CMS-2238-P-102

Submitter : **Mrs. Beth Butcher** **Date: 02/06/2007**

Organization : **Mrs. Beth Butcher**

Category : **Pharmacist**

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.

CMS-2238-P-103

Submitter : Mr. john canestraro **Date:** 02/06/2007

Organization : ohio pharmacists association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

please do not force us (PHARMACISTS) TO QUIT serving our medicaid patients because we are reimbursed at below our wholesale cost. Not only is this bad medicine , but it WILL drive up costs because it will only force us to use name brand medications instead of less expensive Generic alternatives. PLEASE fix the AMP problem before it drives another nail into our health care system. Thanks jcc

Submitter : **Mr. Tony Jones** **Date: 02/06/2007**

Organization : **Mr. Tony Jones**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Proposed rules regarding reimbursement rates to retail pharmacies.

GENERAL

GENERAL

Just released today, a study commissioned by the CCPA (Coaltion of Community Pharmacy), a joint organization of the National Community Pharmacist's Asscociation and the National Assciation of Chain Drugstores, reveals the average cost of dispensing a prescription in the United States is $10.50. This is well above the current fee paid by the Medicaid program of around $4.50 across the nation.

Community pharmacies have been struggling for years to continue serving patients while having to accept these inadequate fees.

Many pharmacies are located in areas of less than 20,000 population. These areas, by their very nature have more patients who are medicaid recipients and low wage earners.

Large corporations will not locate pharmacies in most of these areas due to the fact that they cannot make a reasonable profit.

Any business must charge enough to cover the everyday expenses of operations and hope to make a profit to continue. These current fees, and those being considered do not do that.

Small businesses are vital to this economy, and the 55,000 pharmacies represented by the CCPA include many of those small businesses that care for their patients every day, saving the healthcare system money.

This latest cost of dispensing study reveals and even higher cost of dispensing than the study completed last year by the University of Texas.

That study concluded the average cost of dispensing to be $9.60.

Both studies show a higher cost associated for pharmacies on the west coast and mountain areas, and also for any pharmacy located in small communities.

CMS-2238-P-105

Submitter : Mr. Mark Johannigman **Date:** 02/06/2007

Organization : BVHS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I do not support this bill and it should not pass. The reimbursement rates are below costs and the passage of this bill will cause pharmacies to go out of business.

CMS-2238-P-106 Prescription Drugs

Submitter : **Mr. Daniel Karant** **Date & Time:** **02/06/2007**

Organization : **Medicine Shoppe#1065**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

As a pharmacy owner, we are taxed on our profits, we have employees to pay, we have all the other business costs to pay like lights, heating, cooling, snow removal, and many other things that come out of the "cost" of a drug when we fill a prescription. Merely exchanging dollar for dollar what we pay for the drug is BELOW COST! Businesses do not employ people/voters/taxpayers if they don't make a profit. They simply go out of business. If we are reimbursed according to the new AMP formula, we will be paid about 36% below our actual acquisition cost, not to mention that we have to pay all of our related business operating expenses. This new plan as the formula is currently defined, will drive providers from being able to accept the plans for Medicare and Medicaid. I will not for one remain in a plan that pays below cost. We currently provide service to a large number of patients that are on medicaid, and deliver to them for free. They can't get out and don't have any other way to receive their medications. This will limit their access to drug providers.

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.

CMS-2238-P-107 Prescription Drugs

Submitter : **Mr. Mark Johannigman** **Date & Time:** **02/06/2007**

Organization : **BVHS**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

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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.

CMS-2238-P-108

Submitter : **Mr. Keith Rumpler** **Date: 02/06/2007**

Organization : **Mr. Keith Rumpler**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

How do you define Average Manufacturers' Price? You MUST allow AMP to reflect pharmacies' entire ingredient cost!
If you think you have problems now, wait until you have an all out revolt by pharmacies across the country who start refusing to fill Medicaid prescriptions!
Whatever happened to rational business practice on the part of big government? This is insanity!

