price fluctuations
  - (ii) Reduces risk of Market Manipulation
  - (iii) Mitigates Risk of Pricing Lag
- 3. Use of 11-Digit NDC versus 9-Digit NDC**
  - (i) Represents the most common package size dispensed by retail pharmacies

I support the more extensive comments that are being filed by [REDACTED] regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Pharmacist name

cc. Members of Congress (individualize)

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

# 10 67.

March 3, 2007

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

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

I am pleased to 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 in Wichita, Kansas. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

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

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

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent.

**3. Removal of Medicaid Data**

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that 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**

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

**Submitter :** Mr. Elliot Lekawa  
**Organization :** Mr. Elliot Lekawa  
**Category :** Health Care Professional or Association

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1067-Attach-1.DOC

March 3, 2007

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

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

I am pleased to 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 in Wichita, Kansas. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

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

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

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent.

**3. Removal of Medicaid Data**

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that 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**

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

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

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

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

Sincerely,

Elliot Lekawa

**Submitter :**

**Date:** 02/19/2007

**Organization :**

**Category :** Other Practitioner

**Issue Areas/Comments**

GENERAL

GENERAL

See Attachment

CMS-2238-P-1068-Attach-1.DOC

March 3, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a work for a pharmacy located Cary, North Carolina as a pharmacy student intern. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

**1. Remove PBM and Mail Order from Retail Class of Trade**

- (i) Creates consistency in the Regulation
- (ii) Conforms definition with market reality

**2. Implement a Trigger Mechanism**

- (i) Addresses severe price fluctuations
- (ii) Reduces risk of Market Manipulation
- (iii) Mitigates Risk of Pricing Lag

**3. Use of 11-Digit NDC versus 9-Digit NDC**

- (i) Represents the most common package size dispensed by retail pharmacies

I support the more extensive comments that are being filed by the North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Dana R Fasanella, CPhT  
Doctor of Pharmacy Candidate  
Campbell University School of Pharmacy

**Submitter :** Mr. Chip Cather  
**Organization :** Brewster Family Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

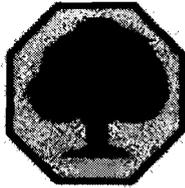
**GENERAL**

GENERAL

See attachment

CMS-2238-P-1069-Attach-1.DOC

CMS-2238-P-1069-Attach-2.DOC



**BREWSTER FAMILY PHARMACY**

360 N. Wabash  
Brewster, Oh 44613  
Phone: 330-767-3436  
Fax: 330-767-3090

March 3, 2007

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

To Whom It May Concern:

I am writing to provide my comments regarding the proposed rule CMS-2238-P.

Firstly, I would like to comment in regards to the determination of average manufacturer price section 447.504 locate on page 77177 of the proposed rule. It states average manufacturer price (AMP) is the price paid by a wholesaler to a manufacturer for a drug that is distributed to retail pharmacy class of trade. I was wondering why a reimbursement paid to a retail pharmacy is determined by what a third party, wholesaler, pays for a drug and not what a pharmacy pays? Just like with everything that is bought and sold in the United States every middleman increases the price of a product in order to make a profit. Therefore, wholesalers increase the price they paid for a drug in order to make a profit from the distribution. From a retail pharmacy perspective we should be reimbursed based on what we would pay for a drug and not what someone else paid for the drug. Even though there is a 250% increase in AMP this still does not offset the calculation fairly for everyone. Ultimately you are creating a bias for larger retail pharmacies. As a small independent pharmacy we do not have access to purchase directly from a manufacturer like other larger retail pharmacies. So if a pharmacy is capable of purchasing directly from a manufacturer then their reimbursement would be AMP x 250%. However, for smaller independent pharmacies we buy from a wholesaler, who adds a percentage on the cost of a drug so they can make money, which in turns leaves our reimbursement at AMP x 250% minus a percentage the wholesaler adds to drug cost. This may not be the case for every single drug, but for those that it does affect you leave small businesses at a direct disadvantage. The rule should be written to allow all pharmacy businesses equal reimbursement. To me the only way to offer equal reimbursement is to base reimbursement on average wholesaler price or average price per unit a pharmacy pays for a prescription drug.

Regarding the section, definition of retail pharmacy class of trade and determination of AMP on page 77178 of proposed rule I would like to make the following comments. I would like to agree with the statement presented that mail order pharmacies should also be excluded from AMP calculations. Mail order pharmacies are given different buying abilities in regards to the price they pay for drugs that independent and chain pharmacies are not given thereby placing them in a similar group as long term care pharmacies. For mail order pharmacies to be included in AMP calculations then the definition should only include drugs that all parties receive equal manufacturer concessions. With the stated argument that removal of mail order pharmacy, long term care pharmacy and PBM prices would not be consistent with past policy and could increase drug manufacturer rebate liabilities, who interest is this looking out for? Would it not be possible for manufacturers to alter the way rebates are offered so as not to increase their liability? If this rule is looked at reducing the cost on government agencies for drugs shouldn't the cost sharing be divided out proportionately across all players in the drug distribution system and not just on retail pharmacies. Retail pharmacies have had to deal with changes in past policies and it would not hurt for other parties to deal with changes too. Also I would like to comment on the use of general public in the definition of retail pharmacy class of trade. How can those patients

mandated to only use mail order pharmacies be considered general public? In my opinion they are no different than those patients in a nursing that all receive their medications from the same pharmacy. Retail pharmacy class of trade should only include those pharmacies that have an equal opportunity to serve the same patient population which in my opinion is only independent or chain pharmacies.

Also in the section titled, definition of retail pharmacy class of trade and determination of AMP on page 77178 of proposed rule I would like to comment on the inclusion of PBM rebates in AMP calculations. The real question is why should rebates a PBM receive affect what a pharmacy is reimbursed? A PBM does not literally buy drugs from a wholesaler or manufacturer so there is no reason that a PBM rebates should affect AMP calculations. No one except the PBM knows what happens to those rebates and I am sure they are not going to tell anyone especially since it is not mandated. I will tell you for sure that those rebates do not come to the pharmacies that actually buy the drugs so there is no way they affect what a pharmacy pays for drugs and therefore should not affect AMP. It is just outright preposterous for anyone to suggest this especially anyone that has any business experience. Lets me try and put it this way, say you are an employee of a business who reimburses you per gallon of gas used for work. You buy gas at \$2.35 a gallon which is the cheapest you can buy. Your employer gets a rebate of 5 cents per gallon of gas used from a certain gas company. Since your employer gets the rebate it is determined you, the employee, should only be reimbursed say \$2.29 a gallon. Do you think that you, the employee, is going think this is fair and a reasonable business practice? I would be willing to bet you wouldn't. So why is a rule going to be proposed to cheat businesses out of money that someone else is getting paid. Rebates paid to PBMs should in no way be included in AMP calculations. These comments also apply in regards to the rebates paid to PDPs being included in AMP calculations. To me and I am sure other people, this rule looks to allow insurers collect more money while only being required to pay out less, essentially putting more money into their hands. In other words someone is willing to take money from one person, pharmacies, and let others, PBMs and PDPs, collect more money without being required to share in the burden of cutting costs to healthcare expenditures. Only price concessions or rebates made directly to a pharmacy should affect the reimbursement paid to such pharmacy. By including these rebates in AMP it is artificially deflating the price a pharmacy pays for drugs.

In section 447.514 titled, Upper Limits for Multiple Source Drugs, I would like to comment on the decision not to use a drugs 11 digit NDC to calculate AMP. I would agree with the comments made that using 11 digit NDCs would allow for greater transparency and would not make calculating AMP more difficult. This would allow for proper reimbursement based on the package size a pharmacy is using allowing a pharmacy to cover the cost of a drug. Also this would prevent over reimbursement that could occur using only a 9 digit NDC. By not using the 11 digit NDC to calculate AMP this will ultimately provide a price advantage to larger pharmacies which in turn will lead to the creation of a monopoly market for large pharmacies. Smaller independent pharmacies will not be able to compete with larger pharmacies who buy drugs at larger quantities at a lower price per tablet. Creating a pricing structure that provides an advantage to larger pharmacies and an inability for other pharmacies to compete is going against laws that prevent the creation of monopolies. Here is actually pricing information in regards to Lisinopril 10mg as our pharmacy could purchase. A 100 tablet bottle of Lisinopril 10mg would cost \$4.81 which is 4.81 cents per tablet. While a 1000 tablet bottle of Lisinopril 10mg would cost \$34.88 or 3.49 cents per tablet. With larger pharmacies more than likely purchasing a 1000 tablet bottle this offers them a 1.32 cents advantage per tablet than pharmacies purchasing a 100 tablet bottle. With the average prescription being for 30 tablets, a month supply, this is roughly a 40 cent advantage per prescription for a larger pharmacy. Say a large pharmacy does 500 prescriptions a day this would equal close to \$200 a day of increased profit for a larger pharmacy as compared to a smaller pharmacy that would purchase a 100 tablet bottle. However, by using an 11 digit NDC this would level the playing field for pharmacies allowing for proper reimbursement for their cost of goods while eliminating over reimbursement on per tablet basis.

As for as the following statement that was made in the proposed rule in the same section 447.514, "Furthermore, we expect that because the AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent it does have an impact, it would encourage pharmacies to buy the most economical package size", I would like to make some comments. It is possible that with AMP marked up 250 percent that it may reimburse a pharmacy for the drug, but as the GAO (Government Accountability Office) report has shown AMP reimbursement would be on average 36% less than a pharmacy's acquisition cost for a drug. However, we will assume by chance that AMP reimbursement does cover the cost of a drug. Using the cost figures for Lisinopril 10mg that were presented above, if reimbursement covers the cost for a 100 tablet bottle this reiterates my comments on providing an advantage to larger pharmacies by only using a 9 digit NDC for AMP calculations. As far as encouraging pharmacies to purchase the most economical package size, the rule is only considering the economical standpoint or reimbursement and not the economical standpoint of a pharmacy's overhead cost. Once again let us take into consideration the cost figures for Lisinopril 10mg as stated above. If a smaller pharmacy only dispenses a limited quantity of Lisinopril 10mg and thereby purchases only 100 count bottles in order to prevent a large overhead and their money being tied up in product that might take months to actually dispense. They could be punished for this if AMP only uses a 9 digit NDC for AMP calculations. So now this pharmacy would have to purchase a 1000 tablet bottle of Lisinopril 10mg, the more economical package size according to the rule, so as to cover the cost of the drug which will tie up roughly \$30 more in product that the pharmacy now can not use to pay their bills, payroll or rent. Take into consideration that a pharmacy needs to carry hundreds to thousand of drugs on their shelf in order to properly run a pharmacy and serve their patients. Purchasing larger package sizes, in order to purchase the more economical package size, so that a pharmacy can make money on a drug will result large overhead and the inability of a pharmacy to pay their bills with more money tied up in product. I am sure anyone with business knowledge will understand what happens to business with larger overhead and a lack of money to pay bills, it is called going out of business.

