CMS-2238-P-458

Submitter : **Mr. Anthony Sartoris** **Date: 02/13/2007**

Organization : **Doc's Drugs Ltd.**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

President of Doc's Drugs, 17 store family owned and operated pharmacies serving the people of rural Illinois since 1978.

GENERAL

GENERAL

See Attachment

CMS-2238-P-458-Attach-1.DOC

Submitter : **Date: 02/13/2007**

Organization :

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.

Submitter : **Mrs. larry milewski** **Date: 02/13/2007**

Organization : **larry's pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Larry's Pharmacy is writng to provide our views on CMS December 20th proposed regulations that would provide a regulatory definition of AMP as welll as implement the new Medicaid Federal Upper Limit program for generic drugs.My pharmacy is a major provider of pharmacy services in the community of Humboldt.

Collection of Information Requirements

Collection of Information Requirements

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 low0cost generic medications.

GENERAL

GENERAL

I urge you to reconsider this proposed regulation. If this regulation is passed I will not be able to continue in business. I cannot give away drugs. I cannot dispense drugs below costs and expect to stay in business. Visit an independent pharmacy and notice the customer care that is given in this type of pharmacy.We don't dispense meds to make a huge profit- but we do care for the customer. However, we do need to make a profit in order to stay in business. Pharmacist need six years of education and their salaries are high. How can I pay my pharmacist if I am dispensing meds below my cost?

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I ask that CMS please do the following: Delay Public Release of AMP data.they sould also define AMP to reflect retail pharmacy purchasing costs. They should delay new generic rates that would significantly underpay pharmacies. And they should require that states increase pharmacy dispensing fees.

CMS-2238-P-461

Submitter : **Date: 02/13/2007**

Organization :

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-462

Submitter : **Mr. Robert Wilkins** **Date: 02/13/2007**

Organization : **Buehler's 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.
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-463

Submitter : **Date: 02/13/2007**

Organization : **Virginia Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

VPhA continues to support federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. 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.

Collection of Information Requirements

Collection of Information Requirements

See attachment

GENERAL

GENERAL

See attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

See attachment

Response to Comments

Response to Comments

See attachment

CMS-2238-P-463-Attach-1.PDF

Submitter : **Date: 02/13/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Leslie Nowalk,

I am a sixth year (last year) pharmacy student. Passing this legislation will ruin my future pharmacy career. I cannot adequately do my job as a pharmacist, improving patients' lives, if I can't even cover the costs of my job. How are independent pharmacies supposed to survive on this legislation? How can you devalue the face of pharmacy? Why should someone like myself go through 6-8 years of schooling when the "reward" at the end is to be paid based on the cost of drug instead of the value of my service?

Please refer below to the statement published by APhA.

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.

Thank you for your consideration of this matter!

Submitter : **Mr. David Cochran** **Date: 02/13/2007**

Organization : **Corley Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This particular rule is a very bad idea. First, it has already been shown that the actual reimbursement proposed will be far less than what we as retail pharmacies can purchase the product for. The formula is taking into account all of the rebates and special pricing afforded to the "closed door" specialties such as nursing homes, mail order houses, and hospitals. This plan would not be so detrimental if we could gain the same pricing as the above mentioned entities. Secondly, AMP was never intended to serve as a baseline for reimbursement. Therefore, the formula must be tweaked to provide a true cost. Thirdly, rebates affordeed to the PBM's should not be used in the calculation since the retail pharmacies never receive any of this rebate in any form. Fourthly, AMP should be reported weekely since pricing of drugs ean change dramatically. If it is done at the end of a month and there is a 30 day grace period on this, the cost could be higher for 2 months before ever being reflected in the AMP cost ealculation. What does this mean to my pharmacy? I am approximately 35% medicaid. I will not be able to accept medicaid if the formula goes into affect as it is written now. I would then have to close my pharmacy or turn away many of my customers. Of course the typical response is that they can go someone else. The chains could in no way handle the increase in volume if most of the independents were forced to close their doors or turn away the medicaid population. This would lead to poor service to a very needy population.

CMS-2238-P-466

Submitter : **Ms. Jessica Knodel** **Date: 02/13/2007**

Organization : **American Pharmacists Association**

Category : **Individual**

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.

CMS-2238-P-467

Submitter : **Mr. Craig Willimann** **Date: 02/13/2007**

Organization : **Pratt's Rexall Drugs, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

CMS-2238-P regarding the implementation of AMP as a reimbursement benchmark for precription drugs will take effect this year.

GENERAL

GENERAL

The implementation of AMP as a measurement for pharmacy reimbursement is as misguided as it gets. AMP will be figured based on pricing that mail-order, outpatient pharmacies, and other pharmacy outlets may get that community pharmacies can't. Commmunity pharmacies don't have access to the rebates, discounts, and special pricing that the other pharmacy types mentioned above do to offset this erroneous AMP pricing formula.

Studies by GAO have shown the detrimental effect imposing this new AMP will have. The federal gov't has already shown their indifference to community pharmacy's plight by the Part-D effects that have already strained our ability to run a business and provide good patient care.