Submitter : **Dr. Eric Everman** **Date: 02/06/2007**

Organization : **Medicine and More Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator Leslie Norwalk,

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.
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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.

If this is not done, and we are not paid fair reimbursement, you will end community pharmacy for good. We will all have to close our doors, and our patients will be left with out QUALITY care!

Submitter : **Miss. Rima El Terk** **Date: 02/06/2007**

Organization : **APHA**

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.
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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.

CMS-2238-P-111

Submitter : Dr. Robbin Sizemore **Date:** 02/06/2007

Organization : Holzer LTC Pharmacy

Category : Pharmacist

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. This would be a great tragedy for residents of nursing homes and foster children of which many still have traditional Medicaid in my state of Ohio. In addition, prescribers may be forced to prescribe brand name drugs which would inevitably cost the state more tax dollars to fund very needed programs and services.
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. Our pharmacy serves a rural population of which about 75% are Medicaid recipients. 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 : John Schlitt **Date:** 02/06/2007

Organization : CVS Pharmacy and Ohio Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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.
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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 : **Amy DeMarsh** **Date: 02/06/2007**

Organization : **BVHS**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

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Submitter : **Mr. David Ver Helst** **Date: 02/06/2007**

Organization : **Ver Helst Snyder Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

r.e. proposed AMP drug cost basis

I own the only remaining pharmacy in Worth County, Iowa. The PBM's controlling Medicare Part D and private insurance plans have all but closed our doors. Their take-it-or-leave-it contracts force me to fill prescriptions at way below my cost of doing business. Now, the federal government wants to pile on by cutting the cost basis for my drugs, using AMP. If you are going to slash my reimbursement for drug cost, are you also going to mandate a dispensing fee that will cover my costs? I doubt it. You are letting PBM's and drug manufacturers rob you blind, but you insist on punishing the health care providers who are actually taking care of our patients! Wake up and correct this travesty before we are all gone.

Submitter : **Mr. Jarid Peak** **Date: 02/06/2007**

Organization : **Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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Submitter : **Mr. Walter Herbster** **Date: 02/06/2007**

Organization : **Walgreens**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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Submitter : **Date: 02/07/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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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 : **Mrs. Belinda Renno** **Date: 02/07/2007**

Organization : **Antwerp Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please consider the following comments,
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.
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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.

Belinda Renno
Owner/Pharmacist
Antwerp Pharmacy, 105 S. Main, Antwerp OH 45813

CMS-2238-P-119

Submitter : **Mr. Keith Wiley** **Date: 02/07/2007**

Organization : **Rite Aid**

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.
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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.

GENERAL

GENERAL

AMP way below actual cost of generic medications is unfair and will drive many pharmacies out of business or force them to quit serving medicaid patients.

Submitter : **Dr. KRISTIE FIELD** **Date: 02/07/2007**

Organization : **Dr. KRISTIE FIELD**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I feel this new ruling would require too much additional work for hospitals to meet these standards for medicare and medicaid. Also since orders from warehouses may vary in terms of generic products and different NDC nubmers this would create even more havoc for hospitals.

Submitter : **Mr. Chris Buchanan** **Date: 02/07/2007**

Organization : **Smith's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attatchment

CMS-2238-P-121-Attach-1.TXT

#121

Subject: Medicaid Program: Prescription Drugs; AMP Regulation

CMS 2238-P RIN 0938-AO20

Smith's Pharmacy 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 Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates one pharmacy in Virginia. We are the only provider of pharmacy services in the community in which our store is 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 (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 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 Costs: 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 the 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 Federal Upper Limits (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 National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Chris Buchanan

CMS-2238-P-122

Submitter : Mr. Daniel Horn **Date:** 02/07/2007

Organization : Dan Horn Pharmacy and Health Services

Category : Pharmacist

Issue Areas/Comments

Response to Comments

Response to Comments

AMP based pricing as it is currently proposed will have a devastating effect on my ability to take care of my medicaid patients. How can any business survive when you must sell for 36% below your cost? Medicaid accounts for 25% of my business. Why does community pharmacy have to shoulder the lions share of reimbursement cuts? We have already conceded much all the while trying to help our patients with Medicare Part D. Your are making it impossible to succeed in this business.