I have alluded to the potential impact on small independent pharmacies through my previous and I would like to further comment on the impact this rule will have on small pharmacies. Throughout the proposed rule document there are many comments on the impact to pharmacies. "We believe that these legislatively mandated section 6001 savings will potentially have a "significant impact" on small, independent pharmacies." "However, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries." "We estimate that 18,000 small retail pharmacies would be affected by this regulation." These comments should demonstrate some HUGE red flags regarding the potential impact this rule will have to pharmacies and patients served by these pharmacies. We all have seen how the Medicare Part D affected pharmacies and patients. We should learn something from the past and not jump into things without being able to quantitatively define the impact a rule will have on pharmacies and patients. This rule has the potential to significantly impact 18,000 small retail pharmacies that may be forced out of business due to low reimbursement. Let us say that these 18,000 pharmacies employ at least 4 employees that equals at least 72,000 employees that may not have a job after this rule is in effect. Everyone is concerned about improving unemployment, but a rule is proposed that could put 72,000 or more people without a job. All because we did not take the time to quantitatively define the impact on pharmacies. Also let us not forget about the patient these pharmacies serve. Assume these 18,000 pharmacies serve smaller towns with on average 2,000 people. That is 36 million patients that could be forced to find another pharmacy to provide them service and those pharmacies might be farther away or more difficult to access. Who is looking out for the patients? Yes pharmacies look to make a profit like any other business, but we are mainly there for the sole purpose of providing quality medical care to patients. Proposing a rule without fully understanding the impact it will have on pharmacies and patients is like playing Russian roulette. You are pulling the trigger not knowing what will happen and will deal with the consequences later. Well one consequence is suicide and after that there is not much one can do. So delay to implementation of rule until it can be determined what the true quantitative impact the rule will have on all parties involved.

There are two sentences, in the section on Effects on Retail Pharmacies on page 77192 of the proposed rule, that greatly irritate me. It is blatantly stated that pharmacies will incur revenue losses on prescription medications with this rule and no one cares. There should never be a rule proposed or passed that will force any business to take a loss on product period. A rule like this forces people out business and prevents people entering a business. It prevents the viability of a business and prevents people from making a living. However, to prevent these losses it is assumed that the business can sell other goods to offset the loss in revenue. I quote, "First, almost all of these stores sell goods other than prescriptions drugs, and overall sales average more than twice as much as prescription drugs sales." First, almost all stores sell other goods other than prescriptions drugs? So the stores that do not sell other goods they are just out of luck I guess. We are in a business to primarily sell prescription goods and not sell everything under sun. We should not be forced to take a loss on our primary business and forced to sell other goods. How does that look to patients when your pharmacist pitches to you about that new item you should not live without "As seen on TV" in order to make up for the loss they are taking on the prescription you just picked up? Also pharmacist look to improve a patients health not make it worse by selling them other goods, like cigarettes, to make up for the loss on prescription medications. I would begin to think patients would not respect their pharmacist as a medical professional if we are forced into this type of business. So how dare a rule look to diminish our profession that we work so hard to achieve. As far as the sale of other goods accounting for more than twice as much as prescription drugs, I do not think this is the case for all pharmacies. Those sales figures might be correct if you are looking at total sales of a store in which the pharmacy is located in a grocery store. Some pharmacies are actually just a pharmacy and are not selling you groceries or a plasma screen TV at the same time. Speaking on the sales of our pharmacy, prescription sales accounted for 90% of our total sales for the 2006 year. Now there is now way that our sales of other goods would offset the revenue loss that would occur using AMP. Our pharmacy is in the business of providing quality care with a focus on health care needs and not selling everything under the sun.

Secondly, in the next sentence it is stated that pharmacies can mitigate the proposed rule by changing purchasing practices. Sure pharmacies can changes their purchasing practices, but it would just force small pharmacies to assume more overhead and further place a strain on cash flow. I do not see how assuming more overhead will mitigate this proposed rule. I have demonstrated how this rule will produce more overhead for smaller pharmacies in previous statements. Also, can it truly be stated that pharmacies can mitigate the proposed rule by changing purchasing practices when no one really knows the impact it will have on a pharmacy? How can you present a possible solution to a problem if you do not even know what the problem will be or how big it will be? There are many players in the whole health care system that play a role in providing a prescription medication. It should not be the entire responsibility of pharmacies to mitigate the cost of decreasing expenditures on prescription medications. Manufacturers are not being forced to mitigate any costs or burdens. Anything that was deemed to effect manufacturers negatively in this proposed rule was abandoned, including the use of an 11 digit NDC and anything that would alter a manufacturer's rebates. All parties involved in the production to dispensing of a prescription medication should share proportionately in the cost sharing involved in reducing medical expenditures.

In section 447.504 Determination of AMP, I think there needs to be more clarification of the following statement; Manufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail pharmacy class of trade. There are many types of coupons and many different requirements for the redemption of these coupons so it should more clearly defined. Pharmacies receive coupons from patients that require electronic redemption from the pharmacy that will reduce a patient's copay by the defined amount. Will these coupons be included in the determination of AMP? Also pharmacies receive coupons that require the pharmacy to reduce a patient's copay by a defined amount, but then to mail the coupons in for redemption. Will these coupons be used in the determination of AMP? I feel that both of these coupon examples should not be used in the determination of AMP. These coupons do not alter the actual cost of a medication they are just reducing a patient's copay so as to allow a patient to receive a medication they can not afford or may not tolerate. I feel that the inclusion of manufacturer's coupons should be more clearly defined or removed all together.

March 3, 2007

I hope you will take these comments into consideration and make necessary changes to the proposed rule. This rule will drastically affect the pharmacy profession. It will force pharmacies to close, employees to look for other jobs and diminish quality care to patients. This rule was supposedly proposed in order to cut costs, but only to shift that cost to others, mainly pharmacies. More time should be taken to actually define the effects the rule will have on small retail pharmacies, which are at the greatest risk.

Thank you

Sincerely,

Chip Cather  
RPh, PharmD, manager  
Brewster Family Pharmacy  
360 N Wabash  
Brewster, OH 44613

**Submitter :** Mr. Thomas Hawkins  
**Organization :** Boone Drug & Healthcare  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

Background

February 18, 2007

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

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

I am pleased to 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(s) is located in Boone, NC. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Remove PBM and Mail Order from Retail Class of Trade
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
2. Implement a Trigger Mechanism
  - (i) Addresses severe price fluctuations
  - (ii) Reduces risk of Market Manipulation
  - (iii) Mitigates Risk of Pricing Lag
3. Use of 11-Digit NDC versus 9-Digit NDC
  - (i) Represents the most common package size dispensed by retail pharmacies

I support the more extensive comments that are being filed by the North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Thomas E. Hawkins, RPh

cc. Members of Congress (Virginia Foxx)

**Submitter :** Mr. Patrick Dorian

**Date:** 02/19/2007

**Organization :** Mr. Patrick Dorian

**Category :** Pharmacist

**Issue Areas/Comments**

**Background**

**Background**

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

**Submitter :** Ms. Amy George

**Date:** 02/19/2007

**Organization :** Ms. Amy George

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I feel that CMS should not be reformed. A pharmacy should not be reimbursed less than what it paid for medication. That is not right nor fair. Doing so would surely put smaller pharmacies out of business. As a pharmacy student I can not see how decreasing reimbursement would benefit me or the thousands of other soon to be pharmacists. Why should pharmacies have to find ways to make money and by raising patients and punishing other patient that do not have government insurance. Another way to get medicaid and medicare undercontrol needs to be formulated.

**Submitter :** Dr. Joseph Collins  
**Organization :** Woodys Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

CMS-medicare/medicaid service is considering lowering reimbursement for prescription drugs to 36% below a pharmacy's actual acquisition cost. We cannot stay in business with reimbursements that low. Service to Medicare and Medicaid recipients will suffer. Pharmacy already has some of the lowest profit margins in retail businesses in America.

I oppose the up coming CMS rule change for AMP pricing that will result in reimbursement rates 36% below acquisition costs and urge higher reimbursement rates for pharmacies.

Sincerely

Joseph J Collins  
PharmD

Woodys Pharmacy  
408 south Broad Street  
New Tazewell, TN 37825

**Submitter :** Miss. Merritt Phelps  
**Organization :** Miss. Merritt Phelps  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Dr. Heather Christensen  
**Organization :** Meijer Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

**Background**

I am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer's price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Greenville, MI. Meijer Pharmacy is a major provider of pharmacy services in the community and your consideration of these comments is essential.

**Collection of Information Requirements**

**Collection of Information Requirements**

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

CMS should exclude pharmacy benefits managers (PBMs) and mail order pharmacies from the definition of retail pharmacy class of trade. PBMs and mail order pharmacies are not community pharmacies, which is where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the general public. The definition of retail pharmacy class of trade should include independent pharmacies, independent pharmacy franchises, independent chains, chain pharmacies, mass merchandisers and supermarket pharmacies.

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

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. Nursing home pharmacies, PBMs and mail order pharmacies receive discounts, rebates, and price concessions that are not available to the community retail pharmacies, making them a fundamentally different class of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacy for medications. Including these elements is counter to Congressional intent.

**3. Removal of Medicaid Data**

Including Medicaid data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. Medicaid, like the PBMs, does not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Inclusion of Medicaid data would have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs and, therefore, be excluded from AMP calculations in the proposed regulation.

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

Reporting of AMP data by the manufacturers on a quarterly basis versus a monthly or weekly basis does not address the issue of price fluctuations when they occur. CMS needs to address this concern and create an exceptions and appeals process, similar to Medicare Part D, which would allow any provider, including a pharmacy, a mechanism to request a redetermination process for a FUL. The redetermination process should include a toll-free number that would be monitored by CMS and include a specific timeframe in which the redetermination process must occur and a procedure by which a redetermined FUL would be updated. This process would mitigate the risk of pricing lag and create a fair reimbursement mechanism for community pharmacy that is timely.

**5. Use of 11-Digit NDC Versus Nine-Digit NDC**

We believe that CMS should use the 11-digit NDC in the calculation of AMP since this is package size most commonly dispensed by retail pharmacies. The prices used to set the FUL should be based on the most common package size dispensed by retail pharmacies, not quantity sizes that would not be purchased routinely by a community pharmacy. 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.

**GENERAL**

**GENERAL**

I appreciate your consideration of these comments and support the more extensive comments that are being filed by the Michigan Pharmacists Association regarding this proposed regulation. Please feel free to contact me with any questions.