I have been forced to cut back my Part-time Pharmacist work time from twice a week to twice a week to cut expenses. I also don't call in for temporary Pharmacy Tech help to cover when one of my Techs are not able to work their normal shift. The effects from your AMP propasal are only going to further deteriorate the ability to provide service and care to our customers.

CMS needs to realize they have already strained the ability of pharmacies to provide quality care. The time has passed to where your requirements for quality care and reimbursement to provide that care are out of balance. How bad does it have to get before CMS gets the point!!!!!!!!!!!!!!!

CMS-2238-P-468

Submitter : **Mr. Jon Copeland** **Date: 02/13/2007**

Organization : **Associated Pharmacies Inc**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

see attachment

Collection of Information Requirements

Collection of Information Requirements

see attachment

GENERAL

GENERAL

see attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

see attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

see attachment

Response to Comments

Response to Comments

see attachment

CMS-2238-P-468-Attach-1.PDF

Submitter : **Jordan Blaney** **Date: 02/13/2007**

Organization : **APhA-ASP**

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.

CMS-2238-P-470

Submitter : **Hal Sims** **Date: 02/13/2007**

Organization : **Medical Arts Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a Pharmacy owner and have been a pharmacist since 1973. I have won 2 national awards and been a "Patient Advocate" for all those years and have been a Service Plus pharmacy. We do not just robotically dispense pills. We are the only pharmacy to offer some valuable services for our patients in this community.

Collection of Information Requirements

Collection of Information Requirements

The AMP regulations as they stand is 36% below our cost for re-imbursement. I won't accept that. The GAO has verified the 36% below cost figures.

GENERAL

GENERAL

AMP is ill-advised at this re-imbursement. I for one will not accept the below cost re-imbursement. If I have to close my doors and the community suffers it will be a shame and these patients are not only patients, but rather friends, which I have proudly helped for years. This is shameful to destroy such an honorable profession and put the patients in jeopardy acrpss the U.S.

Response to Comments

Response to Comments

This current AMP re-imbursement rate will close my doors. We offer services to elderly home bound patients which no one else offers, plus many more specialized services.

CMS-2238-P-471

Submitter : **Date: 02/13/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I am very concerned about my local pharmacy being able to fill prescriptions for the Medicaid recipents in our area. Our community pharmacist is one of the kindest and most respectable citizens in our community. If the proposed rule goes into affect as currently written, I fear that our local pharmacy will no longer be financially able to accept medicaid. We are located in a very rual area with very little healthcare options. The young man that operates the local pharmacy provides a valuable service that we could not live without. The next closest pharmacy is 30 miles away, making it prohibitive for many of the elderly and poor citizens access to their life saving medication.
Sincreley,
Concerned rural citizen of southwest VA

Submitter : **Mr. Joseph Bushardt** **Date: 02/13/2007**

Organization : **Small Business Owner**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

In December, CMS published its proposed rule to implement the part of the Deficit Reduction Act of 2005 that changes the Medicaid program's reimbursement for generic medications. The proposed regulation would base reimbursement for generic medications on 250% of AMP. The proposed regulation outlines what CMS has determined as the most appropriate way to determine AMP, including the sales, discounts, rebates, and price concessions to include in the AMP calculation. It also defines the prices that are included and excluded in "Best Price". Other issues addressed include dispensing fees, federal upper limits for generic medications, and nominal pricing.

Collection of Information Requirements

Collection of Information Requirements

The new regulations on AMP (Average Manufacturer Price) sets the Federal Upper Limit rate at 250% of the lowest AMP for a dosage form and strength of a drug.

GENERAL

GENERAL

How do we solve the healthcare problem? 1. Pharmacy: Allow all retail outlets buy drugs for the same price. Establish a fair cost to dispense a medication and a reasonable markup to establish an allowable price for US government to pay. Disallow kickbacks and special interests for doing business. Let our trained physicians decide what drugs to be used for each patient. This is my area of expertise, so I think you should consult physicians, hospital staffs, and etc to correct the rest.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

1. Do all community retail entities buy drugs at the same price? 2. What are the differencies in purchased drugs for all the retail outlets (HMO's, Mail Order Pharmacies, Hospital Pharmacies, Federal Agency Pharmacies, Chain Pharmacies, and Independent retail pharmacies)? 3. If their is a significent difference, are you discriminating against some retail outlets? 4. What outcome will this legislation have on the outlets with the highest drug purchasing cost? 5. What outcome will it have on rural pharmacies that have high Medicare and Medicaid volumes? 6. What outcomes will it have on the health and well being of the patients in low income rural areas and retirement communities? 7. If small rural pharmacies go out of business, will the price of health care spiral out of control in these areas due to lack of a segment of medical care? 8. The importance of rural health clinics and hospitals have been studied, but have the importance of rural pharmacies been studied? 9. Are difference reimbursements being studied according to the needs of the phamacy outlets patrons (like rural health clinics)? 10. Has the fact of cost of filling a prescription of $10.50 to $12.10 been factured into the equation?