CMS-2238-P-123

Submitter : Dr. Eyad Alsabbagh **Date:** 02/07/2007

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

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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.

CMS-2238-P-124

Submitter : **Dr. Matt Hotek** **Date: 02/07/2007**

Organization : **kdhhs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The cost to implement the changes for this rule are incalcuable. But certainly NOT minimal-
Unless a hospital has barcoding at the point of patient administration, the hospital information system will not yield a 11-digit unique NDC number to submit to the State Medicaid agency. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

The impact on workflow, staffing and financial resources of the hospital is unrealistic and not justifiable given current fiscal and workforce constraints.

CMS-2238-P-125

Submitter : Mr. KEVIN BLACKER **Date: 02/07/2007**

Organization : Blacker's Pharmacy Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

If the AMP passes we will no longer be able to accept medicaid prescriptions. I can not afford to be paid 36% below my acquisition

CMS-2238-P-126

Submitter : **Mrs. Colleen Lindholz** **Date: 02/07/2007**

Organization : **The Kroger Company**

Category : **Pharmacist**

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.

CMS-2238-P-127

Submitter : **Jennifer Kline** **Date: 02/07/2007**

Organization : **Ohio Pharmacist Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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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.

CMS-2238-P-128

Submitter : Mr. William Bidwell **Date:** 02/07/2007

Organization : Giant Eagle

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Bill to cut reimbursaement AMP will be the death knell of community pharmacy -- Pharmacies cannot compete with the prices that hospitals get for drugs, or huge HMOs or military bases. You will be cutting a vital health service at the local level at the knees.

CMS-2238-P-129

Submitter : Dr. James Lindon

Date: 02/07/2007

Organization : Lindon & Lindon, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I agree with the changes

CMS-2238-P-130

Submitter : **Mr. richard rambo** **Date: 02/07/2007**

Organization : **sutcliffe pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Response to Comments

Response to Comments

My business is over 50% public aid patients, I feel to pay me less than it costs me for generic prescriptions is counter productive to all 3 parties involved. The patient, the provider, and the payer, generics save the payer money and also makes more money available to provide more services to patients. The new system will encourage the dispensing of brand name products, because who can provide services to anyone at below cost. This will end up costing us all more money. Providers should be encouraged to dispense generics not discouraged. Thank you for your time I appreciate it Richard D.
Rambo RPH sutcliffe pharmacy 801 w irving pk rd chicago il 60613

CMS-2238-P-131

Submitter : JOHN PETRIE **Date:** 02/07/2007

Organization : CLINIC PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacy owner of an inner city pharmacy that has taken care of poor and aged(Medicaid and Medicare) patients for over 25 years. The proposed 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. As over 60% of my business is Medicaid the impact of the proposed regulation will certainly put me out of business, leaving thousands of Medicaid patients without service. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the products. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away or as in my case,put me out of business!

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 has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total 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 differntly, and without a proper definition, Medicaid reimbursement will NOT cover pharmacy acquistion costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away or put out business altogether, cutting access for patients. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover all acquistion costs, an incentive will be created to dispense more Brand Name prescriptions that would end up costing Medicaid much more.

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

CMS-2238-P-132

Submitter : **Dr. Robert Maley** **Date: 02/07/2007**

Organization : **Dr. Robert Maley**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

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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.