Sincerely,  
 Heather Christensen, PharmD

**Submitter :** Connie Connolly  
**Organization :** Connie Connolly  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

February 19, 2007

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

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

I am pleased to 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 in Maquoketa Iowa. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Remove PBM and Mail Order from Retail Class of Trade
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
2. Implement a Trigger Mechanism
  - (i) Addresses severe price fluctuations
  - (ii) Reduces risk of Market Manipulation
  - (iii) Mitigates Risk of Pricing Lag
3. Use of 11-Digit NDC versus 9-Digit NDC
  - (i) Represents the most common package size dispensed by retail pharmacies

I support the more extensive comments that are being filed by Iowa Pharmacy Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Connie J. Connolly RPh

cc. Senators Grassley and Harkins, Representative (Braley)

**Submitter :** Dr. Tripp York  
**Organization :** Dr. Tripp York  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1077-Attach-1.DOC

February 19, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of Walgreens, a community retail pharmacy located at 826 North Main Street, Shelbyville, TN, 37160. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

### **3. Removal of Medicaid Data**

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

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

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

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

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

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

Sincerely,

Tripp York  
156 Maupin Circle  
Shelbyville, TN  
37160

cc: Senator Lamar Alexander  
Senator Bob Corker  
Representative Bart Gordon

**Submitter :** Dr. Greta Goldshtein  
**Organization :** Roxbury Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

As community pharmacists, we are continuously struggling to provide quality patient care in an environment of ever-shrinking reimbursements. Plans are often not even covering the cost of the medication dispensed, let alone the cost of the vial, label, man-power, rent, and other overhead costs! Never mind any return on our investment into our business! Patients are being forced into impersonal mail-order situations, but they continue to rely on the neighborhood pharmacist for the quality patient information they have always obtained from us. AND we are asked to provide this valuable service free of charge.

We deserve to have the cost of our operations covered by the insurance companies that we work with, PLUS a professional fee. Instead, we face ever-shrinking reimbursements, under one guise or another.

This is one more attempt to cut the reimbursement to the pharmacist, further jeopardizing our ability to provide patient care.

**Submitter :** Mark Kinney  
**Organization :** Independent Pharmacy Cooperative  
**Category :** Health Care Professional or Association

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

Background

February 19, 2007

VIA ELECTRONIC SUBMISSION

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

CMS file code: CMS 2238 P

Federal Register  
Publication Date: December 22, 2006

Re: Prescription Drugs

Dear Acting Administrator Norwalk:

Thank you for the opportunity to comment on the proposed regulations governing the definition of retail class of trade and determination of AMP. The Independent Pharmacy Cooperative (IPC) represents the interests of pharmacist owners, managers, and employees of more than 3200 independent community pharmacies across the country.

The Reason for Ensuring that AMP be an Accurate Reflection of Retail Pharmacy Acquisition Cost

The Average Manufacturers Price (AMP) and the resulting Federal Upper Limit (FUL) impacts not only government Medicaid programs, but now has the far reaching effect of substantially impacting the entire private marketplace as well. Therefore it is essential that the FUL represents an accurate determination of pharmacy s actual acquisition cost. Former CMS administrator McClellan already backed away from posting incorrect AMP data, stating, "They just aren't the right numbers to use&We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement.

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1079-Attach-1.DOC

## 1. Rationale Against CMS Redefining Average Manufacturer Price to Lowest Manufacturer Price

In light of a recent Government Accountability Office (GAO) report (*GAO-07-239 Medicaid Federal Upper Limits, December 22, 2006, hereinafter "GAO report"*), it appears that CMS' initial determination at a proper FUL, based on its newly proposed definition of AMP, falls significantly short of an accurate mark. In that report, dated December 22, 2006 the GAO issued a strong rebuttal to CMS's contention that retail pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure.

The GAO report found that on average, FUL, defined as a ceiling of 250% of the proposed lowest AMP for the drug, was still on average 36% below the acquisition cost to pharmacies. CMS notes that rebates were not included in the GAO analysis. However, where independent pharmacies do receive rebates, the amount would not off set this significant short fall.

Most importantly, the issue of generic drug availability makes the CMS defined Lowest Manufacturers Price unworkable. As smaller generic manufacturers seek to capture market share (many from outside the United States, i.e., India) they would be willing to enter the market with a discounted price of 20-30% in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity.** These small generic manufacturers, (and the larger manufacturers as well) do not have the capacity to provide more than just a percentage of the Medicaid population's utilization. This effectively would require many pharmacies to acquire the product at a cost that is significantly higher than the LMP. To mitigate this outcome is the reason the statute defines manufacturer's price as the average. We would ask CMS to apply the plain meaning of the statute and utilize Average Manufacturer Price in their calculation.

It is also foreseeable that this process will stimulate more frequent generic conversions. The multiplicity of dosage shapes and sizes used for a single patient may contribute to a higher potential for medication misadventures, reduced patient confidence and compliance.

## 2. Retail Pharmacy Class of Trade Definition

IPC requests that CMS change its proposed definition of "retail pharmacy class of trade", proposed 42 CFR Sec. 447.504(e) at p. 130 as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, and traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy. This definition currently encompasses over 55,000 retail pharmacy locations.

In passing the DRA, Congress also gave CMS the authority to create a workable definition of AMP.

IPC requests that CMS adjust its proposed definition of AMP, 44 CFR Sec. 447.504 (a) as follows:

(a) AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the federal Food, Drug, and Cosmetic Act) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include retail pharmacy sales only (chain and independent); volume discounts related to retail pharmacies; AMPs for authorized generics; charge-backs to the extent paid to retail pharmacies; contingent free goods; and only adjustments that reduce the actual price paid by retail pharmacy.

IPC recommends that the following elements, which retail community pharmacy does not receive, be excluded from the calculation of AMP:

- Discounts, rebates and price concessions to PBMs/Mail Order
- State supplemental, state only and SPAP prices
- FFS/depot
- Non-contingent free goods
- Price adjustments that do not affect the actual price paid by retail pharmacy

### **3. The Rational Against Inclusion of PBM Price Concessions and Mail Order Rebates in the Definition of “Retail Class of Trade”**

The Omnibus Reconciliation Act of 1990 through amended Section 1927 of the Social Security Act (the Act), created the Medicaid Drug Rebate Program. The rebate legislation became effective on January 1, 1991. **CMS has indicated that the program affords state Medicaid programs the opportunity to pay for drugs at discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers.** The rebate agreement attaches to sole-source drugs (new, under patent with no generic equivalents); and innovator multiple-source drugs (drugs that have new-drug FDA approval for which generic equivalents exist). **The rebate also includes non-innovator multiple-source generic drugs at 11%.** The purpose of the rebate for both brand name and generic medications is, and has been since its inception in 1991, to ensure that the government is buying in the marketplace like other large private purchasers. The proposed rule would result in the government “double dipping” by realizing the cost benefit on the front-end reimbursement to pharmacies and the back-end manufacturer rebate.

**The PBM/mail order pharmacy business model today is so closely interrelated that the ability to distinguish between price concessions, discounts, rebates and fees of the two entities would likely be impossible.**

Mail order pharmacies are frequently owned and/or operated in the HMO and “closed model” systems that are not available to the general public.

In addition, due to the transient nature of the Medicaid population, the mail order pharmacy model has not been found to drive savings and therefore has not been adopted by almost the entirety of state Medicaid programs. Since mail order pharmacies do not service this population, they should not be included in the definition of “retail class of trade”.

IPC would recommend that PBM/Mail Order price concessions, discounts, rebates and fees not be included in the “retail class of trade” definition.

#### **4. CMS is Setting an Unrealistic Threshold for Outlier Prices in the FUL Calculation**

CMS proposes to set the FUL based on the lowest AMP, as long as that AMP is not more than 70 percent below the second lowest AMP for that drug.

It is particularly harmful to set an exclusion of outliers at an AMP that is so much less (70%) than the next lowest AMP. A reasonable outlier exclusion would be no more than 20%.

#### **5. According to the CBO, CMS’s Costs Savings Assume that States will Increase Dispensing Fees. If the States do not do so, then Pharmacy Reimbursements will be so Inadequate that Most Pharmacies will not be able to Participate in the Medicaid Program.**

*From Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932 Deficit Reduction Act of 2005 Conference agreement, as amended and passed by the Senate on December 21, 2005:*

Based on administrative data on AMPs and prescription drug spending by Medicaid, CBO estimates that those provisions would reduce Medicaid spending by \$3.6 billion over the 2006-2010 period and \$11.8 billion over the 2006-2015 period. **Those savings reflect CBO's expectation that states will raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid.** The estimate also accounts for lower rebates from drug manufacturers resulting from increased use of cheaper generic drugs.

CBO does not reveal to what degree it “expects” states to raise dispensing fees when it calculates its numbers. A study recently completed by one of the four largest world-wide accounting firms, Grant Thornton, has found that the average cost to dispense in the nation was \$10.50. As the current average dispensing fee among the states is only \$4.50, states will be highly challenged to provide an adequate reimbursement to pharmacies, consistent with the documented cost.

**6. Definition of “Dispensing Fee” needs to be Inclusive of the True Costs to Pharmacists/Pharmacies to Dispense Medicaid Drugs.**

An adequate Dispensing Fee definition includes the true costs of: 1) valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling: communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and 2) other real costs such as rent, utilities and mortgage payments. Perhaps most importantly, pharmacies provide important health, safety and counseling services 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 outcome for the patient.

IPC accordingly recommends that the dispensing fee definition section of the final rule be written as follows:

**42 CFR Sec. 447.502 Definitions.**

Dispensing fee means the fee which:

Includes pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient.

Pharmacy costs include, but are not limited to any reasonable costs associated with:

Staffing costs: (a) salaries for pharmacists and technicians, and compensation to other employees such as managers and cashiers; (b) Licensure/continuing education for pharmacists and technicians.

Store operations and overhead: (a) rent or mortgage; (b) Cleaning, repairs, and security; (c) Utilities; (d) Computer systems, software ,and maintenance; (e) Marketing and advertising; (f) Accounting, legal and professional fees; (g) Insurance, taxes, and licenses; (h) Interest paid on pharmacy-related debt; (i) Depreciation; (j) Complying with federal and state regulations; and (k) Corporate overhead.

Preparing and dispensing prescriptions: (a) prescription dispensing materials (packages, labels, pill counters, etc.); (b) compounding the Rx when necessary; (c) special packaging (unit dose, blister packs, bingo cards) and special supplies (syringes, inhalers).

Assuring appropriate use of medication: (a) drug use review; (b) consumer/patient counseling; (c) consulting with prescribers, (d) disease management, and (e) education/training.

Adjustment for medical inflation.

A reasonable profit margin to ensure business viability.

## **7. IPC Supports the use of NDC 11-Digit Codes for Reimbursement Purposes**

CMS states that the National Drug Code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For the purpose of this subpart, it would mean the 11-digit code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code) (p. 19). Identifying package size for reimbursement purposes should lead to a more accurate measurement of acquisition costs – i.e. the cost to pharmacy to purchase the medications.

Pharmacies already maximize product buying decisions. For example, an independent pharmacy would like to buy drugs in 1000-count package sizes in order to take advantage of the economies of scale that exist with the larger package size. However, that medication may be used infrequently. A pharmacist that bought the 1000-count size for such a medication might have to destroy significant amounts of unsold medications. In these situations, switching to an 11-digit NDC would fairly reflect the efficient purchasing of pharmacies.

## **8. IPC Advocates “Smoothing” of AMP Data**

There are frequent, sudden changes in drug prices that are not accurately captured by the currently contemplated reporting period. Indeed, prices change on a daily basis, reflecting market place availability and the number of manufacturers supplying the product in question.

Under monthly pricing, 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. Invoicing to community pharmacy, however, continues to change daily.

Since frequent changes in drug prices and corresponding changes in AMP could negatively impact community pharmacists. Purchase prices could turn out to be significantly higher than reimbursements that are received after purchase and filling of the prescription. To lessen this unfair outcome, “smoothing” of AMP data is necessary because failure to average out AMP pricing could result in significant fluctuations from month to month. IPC recommends that CMS develop a “smoothing” process for AMP.

Respectfully,

Mark Kinney, R.Ph.  
Vice President of Government Affairs  
Independent Pharmacy Cooperative

**Submitter :** Mr. George Warren  
**Organization :** Bay Pharmacy, Inc.  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

First Medicare Part D and now AMP as a boggus cost base for Medicaid payment. How much worst can it get!

I am a second generation pharmacist practicing in Florida. My father and I own and operate four pharmacies. Medicare Part D just forced me to close one of them and I fear the other three are not far behind.

Gross margins have dropped over 10% since January 2006 and will continue to drop should AMP regulations become reality.

Community pharmacists, like myself, perform many valued services to our client base. Patients forced into mail order programs still count on me to help them when medications are delayed in the mail. I could say no and make them wait without meds, however, compassion and responsibility are two of the biggest problems with today's managed care models.

Seven of my employees will loose their jobs on March 31st; I am sick over this. I am telling the world that Medicare Part D closed this pharmacy. Our government representatives need to understand the impact that their vote has.

Say NO to the use of AMP as the cost basis for Medicaid!

There are much better ways to produce cost savings in health care.

Could you maintain a business that looses money every transaction? The GAO report on AMP estimates that pharmacies will loose money on every transaction that uses AMP as a base for reimbursement.

You have created a monster here. Time to regroup and throughout AMP!

**Submitter :** Dr. Chester [Chet] Yee  
**Organization :** Menlo Park Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I am an independent pharmacy owner, and note that the formula for AMP will impact my processing prescriptions at the below y cost levels that AMP will impose. The average dispensing fee per prescription for my pharmacy is around \$11.00, because of the services that I provide my patients. To fill prescriptions for my patients, I need a fair and accurate cost of goods and an adequate dispensing fee. For many years I have allow the lower reimbursement I received for medicare/medicaid patients up to now. If the new AMP is implemented

I will lose money on every medicare/medicaid prescription I fill.

The formula for AMP-based Federal Upper Limits [FULs] in the proposed rule will not cover my pharmacy's actual acquisition costs for generics. To be appropriate, the AMP must be defined to reflect the actual cost paid by my retail pharmacy. this could be accomplished by

excluding all rebates and price concession made by manufacturers which are NOT avilable to retail pharmacies such as mine.

And also excluding all mail order facilities and PBM pricing from AMP

calculation. Mail order facilities and PBMx are extended special prices from drug manufacturers, which are not available to independently owned pharmacies.

**Submitter :** Spencer Smith  
**Organization :** Spencer Smith  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

Background

I've been a registered Pharmacist since 1992. I've run a pharmacy in a small town since 1994. I've had ownership in it since 1998. We opened a second pharmacy in 1995. It is yet to become profitable. I would like to purchase or open a couple more stores. As expected all this will be put on hold to the effects of this are seen.

**Collection of Information Requirements**

Collection of Information Requirements

This is concerning the provisions of the AMP pricing calculation.

**GENERAL**

GENERAL

It doesn't take a rocket scientist to figure this out. We're at the bottom of the chain to provide medicine to patients. We're operating on less than 5% profit. We read in the paper that all the PBM's are having record profits. They get rebates from manufactures. So do the states. They operate with profits in the 20% range. Why not cut the money from the PBM's who are making the most money in this situation? Why not get rid of them entirely? Why pay their CEO millions when that money could go to heathcare? It makes too much "cents" and the PBM's have the "cents" to keep the money going into their pockets and out of ours!

**Provisions of the Proposed Regulations**

Provisions of the Proposed Regulations

I don't fill that all the information has properly been collected and released from and to the people that this will impact the most.

**Regulatory Impact Analysis**

Regulatory Impact Analysis

Once again CMS is cutting reimbursement from the wrong people and providers.

**Response to Comments**

Response to Comments

I believe that many independent pharmacies will be forced to close. The ones likely to be closed are in the rural areas where I am. There will be many people who can't get there medicine w/o driving 20mins. Many people can't do this easily and will not take medicines that they need. This will then lead to more doctor visits and hospital stays. What pharmacies stay in business will have to operate with less help. This leads to more unemployment. This will also lead to more medical errors. This will all cost more than the money they save by reducing our reimbursement below our costs.

**Submitter :** Mrs. Mary Montenery  
**Organization :** The Medicine Shoppe Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. I understand the the payment I would receive for the drugs I buy would be far below what I actually pay for the drugs. If this becomes a reality, then it will not be possible for me to continue to fill prescriptions for Medicaid patients. Many of my patients are covered by Medicaid. Most of them are physically or mentally impaired or limited in some way. I have a full-time courier who delivers prescriptions to patients' homes free-of-charge. Most of these patients are on Medicaid. They are the most needy and most dependent of my customer base. The services I provide are not available from chain drug-stores or mail-order pharmacies. Small independent pharmacies, such as mine, draw customers by providing superior services at little or no additional charge to the patient. Our pharmacies will, of course, close if we cannot make at least a small profit. It will then fall upon the tax payors to provide these services at a much higher cost.

A proper definition of AMP is the first step towards fixing this problem. I ask that the AMP be defined so that it reflects what we actually pay for the drugs we sell. To do otherwise seems to be a conscious attempt to destroy our businesses. We work hard for very small profit margins and we deserve fair treatment.

**Submitter :** Mr. Scott Watts  
**Organization :** Mr. Scott Watts  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

I am pleased to submit my 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 in Juneau Alaska. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Remove PBM and Mail order from retail class of trade
2. Implement a trigger mechanism
3. Use of 11-Digit NDC versus 9-Digit NDC

I support the more extensive comments that are being filed by Alaska Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and as that you please contact us with any questions.

Sincerely,

Scott Watts R.Ph.

**Submitter :** Mr. GLENN STOKEM  
**Organization :** GLENN'S PHARMACY, INC.  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I own a independent pharmacy in a rural area of upstate New York. The formula for AMP will not cover my acquisition costs. AMP should not serve as a basis for reimbursement. AMP should exclude all manufacturer rebates not available to retail pharmacy and exclude mail order and PBM pricing as this pricing is not available to retail pharmacies. NY State has no intention of increasing prescription dispensing fees. The federal government should be encouraging generic drug dispensing not making it financially impossible to do. If this regulation goes into effect on July 1st we will have no choice but to pull out of the medicaid program. This will be a great hardship to the medicaid clients in our area will now have a 30 to 40 mile trip to the next nearest pharmacy. Washington should not be making it harder for people to get basic health care. This is a cold hearted regulation that will hurt many people in rural areas. Dropping out of the medicaid program is not a decision I am considering lightly. No business can remain viable by selling items below cost. This includes retail pharmacies. I feel that pharmacies should be encouraged to dispense generic drugs, not penalized for it. I realistic reimbursement level for generic drugs that encourages the dispensing of generic drugs will ultimately save the medicaid program money.

**Submitter :** John Skovmand

**Date:** 02/19/2007

**Organization :** John Skovmand

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-2238-P-1086-Attach-1.DOC

To: Leslie Norwalk  
Acting Administrator, CMS

AMP (Average Manufacturer Price) is intended to approximate the drug product cost component for Medicaid prescriptions dispensed. The proposed formula for calculating AMP is flawed because it includes discount pricing to mail order dispensaries and doctors, which is immaterial and irrelevant as neither of these classes of trade dispense medications under Medicaid. All Medicaid prescriptions are dispensed by community pharmacies, which do not have access to the special pricing given to these classes of trade. Additionally, rebates that are paid to pharmacy benefit managers are not available to community pharmacies. These discounts should be removed from the calculation of AMP.

RSP (Retail Survey Price), as currently proposed by CMS includes pricing from mail order and nursing home pharmacies which artificially and unjustly skew the price downward as noted above.

It is unreasonable to believe that the individual states will make up the difference between actual product cost and the artificially low reimbursement proposed by CMS by increasing the dispensing fee.

AMP attacks generic drug dispensing, the most cost effective way to treat many patients. If dispensing generics causes pharmacies to loose money, they will turn to more expensive name brand drugs, which will drive the Medicaid budget higher.

If pharmacies cannot cover their cost of doing business, they will stop filling Medicaid prescriptions. Where will those Medicaid patients go? They will go to hospitals and emergency rooms, which are much more costly alternatives, driving the Medicaid budget higher still.

My pharmacy's business is 20% Medicaid. If we loose 20% of our business because of unreasonably low reimbursement, some of my employees will be out of a job and onto welfare and Medicaid.

Pharmacies are already bearing the brunt of the Part-D burden through lower reimbursement rates. It is unreasonable to balance the Medicaid budget on the backs of pharmacies.

I urge CMS to redefine AMP and RSP, as described above, to more accurately approximate the cost of products dispensed to Medicaid patients, to provide a fair and just reimbursement to pharmacies for the care they provide to Medicaid patients.

Sincerely,  
John Skovmand, Pharmacist  
Seeber's United Drug  
110 W. Harvard Blvd, #H

Santa Paula, CA 93060

**Submitter :** Mrs. Peggy Harmon  
**Organization :** McLeskey-Todd Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

February 19, 2007

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

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

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

1. Remove PBM and Mail Order from Retail Class of Trade
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
2. Implement a Trigger Mechanism
  - (i) Addresses severe price fluctuations
  - (ii) Mitigates Risk of Pricing Lag
3. Use of 11-Digit NDC versus 9-Digit NDC
  - (i) Represents the most common package size dispensed by retail pharmacies

I support the more extensive comments that are being filed by the South Carolina Pharmacy Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,  
Peggy Harmon

Pharmacist name

cc. Members of Congress Gresham Barrett, Bob Inglis, Sen. Jim DeMint

**Submitter :** Mr. Lane Call  
**Organization :** Individual Practicing Pharmacist  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

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

ATTN Leslie Norwalk

Having owned a independent pharmacy for 40 years and at the end of that time saw then dim future for independent pharmacy. I was working harder to service may customers and receiving less because the Bigs ( Mail order, hospital outpatient, and outpatient clinics) could receive better price on their inventory. They made an un-level playing field just because they had consolidated there money and could throw weight to manufactures and receive a lower price. Government is promoting unfair competition.