CMS-2238-P-133

Submitter : **Joseph McAuliffe** **Date: 02/07/2007**

Organization : **Pohlman Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This regulation has to be changed if CMS expects pharmacists to continue to fill prescriptions for Medicare and Medicaid patients. There is now way to stay in business if we can not make a profit. There is a way to fill these prescriptions ans still make a profit and take good care of the patients just as we have done for many years. If you will visit www.acpcn.org, you can see an easy solution to the problem without the pharmacists going broke or the government having to spend nearly as much for prescriptions. Please, see this web site and try an alternative solution. Click on 'Pharmacy faxes' and then ACP*CN game plan for 2007. This will give a good alternative to the AMP.

CMS-2238-P-134

Submitter : **Dr. Brad Welage** **Date: 02/07/2007**

Organization : **The Kroger Co.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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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.

CMS-2238-P-135

Submitter : Dr. hale dimetry **Date:** 02/07/2007

Organization : promise pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

our pharmacy has been in busniess for 7 month. we are exceeding our goal in volume of patients utilizing our services. however, the amount of revenue from the prescriptions sale is way below our expectations. i do agree that the use of lower pricing for ingrediant cost will save the system a lot of money, but the compensation for the pharmacist should reflect the amount of time and professional knowledge he or she spend in safely dispensing the prescription. not only that but also the time the pharmacy spends answering patients questions in health care issues as well as insurance issues. we are the most utilized health care professionals since we are readly availaible while being the least paid per patient. dispensing fees have reached a low 50 cents per rx for 30 days and zero, yes zero cents for 90 days supply. many of us are considering closing our pharmacies eventhough all of our patients are pleased of our services and personal attention. please save the independent pharmacies. help our economy grow stronger through comeptition and not monopoly. the chain pharmacies are able to survive and make profit because of their very low acquisition costs. do i have to give up me dream of having my own practice because i am not too big to acquire the same pricing. this is no free market nor is it the U.S.A , the greatest nation.

Collection of Information Requirements

Collection of Information Requirements

amp can be used to determine ingrediant costs while increasing the dispensing fee for pharmacies to minimum of $10 per prescription.

Submitter : **Mr. nilkesh patel** **Date: 02/07/2007**

Organization : **Mr. nilkesh patel**

Category : **Individual**

Issue Areas/Comments

Background

Background

I have been a pharmacist for 10 years and pharmacy owner for 2 & 1/2 years. Before my ownership i did not understand and i didn't care as long as i got a paycheck for one of the big chains. Now i understand and do care what goes on, slowly the government is knowingly helping the big chains get more market share by closing down the little independent pharmacy. How can we survive on the new payment system. Goto any independent and look at the invoice and then look at what rates we will be paid and the math is simple, we will lose money. Please understand not every pharmacy has the same cost of goods even among the independents. The chains have a better cost of goods than the independents. Close door pharmacy may have better cost of goods than the chains. Hospital have better cost of goods than chains. VA has better cost of goods than hospitals. If you take the average of all costs, the cost will be lower than what any independent in the country could purchase at. This is still not taking in to account any other cost of filling a prescription.If we the onbodies have this informations why doesen't the government.
Thank you for your time. Please be JUST.
Nilkesh Patel

Submitter : Mr. Timothy Hoffman **Date:** 02/07/2007

Organization : personal comment

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Go ahead. Slash the reimbursement. I am so sick of seeing proposed legisilation that is supposedly to benefit the greater good and save money, but goes about it the completely wrong way. Get it out of your system. When people suffer because they loose access points to pharmaceuticals and cannot obtain their medicine, and lose access to fast, free medical advice, maybe you will begin to actually guage the situation and make an informed decisions based on facts and not influence of constituents. It takes time. Lots of time, more than it takes to draft legistlation with loop holes yet to be exploited.

I do think that big business loves this though. Why you are at it, why don't you just go ahead and ammend the language to pass on even more of the big business advertising budgets on to the consumer. Make it official. Add insult to injury. Please! What are you waiting for? You don't hesitate with any other bad ideas. Go full throttle and do it 100% bad instead of 50%.