Lane Call, Pharmacist  
Layton, Utah

**Submitter :** Dr. Kristi Miller  
**Organization :** TPA  
**Category :** Drug Industry

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Mr. JOHN BLACK  
**Organization :** Mr. JOHN BLACK  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

**Submitter :** Mr. Babulal Bhorania

**Date:** 02/19/2007

**Organization :** K & S Pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

See attachment

CMS-2238-P-1091-Attach-1.DOC

CMS File Code: CMS-2238-P  
Rule Title: Medicaid Program; Prescription Drugs  
Federal Register Publication Date: December 22, 2006

Dear Leslie Norwalk,

I am deeply concerned with the new act that is being proposed and would like to submit my strong opposition to it as a private Pharmacy owner. If this law is put into place it will be impossible for private Pharmacies, like my own, to survive. This law will cause us to lose money and force patients to turn to retail chains. Many patients who come to K & S Pharmacy are registered in the Medicaid drug program and therefore will impact my Pharmacy very negatively. I strongly urge the board not to support and implement this proposition. Thank you for your time.  
Sincerely,  
Babulal Bhorania

**Submitter :** Dr. RANDY ELLISON  
**Organization :** VALU-RITE PHARMACY  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Background**

**Background**

--I am a community pharmacist and owner with 36 years of experience in retail pharmacist.I have owned my own business(s) since 1980.I consider myself fairly well-informed on pharmacy matters and belong to several professional organizations.

I am commenting on this AMP issue because I think it is one of the most mis-guided "projects" that my profession has had to face in my 36 years of experience.The current plan will not work for many reasons.I am sure that by now,you have been informed of most of those reasons by our professional organizations.Please investigate the facts as they are being told to you by these organizations.First of all,AMP was never intended to be used a method of calculating payment to anyone.It does not "figure in " all the variables that occur in the pharmacy market place....i.e.,it doesn't include mail-order pharmacy prices in retail pharmacy class of trade,or include PBM rebates,discounts,etc. for drugs,treatment of manufacturer coupons,or several other pricing issues.

At this date,we don't have all the figures in for how badly retail pharmacy did in 2006 due to Medicare plan D and the continuing regression of reimbursement from PBMs,so I think it is too soon to be formulating any new "hits" on the retail pharmacy sector.

Please look at the recent GAO findings on how this ruling would effect retail pharmacy....it would be devastating!!There needs to be a fair and comprehensive study(and I think some are being done right now!) on what the actual "cost of dispensing" a prescription is.Take those findings and work with that to formulate a method that is fair for this profession that has served the general population so well.

Thanks for the opportunity to speak and please call on me to discuss this matter further....

Randy Ellison  
rellison@optilink.us  
Valu-Rite Pharmacy  
Dalton,Ga.  
ph.706-217-2700

**GENERAL**

**GENERAL**

--Please see the background section...that has my comments in it!!

**Submitter :** Karen Gallus  
**Organization :** Karen Gallus  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

February 19, 2007

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

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

I am submitting these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacist at Unity Community Pharmacist in Fridley, MN. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Remove PBM and Mail Order from Retail Class of Trade
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
2. Implement a Trigger Mechanism
  - (i) Addresses severe price fluctuations
  - (ii) Mitigates Risk of Pricing Lag
3. Use of 11-Digit NDC versus 9-Digit NDC
  - (i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely,

Karen Gallus Pharm.D.

**Submitter :** Dr. christian riffert  
**Organization :** The Beaverton Pharmacy  
**Category :** Pharmacist

**Date:** 02/19/2007

**Issue Areas/Comments**

**Collection of Information Requirements**

**Collection of Information Requirements**

A general summary is provided in this section on the debate about including nursing homes and mail order pharmacies in the calculation of AMP. Much of this debate is based on the "pharmacy industry believing that these pharmacies pay less for their drugs than do retail pharmacies, and thus inclusion of such prices would lower AMP below the price paid by such retail pharmacies." I commend your thoughtfulness regarding this subject and wish to further elaborate why this is. First, there is not a level playing field, pharmacies must operate independantly and are prevented BY LAW from organizing and negotiating for better rates. Also, many mail order pharmacies are, or have been owned by the very drug companies that report there AMPs to CMS. For example, MerckMedco, recently spun off to the Medco PBM away from direct Merch ownership, no doubt will realize artificially low prices on drugs purchased from Merch pharmaceutical manufacturer. Additionally, mail order pharmacies are able to purchase large volumes of drugs, therefore obtaining lower prices. How is this done, by dispensing large volumes of prescriptions very efficiently-- efficiently as can be because they are not "bothered" by patient distractions such as counseling patients on appropriate use of drugs (as required by OBRA'90), or by being reachable for patient questions, a core service provided by community pharmacists virtually FREE OF CHARGE. Try calling another professional and having your questions readily answered within minutes of being asked for no fee as a community pharmacist would, then try calling a mail order pharmacy and talking to anyone about anything and it can easily be seen that mail order pharmacy is not indicative of the retail pharmacy trade as a whole.

It is also stated that manufacturers find it difficult to capture data relating to PBM pricing and how it relates to AMP. This could be because there is NO TRANSPARENCY involved in PBM price negotiations, as well as the rest of their business practices. They operate in a void with little regulation, often practicing medicine and pharmacy by dictating what medications their members will be on. This lack of transparency is apparent when it is stated in this proposed rule that it is unknown how much of the rebates are passed from the PBM to the insurer and to the pharmacies. Let me be perfectly clear that NONE is passed on to pharmacies. And that an unknown amount is passed on to insurers. It would be interesting to see if the federal government could even discover this figure.

**GENERAL**

**GENERAL**

This act is largely a folly that will not accomplish it's aims. First, the recent GAO report showing that pharmacists will lose approximately 40% from the acquisition cost of generic drugs if this act is implemented, as is, while leaving brand name drugs untouched shows the ineptness of what the act is trying to do. If pharmacists are losing money on generics will it be any surprise when they encourage physicians and patients to take brand name drugs which will be the only drugs that pharmacists can dispense and still make money on? And, in so doing, would this not end up further increasing costs? That is assuming that any retail pharmacies would even continue to participate with these paltry reimbursement rates (of which my pharmacy will not) that would not even cover the acquisition cost of the drugs that we purchase much less our time counseling the patient and overhead associated with filling the prescription. We would essentially be paying to do the work. Hardly a motivating cause for pharmacists to provide services. In effect, this act would eliminate almost all retail pharmacies from filling prescriptions for programs that use this form of AMP calculation in their reimbursement formula, and those that continued to do so would surely not stay in business long if they lost money filling the prescriptions. When brand name utilization is at record highs, and no retail pharmacies remain open, will the deficit reduction act have met it's proposed goals?

The biggest problems I can see with this bill is that generic drug utilization, the very drugs that cost pennies to dollars to buy, will be in the cross hairs. These are the drugs that should be MANDATORY for all medicaid recipients to be on. They should not only be encouraged to be on these drugs, but Brand name drugs should not even be allowed it a generic is available. Our local county health plan does this on a daily basis by implementing a formulary that is generic intensive. This is able to be done because there are generics in almost every class of drug that can be given in place of brand drugs. When there is not, the physician can make a request for the brand name drug. In so doing, their prescription costs, while unknown to me, would be fractions of the costs of plans that cover many brand drugs (even with rebates). Targeting pharmacies where margins are often less than 1-2% on brand name drugs, and then further cutting profits on the only drugs that are cost effective (generics) is a prescription for disaster, as opposed to deficit reduction.

Submitter : Dr. Jay Currie  
 Organization : Dr. Jay Currie  
 Category : Pharmacist

Date: 02/20/2007

**Issue Areas/Comments**

**Collection of Information Requirements**

**Collection of Information Requirements**

I agree that we need to do all we can to get the best price for medications being reimbursed by the government. However, as described in this proposed rule, the method of determination of the AMP is intrinsically unfair to pharmacists. As an example, included in the calculation are rebates and other incentives paid to pharmacy benefit managers (PBMs) by manufacturers. Yes, this is a factor in the net cost of drugs, but this is money kept by the PBMs and these rebates are never seen by pharmacists. They are not passed on to pharmacists as they purchase the drugs from manufacturers or from wholesalers. The same is true of the non-market pricing that mail-order houses can obtain which are not available to other pharmacists. It is not fair to reimburse pharmacists based on a pricing structure that is not available or even applicable to them. As a measure of this unfair structure, the GAO issued a report, GAO-07-239R, December 22, 2006, indicating that by using the proposed formula, pharmacists would be reimbursed 36% less than their acquisition costs for a drugs. Further reduction in this reimbursement as the President has proposed in the 2008 Federal Budge would result in disasterous consequences to the drug distribution infrastructure in this country. Additionally the Chief Counsel to the HHS Inspector General testified before the House Oversight and Govt Reform Committee on 2/9/07 regarding how pharmaceutical companies and middlemen in the drug pricing system manipulate prices withing the health care system. This is done to their gain. Pharmacists are often significantly disadvantaged in this system and the government ultimately pays more for drugs as well. A system needs to be put into place for drug pricing that leverages the best price from the drug manufacturers, not from pharmacists who cannot buy the drug at that best price.

**GENERAL**

**GENERAL**

I am writing to express my concern regarding the proposed CMS calculation of average manufacturer price (AMP) in the determination of federal upper limit (FUL) for reimbursement as described in [CMS-2238-P].

How can reimbursing at less than acquisition cost, with the small fees paid in addition to this cost be fair to the care providers. They cannot keep a practice open loosing money on each transaction.

The proposed rule expresses concern over government price-fixing of drug prices. However, given the reimbursement paid to pharmacists by Medicare Part D, PDPs and under this system for Medicaid implementation by the States, for a large share of the market, the government is fixing prices for what is paid to the care provider. This concern should also be noted.

Given the complexity in our health care reimbursement system, we need reform in how pharmacists are reimbursed for product dispensed to beneficiaries. The current system has not intrinsically changed since prior to computers being used in the process. The technology is available today to take the pharmacists out of the middle of this transaction and optimize the pricing leverage that should be in the system.

I would urge you to consider this type of reform, but in the mean time, we must be extremely cautious in further punishing the pharmacist in this process. The PBMs are making more from processing the claims than the pharmacists are in providing product and services to the beneficiary. There is considerable money to be saved in the system, but it is not from the pharmacist, it is from the drug companies who set the prices to the pharmacists, and from the PBMs who set the reimbursement to the pharmacists. Let's go where the money is!