The proceeding was just my opinion, whether it be good or bad. It is not intended to be personal, but to get your attention in the right place, the problem. Look at the problem in full, and think about it. Take your time. There has got to be some different and potentially better ways to save money. Seriously . . .

Submitter : **Miss. Melissa Totten** **Date: 02/07/2007**

Organization : **Ohio Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

Response to Comments

Response to Comments

I am writing to express my great concern about CMS-2238-P. 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. Failing to issue a clear definition will certainly result in many pharmacies going out of business and compromised patient care. Your attention to this matter is greatly appreciated!

Submitter : **howard feder** **Date: 02/07/2007**

Organization : **myrtle ave. pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

OVERVIEW
CMS s Costs Savings Estimates Ignore Increased Costs
AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:
The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower
2
than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006. -GAO-07-239R
p.4
This finding validates community pharmacy s contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost. The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.
None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.
Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates
AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report Medicaid Drug Rebate Program Inadequate Oversight Raises Concerns about Rebates Paid to States (GAO-05-102).
However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in Best Price but should not be included in AMP.
An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.
3

GENERAL

GENERAL

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the 4

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those adjustments to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that inform

Submitter : **Miss. Mary Sparks** **Date: 02/07/2007**

Organization : **Miss. Mary Sparks**

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.

Collection of Information Requirements

Collection of Information Requirements

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.

GENERAL

GENERAL

Submitter : **Mr. Chris Altman** **Date: 02/07/2007**

Organization : **Ohio Northern Univsersity**

Category : **Other Health Care Provider**

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 : **Dr. David Uddin** **Date: 02/07/2007**

Organization : **Dr. David Uddin**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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

It seems that attempts to "save" money actually come at someones else's cost, in this case community pharmacies.

CMS-2238-P-143

Submitter : **Mr. William Branning** **Date: 02/07/2007**

Organization : **Mr. William Branning**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed regulation is arbitrary and ridiculous. How can pharmacies be expected to survive when they receive only 25% of what they pay for the medication?
The federal government must be smoking some of what they have made illegal!
If you want to reduce costs, try eliminating non productive costs such as excessive regulation, legal liability and endless levels of bureaucracy.

Submitter : Ms. Amy Dill **Date:** 02/07/2007

Organization : OPA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

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Submitter : **Date: 02/07/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

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Submitter : **Mark Fitzgerald** **Date: 02/07/2007**

Organization : **Fitzgerald's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Regulatory Impact Analysis

Regulatory Impact Analysis

AMP - It appears that everyone agrees that AMP is not the correct way to reimbursement pharmacies, for the service they are supplying. Getting reimbursed less than what it cost you to purchase something goes against everyones common sense.

Many pharmacies will be forced to turn away many of the customers that count on them every single day for product and information. This will cause many people to who aren't as compliant as needed to begin with to even stop taking the medications they require because they can't find anyone to provide them what they want.

Submitter : **Mr. Harry Webb** **Date: 02/07/2007**

Organization : **Webb's Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I own two independent community pharmacies in small communities in north central Indiana. One is in Rochester (population 7000) and the other is in Akron (population 1500). The current AMP calculation proposal as presented will force me to withdraw from the Medicaid program. I simply cannot continue in a program that reimburses me 30% below my acquisition cost. The following comments prepared by NCPA reflect my position.

GENERAL

GENERAL

Summary of Key Points: (i.e. "see attachement")
_ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule
will not cover pharmacy acquisition costs for multiple-source generic medications
_ Average Manufacturer Price (AMP) was never intended to serve as a basis for
reimbursement.
_ To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
1. Excluding all rebates and price concessions made by manufacturers which
are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

CMS-2238-P-147-Attach-1.DOC

#147

Comments submitted by
Harry Webb
Webb's Family Pharmacy
Rochester, IN 46975
Akron, IN 46910

I own two independent community pharmacies in small communities in north central Indiana. One is in Rochester (population 7000) and the other is in Akron (population 1500). The current AMP calculation proposal as presented will force me to withdraw from the Medicaid program. I simply cannot continue in a program that reimburses me 30% below my acquisition costs on generic medications. The following comments prepared by NCPA reflect my position.