Pharmacists have born an unreasonable financial burden in the implementation of the Medicare Drug Card Program and in the final implementation of the MMA Medicare Part D Program. This change in Medicaid reimbursement will dramatically impact the drug distribution infrastructure in this country and will negatively impact access to care for all in this nation, especially in rural areas. I urge you to re-evaluate these proposed rules and engage pharmacists to assist in developing a strategy to go after the real savings to be had in the system.

I offer you my assistance and the assistance of pharmacy's professional organizations in this effort.

Jay D. Currie, Pharm.D.  
 102 Ink Road NW  
 Mount Vernon, IA 52314-9722  
 319-895-8518

**Submitter :** Mr. Reid Barker  
**Organization :** Utah Pharmacists Association  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**Background**

**Background**

The Utah Pharmacists Association (UPhA) is a State Pharmacy Organization that represents over 450 Chain and Independent retail pharmacies in the state of Utah.

These pharmacies provide prescription services to Medicaid and Medicare patients in urban, suburban and rural communities. Prescription services are also provided to non-Medicaid and Medicare patients through contractual agreements with PBM s, regional and national health plans and various governmental organizations.

As a group, UPhA is concerned that the proposed cuts to pharmacy reimbursement will impact the ability of many Utah pharmacies to remain profitable and thus affect their ability to stay in business to serve Medicaid patients. In many rural areas, there is only one pharmacy for miles and it is an independent. If these pharmacies were to close their doors, the health care of all patients in these areas would suffer, especially Medicaid patients who may find more of a hardship to travel larger distances to obtain their prescriptions.

The proposed AMP based reimbursement will result in pharmacies dispensing Medicaid prescriptions below their costs. Independent retail pharmacy will be especially hard hit and 40% of all prescriptions are filled by Independent pharmacies. To remain competitive retail pharmacies have been forced to operate with ever eroding profit margins. These thin margins cannot support a cut of the magnitude that the AMP based reimbursement will impose. UPhA understands that budget cuts are imminent, but retail pharmacies should not be expected to subsidize the Medicaid budget.

It is the opinion of UPhA that CMS should issue a final regulation that protects Medicaid beneficiaries access to their local community pharmacist, creates incentives to use generic drugs, and strengthens the pharmacy infrastructure.

We appreciate the opportunity to share our comments.

**GENERAL**

**GENERAL**

Please see attachment.

CMS-2238-P-1096-Attach-1.PDF



1850 South Columbia Lane, Orem, UT 84097

801-762-0452  
801-762-0454 Fax  
upha@upha.com

February 15, 2007

Centers for Medicare and Medicaid Services

File Cod: CMS-2238-P

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

(42 CFR Part 447)

To Whom It May Concern:

The Utah Pharmacists Association (UPhA) is a State Pharmacy Organization that represents over 450 Chain and Independent retail pharmacies in the state of Utah. These pharmacies provide prescription services to Medicaid and Medicare patients in urban, suburban and rural communities. Prescription services are also provided to non-Medicaid and Medicare patients through contractual agreements with PBM's, regional and national health plans and various governmental organizations.

As a group, UPhA is concerned that the proposed cuts to pharmacy reimbursement will impact the ability of many Utah pharmacies to remain profitable and thus affect their ability to stay in business to serve Medicaid patients. In many rural areas, there is only one pharmacy for miles and it is an independent. If these pharmacies were to close their doors, the health care of *all* patients in these areas would suffer, especially Medicaid patients who may find more of a hardship to travel larger distances to obtain their prescriptions.

**The proposed AMP based reimbursement will result in pharmacies dispensing Medicaid prescriptions below their costs.** Independent retail pharmacy will be especially hard hit and 40% of all prescriptions are filled by Independent pharmacies. To remain competitive retail pharmacies have been forced to operate with ever eroding profit margins. These thin margins cannot support a cut of the magnitude that the AMP based reimbursement will impose. **UPhA understands that budget cuts are imminent, but retail pharmacies should not be expected to subsidize the Medicaid budget.**

**It is the opinion of UPhA that CMS should issue a final regulation that protects Medicaid beneficiaries access to their local community pharmacist, creates incentives to use generic drugs, and strengthens the pharmacy infrastructure.**

We appreciate the opportunity to share our comments.

### **Definition of Retail Pharmacy Class of Trade and Determination of AMP**

CMS believes, based in part on the OIG and GAO reports, that sales and discounts to mail order pharmacies shall be included in the AMP price calculation along with independent and chain retail pharmacies.

Retail Pharmacy Class of Trade means that sector of the drug marketplace which dispenses drugs to the general public and which includes all price concessions (except prompt pay discounts) related to such goods and services. CMS proposes to exclude from AMP the prices of sales to nursing home pharmacies. CMS will include in AMP the prices of sales and discounts to mail order pharmacies. Inclusion of these lower mail order pharmacy prices would decrease AMP, thereby decreasing manufacturers current rebate liabilities the State Medicaid programs and other entities.

#### **Comments:**

*Mail order pharmacies should be excluded for the following reasons:*

- 1. All major mail order pharmacies in the U.S.A. are owned by PBM's. The alignment of the PBM, its customers and their mail order division permits them to leverage manufacturers for substantial rebates which are not available to retail pharmacies.*
- 2. CMS states that the exclusion of mail order and PBM prices would substantially reduce the number of transactions included in AMP. Mail order pharmacies provide some prescriptions to Medicaid patients PBM mail order companies provide approximately 20% of the prescriptions dispensed to the non-Medicaid market.*
- 3. Mail order pharmacies favor the purchase in very large package sizes (NDC-11) yielding the lowest per unit price in the marketplace. These package sizes are neither accessible to nor feasible in a typical independent retail pharmacy due to smaller sales volume, inventory management and return on investment factors. It is not economically feasible for small independent pharmacies to purchase large package sizes as a standard of operations.*
- 4. PBM's operate mail order facilities in the U.S.A. and they earn certain rebates, discounts and other price concessions that are not available to retail pharmacies. Inclusion of PBM price concessions in the calculation of AMP places retail pharmacies at a significant price disadvantage because these price concessions are not available to our pharmacies.*

5. ***PBM's do not distribute drugs except through their privately owned mail order facilities. Drugs dispensed and distributed through retail pharmacies are purchased and owned by the retail entities. PBM's "credit" their sales revenues as if they own the inventory, but they do not. Rebates earned by a PBM for sales of drugs at the retail pharmacy are not, in any fashion, shared with the pharmacy.***
6. ***PBM's are not wholesale distributors therefore there is no method for distributing these lower cost drugs to the retail sector.***

***As a result mail order pricing should NOT be considered in the AMP calculations.***

**Conclusion:**

***If the Final Rule permits the inclusion of mail order pricing in the calculation of AMP then these mail order pharmacies will have an unfair competitive advantage over retail pharmacy where 80% of consumers currently access these products.***

**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**

**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 should exclude rebates paid to PBMs from AMP calculations: These rebates are not available to our retail pharmacies, and indeed, none of these funds are ever received by our pharmacies. 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.*

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

**PBM Transparency is 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. PBMs have been allowed, due to a lack of regulation, to keep most if not all of their information hidden, thus there is no transparency in the PBM Industry.*

**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 NDC code.

Our pharmacies already purchase the most economical package size as determined by individual pharmacy volume. They 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-digit NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

**Financial Impact on Our Pharmacies**

The GAO findings demonstrate the devastating impact the proposed rule will have on our pharmacies and especially our 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 state dispensing fees.

The impact on our 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 unlikely that Utah would set their Medicaid dispensing fee high enough to cover the average \$12.39 per prescription cost of dispensing for Utah pharmacies as determined by the most recently completed Grant Thornton, LLP Cost of Dispensing Study.

**UPhA would respectfully ask that CMS consider what is fair and equitable for retail pharmacies in determining what and how AMP should be calculated.**

**THREE OF OUR BOARD MEMBERS EXAMINED FINANCIAL DATA FROM THEIR PHARMACIES TO DETERMINE THE EXACT FINANCIAL IMPACT OF AMP ON GROSS AND NET PROFITS. The table below summarizes the data.**

<b>IMPACT OF AMP PRICING ON STORE PROFITS</b>	<b>STORE A</b>	<b>STORE B</b>	<b>STORE C</b>
% of all prescriptions that are Medicaid	12.0%	2.8%	7.2%
% of dollar volume that is Medicaid	11.4%	2.5%	7.0%
% of Medicaid prescriptions that are Generic drugs	65.1%	61.9%	65.5%
Current average GROSS PROFIT per Medicaid RX Combined brand and generic drugs	\$16.75	\$17.42	\$18.50
Brand drugs	\$6.64	\$14.00	\$8.49
Generic drugs	\$19.10	\$19.54	\$23.75
Proposed AMP gross profit per Medicaid RX	\$5.29	\$8.13	\$4.38
<b>Proposed AMP effect on gross profit &lt;Loss&gt;</b>	<b>&lt;\$169,150&gt;</b>	<b>&lt;\$9,269&gt;</b>	<b>&lt;\$35,026&gt;</b>
Current net profit per Medicaid RX	\$4.36	\$5.03	\$6.11
<b>Proposed AMP net profit per Medicaid RX &lt;Loss&gt;</b>	<b>\$&lt;7.10&gt;</b>	<b>&lt;\$4.26&gt;</b>	<b>&lt;\$6.59&gt;</b>
<b>Proposed AMP effect on net profit &lt;NET LOSS&gt; (Amount below pharmacy's acquisition cost!)</b>	<b>&lt;\$104,796&gt;</b>	<b>&lt;\$4,247&gt;</b>	<b>&lt;\$9,325&gt;</b>

The following assumptions are made:

AMP is calculated as FUL (current cost minus 36%) times 150%

The Utah Medicaid dispensing fee will be increased by \$1 from \$3.90 to \$4.90  
(this is pure speculation at this point in time)

The current cost to dispense a prescription in Utah is \$12.39 from the Grant  
Thornton Cost of Dispensing Study