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.—pg.29
Public Access Defines Retail Pharmacy Class of Trade. CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be "publicly accessible." Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in AMP.
NCPA recommends "retail pharmacy class of trade" include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.—pg. 31-33
Inclusion in Best Price of PBM rebates, discounts and other price concessions— pg. 53
Treatment of Manufacturer coupons with regard to Best Price—pg. 55
Inclusion of Direct-to-Patient Sales with regard to AMP—pg. 41
AMP Must Differ From Best Price If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

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

prices, and therefore these transactions should also be excluded from AMP calculation.

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.
For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater.
In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.

How PBM price concessions should be reported to CMS.—pg. 33
PBM Transparency Necessary to Assess Manufacturer Rebates PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

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

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.—pg. 70
AMP Must Be Reported Weekly There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues

to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP—pg 80
AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy. We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code. Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.
Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost.

The 11-digit NDC must be used when calculating the FUL. Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110
CMS discusses impact on pharmacy:
On independents: potential "significant impact on small, independent pharmacies."—pg. 101
On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011
("a small fraction of pharmacy revenues").—pg. 108
"We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110
Impact on small pharmacies demonstrated by GAO findings The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees. The impact on independent pharmacies also cannot be mitigated by an increase in state set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study. Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark

Submitter : **Dr. Javier Vazquez** **Date: 02/07/2007**

Organization : **Dr. Javier Vazquez**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

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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.

CMS-2238-P-149 Prescription Drugs

Submitter : **Jessica Everhart** **Date & Time:** **02/07/2007**

Organization : **Jessica Everhart**

Category : **Pharmacist**

Issue Areas/Comments

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Submitter : **Mr. HARSHAD PATEL** **Date: 02/07/2007**

Organization : **MEDICINE SHOPPE**

Category : **Pharmacist**

Issue Areas/Comments

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Submitter : Mrs. NIVEDITA PATEL **Date:** 02/07/2007

Organization : ST ELIZABETH'S PHARMACY

Category : Pharmacist

Issue Areas/Comments

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Submitter : **Mr. Shane Lindsay** **Date: 02/07/2007**

Organization : **University of Cincinnati College of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

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Submitter : **Dr. John Clark** **Date: 02/07/2007**

Organization : **Moose Professional Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

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Leslie Norwalk,
Redefining the Average Manufacturers Price (AMP) for use as a Federal Upper Limit(FUL) in Medicaid reimbursement to community pharmacies will negatively impact a vital part of our nation's health care delivery system due to the following reasons.

1. AMP based FUL reimbursements will not cover a retail pharmacy's acquisition cost. A recent GAO report (GAO-07-239R) showed that the average reimbursement under the proposed AMP based FUL reimbursement rate was 36% less than the acquisition cost for 77 multiple source outpatient prescription drugs. This type of loss on each Medicaid transaction will not sustain a pharmacy that serves Medicaid patients in rural areas. That would cause disastrous consequences and adverse outcomes for these Medicaid patients as they may stop taking their medication because a pharmacy is out of their reach.

2. AMP should not be a benchmark for reimbursement because it does not reflect the actual cost of a retail pharmacy's acquisition cost. The AMP price reflects rebates paid by manufacturers to third party payors such as Medicaid, Caremark, Medco, and Express Scripts. These rebates are unavailable to retail pharmacies. The acquisition cost of mail order pharmacies owned by third party payors like Caremark and Medco are also reflected in the AMP, but should be excluded from calculating AMP because these pharmacies are not open to the general public and only accessible by people covered under these payors. Furthermore, mail order pharmacies are extended special prices that are not extended to publicly traded pharamcies like CVS, Walgreens, and privately owned pharmacies.

Lastly, the strategy to cut costs by reducing reimbursement for generic medications is difficult to sustain in the long term as many pharmacists may make therapeutic substitution recommendations to the patient's physicians for brand name drugs because Medicaid would be more likely to cover the true cost of reimbursement under the current definition of the AMP-FUL reimbursement structure. This would increase Medicaid costs exponentially. Instead, the dispensing of generics should be incentivized with a $15.00 dispensing fee plus a reasonable reimbursement for the cost of the drug. This type of plan would motivate pharmacists nationwide to work with patients to find a therapeutically equivalent alternative to costlier brand name medications.

Thank you Leslie for taking the time to read this comment.
Respectfully,
John Clark

Submitter : Mr. Michael Crotty **Date:** 02/07/2007

Organization : Mr. Michael Crotty

Category : Pharmacist

Issue Areas/Comments

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Submitter : **Mr. Kent Pattison** **Date: 02/07/2007**

Organization : **Chapman Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

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Submitter : **Dr. Edward Cassidy** **Date: 02/07/2007**

Organization : **Hawkey's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

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I am concerned about the definition of AMP. Please have a clear cut definition of what AMP is and how much it will be. It neededs to be at least the cost of ingredients by tne pharmacy plus enouth profit to maintain business. I am the only pharmacy in this zipcode and just bought the pharmacy. I (and the people of my community) can not afford for you to experiment with the definition of AMP. if reimbursments are not correct at the start i will be forced to close and our community will lose a good part of its service and identity. without basic services like a pharmacy we are no longer a community but rather just a collection of homes in the country. I'm not asking for a handout just a fair reimbursment. thanks for your time, Edward P. Cassidy, R. Ph.

Submitter : **Mrs. Christy Garmon** **Date: 02/07/2007**

Organization : **Pharmacy Student, Samford University**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am a 2nd year PharmD student at Samford University. I want to comment on the implimentation of the Deficit Reduction Act of 2005 (DRA) that changes the Medicaid program's reimbursement for generic medications to one based on 250% of the Average Manufacturer's Price (AMP). Implimentation of this will have a devastating effect on the profession of pharmacy! As I resident of Alabama, there are numerous counties that have small independant pharmacies as their only means of medication & health care. Pharmacist rank as the 2nd most trusted profession in America, and the majority of medicaid patients come to their local pharmacist for medical advice before going to a physician. The proposed reimbursement based on AMP will put many of these pharmacy out of business. You say your goal is to save money, but when these pharmacies go out of business health care cost WILL increase. What is going to happen to patients who stop being compliant with their medication regimen because they now have to drive maybe 30 miles to the next time to find a pharmacy that can afford to stay open and fill their medications? What is going to happen to the numerous patients that consult a pharmacist for medical advice instead of going to the Dr? I will tell you what is going to happen...they will end up in the hospital and THAT will drive up health care cost!!! Whoever came up with this law needs to seriously take into account the quality of life of the individuals they serve and NOT the amount of dollars drug manufacturers can put into his/her pockets!!!

Submitter : **Mrs. Linda Pattison** **Date: 02/07/2007**

Organization : **Chapman Pharmacy**

Category : **Other Technician**

Issue Areas/Comments

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Response to Comments

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Submitter : **Mrs. Shannon Davis** **Date: 02/07/2007**

Organization : **University of Cincinnati**

Category : **Academic**

Issue Areas/Comments

Regulatory Impact Analysis

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Submitter : **Date: 02/07/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

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GENERAL

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Response to Comments

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In addition to the above listed problems this issue will cause, this impedes a pharmacy's ability to function well due to staff cuttings. The pharmacy I am working at now functions with minimal personnel to make profit. This increases workload and potentially errors due to overload. Staff are overworked and underpaid to carry this important function of dispensing medications.