**The net loss is defined as the amount BELOW THE PHARMACY'S ACTUAL  
ACQUISITION COST!**

#### **THE DETAILS OF THE CALCULATIONS ARE PROVIDED BELOW.**

##### **STORE A (the average of two small pharmacies with one owner)**

1. Medicaid represents 12.0% of the total prescriptions dispensed and 11.4% of the total prescription dollar volume. 91% of the total dollar business in these two stores is prescriptions.
2. 65.1% of all Medicaid prescriptions dispensed are generic.
3. Current average gross profit per Medicaid prescription is:
  - a. Brand Prescriptions \$6.64
  - b. Generic Prescriptions \$19.10
  - c. Brand and Generic Prescription overall average gross profit \$16.75 which allows for a \$4.36 profit on each Medicaid prescription using the Grant Thornton \$12.39 average cost of dispensing calculation for Utah pharmacies.
4. Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:
  - a.  $\$8.54$  (average acquisition cost on each generic Medicaid prescription)  $\times$   $36\% = \$5.47$  (average FUL per generic Medicaid prescription)
  - b.  $\$5.47 \times 150\% = \$8.20$  (average AMP per generic Medicaid prescription)
  - c.  $\$8.20 + \$4.90$  (current Utah Medicaid dispensing fee is \$3.90 and it has been indicated to UPhA by the Utah State Medicaid Division that they are considering giving the pharmacies a \$1.00 increase to cover AMP deficits)  $= \$13.10$  (average total reimbursement per generic Medicaid prescription)
  - d.  $\$13.10 - \$8.54$  (current average acquisition cost of each generic Medicaid prescription)  $= \$4.56$  (average gross profit per generic Medicaid prescription after AMP is implemented)
  - e. Brand and Generic Medicaid Prescription overall gross profit will be \$5.29 per prescription after AMP is implemented. This will result in a net loss of \$7.10 on every Medicaid prescription dispensed using the Grant Thornton Cost of Dispensing Study. **This will result in a net loss of \$104,796 in total profit to these two small pharmacies.**

##### **STORE B**

1. Medicaid represents 2.8% of the total prescriptions dispensed and 2.5% of the total prescription dollar volume. 96% of the total dollar business in this store is prescriptions.
2. 61.9% of all Medicaid prescriptions dispensed are generic.
3. Current average gross profit per Medicaid prescription is:
  - a. Brand Prescriptions \$14.00
  - b. Generic Prescriptions \$19.54

- c. *Brand and Generic Prescription overall average gross profit \$17.42 which allows for a \$5.03 net profit on each Medicaid prescription using the Grant Thornton \$12.39 average cost of dispensing calculation for Utah pharmacies.*
- 4. *Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:*
  - a. *\$9.63 (average acquisition cost on each generic Medicaid prescription) x 36%=\$6.16 (average FUL per generic Medicaid prescription)*
  - b. *\$6.16 x150% =\$9.24 (average AMP per generic Medicaid prescription)*
  - c. *\$9.24 + \$4.90 (current Utah Medicaid dispensing fee is \$3.90 and it has been indicated to UPhA by the Utah State Medicaid Division that they are considering giving the pharmacies a \$1.00 increase to cover AMP deficits) =\$14.14 (average total reimbursement per generic Medicaid prescription)*
  - d. *\$14.14-9.63 (current average acquisition cost of each generic Medicaid prescription)=\$4.51 (average gross profit per generic Medicaid prescription after AMP is implemented)*
  - e. *Brand and Generic Medicaid Prescription overall gross profit will be \$8.13 per prescription after AMP is implemented. This will result in a net loss of \$4.26 on every Medicaid prescription dispensed using the Grant Thornton Cost of Dispensing Study. **This will result in a net loss of \$4,247 in total profit to this small pharmacy.***

#### **STORE C**

- 1. *Medicaid represents 7.2% of the total prescriptions dispensed and 7.0% of the total prescription dollar volume. 97% of the total business in this store is prescriptions.*
- 2. *65.5% of all Medicaid prescriptions dispensed are generic.*
- 3. *Current average gross profit per Medicaid prescription is:*
  - a. *Brand Prescriptions \$8.49*
  - b. *Generic Prescriptions \$23.49*
  - c. *Brand and Generic Prescription overall average gross profit \$18.50 which allows for a \$6.11 profit on each Medicaid prescription using the Grant Thornton \$12.39 average cost of dispensing calculation for Utah pharmacies.*
- 4. *Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:*
  - a. *\$12.82 (average acquisition cost on each generic Medicaid prescription) x 36%=\$8.20 (average FUL per generic Medicaid prescription)*
  - b. *\$8.20 x150% =\$12.30 (average AMP per generic Medicaid prescription)*
  - c. *\$12.30 + \$4.90 (current Utah Medicaid dispensing fee is \$3.90 and it has been indicated to UPhA by the Utah State Medicaid Division that they are considering giving the pharmacies a \$1.00 increase to cover AMP deficits) =\$17.20 (average total reimbursement per generic Medicaid prescription)*
  - d. *\$17.20-12.82 (current average acquisition cost of each generic Medicaid prescription)=\$4.38 (average gross profit per generic Medicaid prescription after AMP is implemented)*
  - e. *Brand and Generic Medicaid Prescription overall gross profit will be \$5.80 per prescription after AMP is implemented. This will result in a net loss of \$6.59 on every Medicaid prescription dispensed using the Grant Thornton Cost of Dispensing Study. **This will result in a net loss of \$18,181 in total profit to this small pharmacy.***

Here are some **actual acquisition costs** of 10 random generic drugs. This is the average acquisition costs from the four pharmacies used in the example above. These are provided to CMS as a basis for AMP comparison only.

Drug name	Qty	Acquisition cost	Proposed AMP
Oxycodone/APAP 7.5/500	30	\$12.13	\$11.64
Mupirocin 2% Oint	22g	11.09	10.64
Diazepam 5 mg	60	1.45	1.39
Prenatal Plus	30	1.13	1.08
Amoxicillin 875 mg	60	19.14	18.37
Ibuprofen 800mg	90	3.36	3.22
Clonazepam, 1mg	90	4.34	4.16
SMZ-TMP DS	28	4.12	4.03
Hydrocodone/APAP 10/500	120	13.70	13.15
Hydrocodone/APAP 5/500	14	1.30	1.24
Totals		\$71.76	\$68.92

This table of acquisition costs shows that AWP will be **below** the cost of an average pharmacy. Now add a dispensing fee of \$4.90 that is \$7.49 below the average cost to fill a prescription (\$12.39 per RX in Utah) and **the loss is only magnified.**

***AS YOU CAN SEE FROM THESE CALCULATIONS, THE IMPLEMENTATION OF AMP AS IT IS CURRENTLY OUTLINED WILL HAVE A DISASTROUS EFFECT ON OUR PHARMACIES, ESPECIALLY ON OUR INDEPENDENT PHARMACIES.***

***UPHA AND THE PHARMACIES WE REPRESENT ARE WILLING TO HELP IN REDUCING THE COST OF HEALTH CARE TO THE AMERICAN PEOPLE AND ARE WILLING TO FURTHER INCREASE THE GENERIC UTILIZATION AND THERAPEUTIC SUBSTITUTION THAT WILL DRASTICALLY DECREASE THE COST OF MEDICAID PRESCRIPTION DRUGS.***

***IT IS OUR BELIEF THAT AMP WILL GREATLY DECREASE THE NUMBER OF RETAIL PHARMACIES IN OUR STATE AND THUS DECREASE PATIENT ACCESS TO HEALTH CARE FOR THOSE WHO NEED IT MOST. WE RESPECTFULLY ASK THAT CMS CONSIDER THE DETRIMENTAL OUTCOMES THAT WILL BE REALIZED IF AMP IS IMPLEMENTED AS CURRENTLY OUTLINED.***

*If you have any questions please feel free to contact our office.*

*Sincerely,*

*Reid Barker  
Executive Director*

**Submitter :** Mr. John Stenger Jr  
**Organization :** The Medicine Chest Pharmacy  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**Background**

**Background**

Suggested change in cost basis for community pharmacy reimbursement from a discount from Average Wholesale Price to AMP.

**GENERAL**

**GENERAL**

With regard to the implementation of Medicare Part D in 2006, there are and have been concerns from various perspectives. From my perspective as a practicing community pharmacist, the implementing of Medicare Part D has put our area under increased financial pressure. While Part D may have considered a boon to other areas such as drug manufacturers, pharmacy benefit managers and insurance companies, I can not from my experience say the same for community pharmacy.

The proposed change in cost basis for the medications dispensed under Medicare Part D from a discount from Average Wholesale Price to AMP will make a bad situation for Community Pharmacy worse.

I believe pharmacies are providing a valid healthcare service. For us to continue to provide this valuable service we need fair reimbursement to cover costs related to providing our service.

I am requesting that community pharmacy not be penalized further by additional attrition in payment for the services we render. Please delve further into the profit structure of the insurance companies involved along with PBMs and have them share more equitably in fee reductions for their services as well

**Submitter :** Mr. Michael Jackson  
**Organization :** Florida Pharmacy Association  
**Category :** Health Care Provider/Association

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

See Attachment

CMS-2238-P-1098-Attach-1.DOC



# Florida Pharmacy Association

*Supporting Florida Pharmacy Since 1887*

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

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

The Florida Pharmacy Association (FPA) is the oldest and largest organization representing the profession of pharmacy in Florida. We would like to thank you for allowing us to provide comment to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of average manufacturer pricing (AMP) as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. This issue is extremely important to our state's pharmacy provider. Florida estimated population for the 2000 census is over 15 million according to the US Census Bureau. Of that 15 million nearly 2.8 million citizens in this state are over the age of 65. It is this population that is most affected by changes in pharmacy services.

While Florida has several urban population centers, this state also has a significant number of rural areas where the only health care provider available to deliver pharmacy services are family owned small businesses. While our comments are related to proposed regulations we have grave concerns on how these changes will affect the rural community pharmacies ability to care for the frail and the elderly. There are also other concerns that we have over the viability of those pharmacies providing specialty services in urban areas.

## **Summary**

The Florida Pharmacy Association continues to support federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. Our profession has invested considerable resources and sacrificed operating margins to help our government implement the Medicare Part D program last year. While we are supportive of these efforts, we are compelled to offer the following comments on the 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. Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510. §447.504 which address the methodology CMS will employ to determine AMP when the final regulation goes into

effect. The methodology set forth in §447.504 will create three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. §447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed in §447.510 will create five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself creates an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome.

Additionally FPA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

#### **§447.504 Determination of AMP**

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

##### *Defining Retail Pharmacy Class of Trade*

Comments regarding Section 6001 (c) (1) of the DRA amending 1927 (k) (1) of the Act which revises the definition of AMP as it relates to "Definition of Retail Class of Trade and Determination of AMP" state that: "We believe, based in part on the OIG and GAO reports, that retail pharmacy class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such goods and services. As such, we would exclude the prices of closed system pharmacies such as nursing home pharmacies (LTC) because they do not dispense to the general public. We would also include in AMP the prices of sales and discounts to mail order pharmacies."

Proposed Section 447.504(e) comprises an overly inclusive definition of "retail class of trade." The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition.