Submitter : **Mrs. Melissa Willis** **Date: 02/07/2007**

Organization : **HealthCare Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

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Submitter : **Mr. Seth Terlecky** **Date: 02/07/2007**

Organization : **ASP**

Category : **Pharmacist**

Issue Areas/Comments

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Submitter : **Mr. Joseph Jeffries** **Date: 02/07/2007**

Organization : **Mr. Joseph Jeffries**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

On July 1, CMS plans to begin reimbursing for generics based on Average Manufacturers Price (AMP), which it proposed in a regulation released Dec. 15.

GENERAL

GENERAL

Community pharmacies, both chains and independents, will lose money on virtually every generic prescription. The Government Accountability Office (GAO) says that community pharmacies will be paid on average 36% below their acquisition cost for every Medicaid generic drug prescription they fill under a reimbursement formula proposed by the Centers for Medicare & Medicaid Services (CMS). It makes no sense to reduce reimbursement on the medications that could save the entire system 30 billion dollars. Why would CMS skimp here when the majority of costs are associated with expensive, and many times unnecessary, brand named drugs? Just look at the average consumer cost of a brand drug (over $100) and a generic drug (under $40). And you're changing the reimbursement on the $40 drug?? You should be suggesting or even incenting that pharmacists be able to change drugs within a therapeutic class. And further, CMS should work with the FDA to restrict the use of brand samples in the doctors office. This is what drives the high percentage of brand Rxs in the U.S. The doctor doesn't even consider a generic because all she has are free samples of brand drugs. Ask someone in the CMS office who is on Lexapro. They could be taking generic Celexa at a huge savings to us all. But if you try to cut the reimbursement to 36% of the pharmacy's cost, then even the pharmacy won't be able to stock generic Celexa. You will essentially be increasing the rate of brand name drug use in this country. Is that what you really want?

Submitter : **Miss. Lauren Palowitz** **Date: 02/07/2007**

Organization : **Ohio Northern University**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Leslie,
Hello, I am Lauren Palowitz. I am currently a 6th year Pharmacy student at Ohio Northern University. I hope to someday open my own pharmacy and I am concerned about how this will affect my pharmacy. I realize that as I student I haven't fully grasped this concept, but I don't understand why the pharmacy is the organization that will be shorted, when the drug companies are who make the greatest profits. I hope to see in the future a way that drug companies have some regulation of what CMS will pay and therefor how much they can charge the pharmacy, but at this point in time, I do not feel that it is fair to pentalize the pharmacy and pay them less than they are paying for a medication.
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Thanks,
Lauren Palowitz
Pharm D Candidate
Expected Graduation May 07

Submitter : **Mr. Todd Doxtater** **Date: 02/07/2007**

Organization : **ShopKo Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

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I am writing to express my concern over proposed regulations concerning reimbursement on generic medications. I am a staff pharmacist at ShopKo Pharmacy in Kimberly, WI. I do not have decision making power over pricing, purchasing, or third party contracts, but I believe that lowering of reimbursement rates will affect my practice of pharmacy.

It is obvious that as reimbursement rates decline, so will payroll allocated to pharmacist hours. I take pride in consulting patients on the importance of their medication therapy and the effects on their overall health. On a minute by minute basis, I am reviewing proper dosing, drug interactions, drug disease interactions, cost saving alternatives, not to mention that the right medication is in the right bottle for the right patient. If these responsibilities do not warrant a fair reimbursement from Medicare or other third parties, the contribution of pharmacists and the outcomes of medication therapy will be jeopardized and the safety of the patient will be severely compromised.

I support the comments being filed by the National Association of Chain Drug Stores regarding the proposed regulation. I appreciate your consideration of these comments and ask that you contact me with any questions. Thank you.

Sincerely,

Todd Doxtater, R. Ph.
505 Kokke Lane
Kimberly, WI 54136
920 687 0548