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own

definition of retail pharmacy in its December 22, 2006 report entitled: "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs," the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not met by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. 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, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Indeed there have been several attempts to move Medicaid patients to mail order services in this state of which we have not seen significant success. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments. FPA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. The FPA is unaware of any state that licenses PBMs, as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

Mail order pharmacies are structurally similar to pharmacies that service nursing homes, which have been excluded in the proposed rule from the retail class of trade. Both types of operations are "closed door" in that they sell only to facilities or plans with which a contractual relationship exists. As with nursing home pharmacies, discounts and rebates that are available to mail order pharmacies rely greatly on the ability of the pharmacy to play a significant roll in determining which medications are dispensed. These same types of discounts are not available to traditional retail pharmacies.

As with the nursing home pharmacies, mail order pharmacies that operate as a closed door operation should not be included in the retail class of trade. As such, we believe section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade. Excluding mail order and PBM pharmacies from the definition of the retail trade of pharmacy would offer numerous benefits to pricing data and regulatory oversight, including reduced recordkeeping requirements, reduced risk of price fluctuations, and limiting the need for additional regulatory burdens. Since there would be fewer transactions, fewer records will need to be maintained by manufacturers and reported to CMS, thus reducing the reporting requirements of manufacturers. Since mail order pharmacies are most likely to participate in discounts, rebates and other forms of price concessions, the nature of these complex contractual arrangements are more likely to lead to misstatements and errors in accounting and the need for re-statement of pricing information – particularly between quarters - creating pricing volatility and fluctuations in AMP values. Excluding mail order and PBM pharmacies from AMP calculations thus assists to provide greater certainty and reliability in pricing data. Vertical integration between manufacturers and mail order pharmacies creates transactions that are not arms length and thus afford opportunities for market manipulation. In the future, CMS would likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that “removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29.” Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to 1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP.

CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

#### *Inclusion of Medicaid Sales*

It is our belief that 447.504(g) (12) should exclude Medicaid from AMP Data. Unlike Medicare Part D and non-Medicaid SCHIP, which have private party negotiators on formularies and reimbursement rates, Medicaid reimbursement structures vary state-to-state, with some having non-market based reimbursement rates. Moreover the inclusions of Medicaid data more likely than not would create a circular loop negating the validity of AMP. Given the above statements it is clear that counting Medicaid will

have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

### *Discounts, Rebates and Price Concessions*

The Florida Pharmacy Association contends that certain discounts, rebates and price concessions found in §447.504(g) (6) and (9) should not be included in the AMP calculation. Price concessions provided by drug companies to PBM and mail order pharmacies in the form of rebates, chargebacks or other contractual arrangements which, by their very relationship are not available to out-of-pocket customers or third party private sector parties. The proposed regulation concedes that the benefits of these rebates, price concessions, chargebacks and other contractual arrangements may not be - and the FPA generally believes that they are not - shared with the community retail pharmacy networks, out-of-pocket customers, and third party payors, and, thus, they are not available to the "general public." Since PBM and mail order pharmacies (i) now often are vertically integrated with manufacturers and others in the supply chain, (ii) have contractual arrangements in many states that are not transparent in the healthcare system, and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade, they are clearly distinguishable from the community retail pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to reconsider the inclusion of mail order pharmacy rebates, chargebacks and other price concessions.

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, we have no evidence that they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers - the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. Small family owned pharmacies in rural communities cannot foresee such arrangements. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern 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.”<sup>1</sup> Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data that “AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs.”<sup>2</sup> The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

#### **§447.510 Requirements for Manufacturers.**

This section of the proposed regulation addresses how manufacturers are to provide CMS with AMP data and defines the timing of the reporting and outlines the record keeping requirements. The methodology employed to set forth the above tasks creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to ‘clawback’ in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself presents an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome. The following comments address each of these areas of concern.

#### *Market Manipulation*

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the ‘rebate period’ and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the “manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period”.<sup>3</sup> The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

As the entities engaged in the profession of pharmacy become more vertically integrated the potential for misuse of this dual reporting mechanism increases. Potentially, a manufacturer with a vertically integrated market position could use the

---

<sup>1</sup> Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.

<sup>2</sup> GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

<sup>3</sup> §447.510(d)(2)

'rebate period' based reporting to manipulate AMP. Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual time-frame reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP.

Furthermore, this ability would exist for a period of three (3) years, the allowable time for revisions. This undue flexibility, afforded to find a market price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

#### *'Claw-back'*

Given that the proposed regulation allows substantial flexibility, with regard to financial restatement, we would recommend that CMS clearly state its intent on the ability or inability to recoup erroneous payments or for a provider to claim shortages based on incorrect AMPs. Since removing the manufacturers ability too restate AMP would be to restrictive, guidance from CMS on this issue is paramount.

#### *Pricing Lag*

Under the proposed regulation, the AMP first reported to CMS could be as many as 30 days old. As such, the data will be out of date prior to dissemination to the states and the general public, a process potentially taking another 30 to 60 days. Additionally, the flexibility given the manufacturer to report discounts employed and the restatement figures will add significant variability to this lag. Material lag in AMP degrades transparency and places an undue burden upon the retail pharmacy class of trade. The technical difficulties and associated overhead burdens of limiting or eliminating this structural lag may prove to be insurmountable. Therefore, CMS should provide guidance to the states and other users of AMP on the proper method to address any issues resulting from the structural lag.

#### *Severe Price Shifts*

The inherent market volatility, associated with pharmaceutical manufacturing, occasionally results in dramatic shifts in price structure. The proposed regulation is noticeably silent in offering any mechanism to account for this fact. Severe price shifts and the significant issues associated with pricing lag can be effectively addressed with the implementation of trigger mechanisms. CMS should identify a reasonable and appropriate percentage shift in real time price that would trigger a review and recommendation by the Office of the Inspector General (IG). It is recommended that CMS clearly define the stakeholders empowered to alert CMS of significant price shifts. Once alerted the IG would research and then recommended an updated AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would

then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

In its simplest form the trigger mechanism could accomplish the following: (i) limit the affects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to date calculation of AMP. The ability to adjust the posted AMP, between reporting periods, will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag.

The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the IG will act as a damper to market manipulation. The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanisms ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP.

Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

### *Record Keeping*

The proposed regulation states in §447.510(f)(1) that "[a] manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period". This time requirement is unduly burdensome and a substantial departure from the Internal Revenue Services' seven (7) year standard for audit record keeping. We recommend that CMS adjust the record keeping requirement in the proposed regulation to be consistent with the widely accepted seven (7) year standard.

### **Additional Comments**

#### *Use of the 11-Digit NDC Rather Than the 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, yet then states 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.” However, there is also no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-digit level for generic drugs in determining FULs.

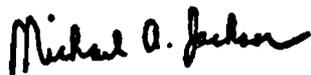
We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies.

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.

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

Thank you.

With kindest regards,

A handwritten signature in black ink that reads "Michael A. Jackson". The signature is written in a cursive, flowing style.

Michael A. Jackson, R.Ph.  
Executive Vice President and CEO  
Florida Pharmacy Association  
610 North Adams Street  
Tallahassee, Florida 32301  
(850) 222-2400  
mjackson@pharmview.com

**Submitter :** Dr. Dana Caldwell  
**Organization :** Cobblestone Pharmacy  
**Category :** Pharmacist

**Date:** 02/20/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-1099-Attach-1.PDF

1099

***Cobblestone Pharmacy & Compounding Center***  
 Your "Good Neighbor" Pharmacy in Paradise  
 Dr. Dana B. Caldwell & Paul Vesely, Pharmacists

6585 Clark Road, Suite 100  
 Paradise, CA 95969  
 530-877-3712, fax 877-5739  
 Toll Free 1-888-233-9055  
 E-mail: cobblestone@pacbell.net

February 15, 2007

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

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

I am a sole proprietor of Cobblestone Pharmacy in Paradise, California and have been serving this community and surrounding areas for 33 years. I am writing to give my views on the new proposed regulation that would define AMP and implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

If the proposed regulation is adopted, I believe the changes in reimbursement will have a significant negative economic impact on my business. My ability to operate my business and pay the expenses to just stay in business is very questionable. My ability to provide pharmacy services to Medicaid beneficiaries and the general public will be severely curtailed.

This regulation should not be adopted in the present form; substantial changes and revisions must be made.

I have worked very hard to make the new Medicare Part D program viable and to provide the services to our elderly population who are the primary beneficiaries of the Medicare Part D program. That program and the limited and decrease reimbursement from the payers has already had a great impact on my business and now this proposed regulation is about to cut our reimbursement rate even lower. This has to stop...NOW.

I ask that CMS please do the following:

**Delay Public Release of AMP Data:**

The centers for Medicare and Medicaid Services (CMS) should not make Average Manufacturers Price (AMP) data public until a final regulatory definition of AMP is released. This definition should reflect the prices that a traditional retail pharmacy is able to purchase medications. AMP should not include any "rebates" or "promotional incentives" paid by manufacturers to PBMs or Mail Order pharmacies. PBMs and Mail Order pharmacies are NOT traditional retail pharmacies serving their communities. These "rebates" and "promotional incentives" are not passed on to traditional retail pharmacies.

**"Pill-er of the Community"... We Deliver Personal Service**

Release of flawed and inaccurate data concerning AMP will adversely affect community retail pharmacy if used for reimbursement purposes. CMS has already delayed release of this date and I urge that release of this date be delayed again.

**Define AMP to Reflect Retail Pharmacy Purchasing Costs:**

CMS' proposed regulatory definition is severely flawed because it does not reflect the prices at which retail pharmacies purchase medications.

EXCLUDE any PBM price concessions - rebates, discounts or other price adjustments provided by the manufacturer to the PBM.

EXCLUDE the prices of sales to Mail order pharmacies and any discounts they receive.

EXCLUDE any Medicare Part D sales of medications – rebates paid by the manufacturer to the PDP or MA-PD.

EXCLUDE SPAP price concessions

EXCLUDE Manufacturer coupons redeemed by any entity other than the consumer

EXCLUDE sales to hospital pharmacies, in-patient or out-patient.

Retail pharmacy does not benefit from any of these special pricing purchasing agreements or rebates. AMP should be calculated only for prices that traditional retail pharmacies who serve the general public pay for prescription medications.

**Delay New Generic Rates that Would Significantly Underpay Retail Pharmacies:**

The new Federal Upper Limits (FUL) will severely cut the rate of reimbursement paid to pharmacies; these cuts will be devastating to many retail pharmacies. Implementation of these FULs must be suspended. A recent GAO report found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new AMP-based FUL system.

**Require that States Increase Pharmacy Dispensing Fees:**

CMS should mandate that states increase dispensing fees paid to pharmacies to offset potential losses on generic drug reimbursement. 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.

Thank you for accepting these comments. I am a member of the American Pharmacists Association, the California Pharmacists Association and other pharmacy groups that are requesting that changes be made in the AMP regulation.

Sincerely,

Dana B. Caldwell  
Dr. of Pharmacy

*"Pill-er of the Community"... We Deliver Personal Service*