Regulatory Impact Analysis

Regulatory Impact Analysis

This legislation is clearly a one sided study of big business to our present legislators that will have a negative impact on many small businesses and their patients. This legislation could easily cost the US more than the money it expects to save over the next few years. If you want reform, why do you attack the 8% part of the budget instead of going after the 92%?

Response to Comments

Response to Comments

1. This legislation could cost the independent pharmacy (who pay the greatest price for drugs) as much as $3 to $4 per generic prescription to fill which would mean a net loss to fill these prescriptions. 2. In rural areas where their are a lot of low income patients, this would mean that many small businesses would go out of business. 3. All educated people know that the way to save money in a drug program is to dispense generics, and AMP discourges dispensing generics. 4. When you lose pharmacy outlets in rural areas, the health care in that area will skyrocket. 5. If big business says mail order to these areas will surfice, then they are dead wrong because of the more prevelance of the inability to do what is required to obtain their medicines. 6. I believe the US will have less healthcare for more money.

Submitter : **Date: 02/13/2007**

Organization :

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

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.

Submitter : **Trish Hernandez** **Date: 02/13/2007**

Organization : **Wal-Mart Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 13, 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 New Bern, 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,

Trish L Hernandez,RPh

Submitter : **Dr. Lori Brown** **Date: 02/13/2007**

Organization : **Kerr Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located in Raleigh, 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,

Lori Brown, PharmD
Manager of Clinical Services, KDICS
Residency Preceptor and Adjunct Faculty, UNC School of Pharmacy

CMS-2238-P-476

Submitter : **Dr. J` David Hester** **Date: 02/13/2007**

Organization : **Rhea Medical Center**

Category : **Pharmacist**

Issue Areas/Comments

Response to Comments

Response to Comments

Our CPSl does not produce an 11 digit NDC code. To submit such a code would be many extra man hours to manually submit such numbers. As I'm such you are aware, many small rural hospital, like ours, are already having trouble meeting patient needs with staff we have. Our pharmacy has one full time pharmacist and one certified tech.
J. David Hester, DPh

Submitter : **Dr. Jason Dorsey** **Date: 02/13/2007**

Organization : **University of Toledo**

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.
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. Donald Hagler** **Date: 02/13/2007**

Organization : **Reagan Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am writing you concerning the Deficit Reduction Act of 2006. We are a small community pharmacy in southeast Alabama. If the Deficit Reduction Act is enacted as law the way it is currently written, we will no longer be able to accept state medicaid patients. As with any business, we cannot operate at a loss. If you will take the time to investigate, you will see that the reimbursment rate is less than the actual cost of the medication we are dispensing. Average Manufacting Price (AMP) plus 250% is still LESS than our actual acquisition cost (AAC). AAC is what we actually pay for medications, bottom line.. that is it. We can't be expected to sell medications at at loss.. such as this law will mandate that we do. If AMP is not defined in such a way that will allow us a reasonable profit, we will no longer accept medicaid at our pharmacy. Thousands of needy medicaid recepients will not be able to obtain there life-saving medications. They will have to go to the nearest emergency room for their illnesses, which will prove to be an enormous cost to the government for healthcare. We at Reagan Pharmacy provide more than just medicine, we provide conseling, delivery, Medication Therapy Management, Disease State Management, and many other services that prove to be helpful to our patients. Without Reagan Pharmacy and thousands of other community pharmacies across this nation, thousands upon thousands of needy patients will be denied the healthcare they deserve. Please help us help them by defining AMP to assure us of a reasonable and fair profit.

Sincerely,
Don Hagler, R.Ph.

Submitter : **Mr. Scotty Baker** **Date: 02/13/2007**

Organization : **Baker's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

36 plus years of pharmacy practice.Multiple work experiences including retail, chain and hospital. Positions held - staff pharmacist, manager, purchasing manager, pharmacist-in-charge and owner. I have sat on boards, served in the state pharmacy association and have intimate knowledge of price manipulations by drug companies, PBM's, non-profit hospital pharmacies, chains and goverment agencies. I currently own and manage an independent pharmacy in a very small rural town of 1,500 people in north central Arkansas.

Collection of Information Requirements

Collection of Information Requirements

It appears that reimbursement will be limited to "estimated acquisition cost." Vol 71 No.246 12/22/2006 page 77176 Section 447.502 Definitions - If this is true all retail pharmacies in Fulton County Arkansas will close their doors within days of implimentation of the Deficit Reduction Act of 2005. Selling medications below cost is economic suicide. For every seller there must be a profit whether it be for services or for merchandise. Pharmacy sells both and must have a profit to survive. Selling below cost will bankrupt even the best managed, best staffed and best financed pharmacy.

Mail order pharmacies are not retail pharmacies. page 77178-77179 sec 447.504 They do not provide the expected and needed services a retail pharmacy provides. Nor do they provide identical medications. A drug company makes a profit by selling medications.
A drug company charges many times the cost of the ingredients to cover ALL their cost. They do not sell medications to different classes of trade (mail order, hospitals, government, retail, just to name 5 classes) at the same price but they always know what the cost is. Retail pharmacy almost without exception pays the highest prices. I have seen differences in price range from 3% to more than 5000%. Volume of sales is a common excuse drug companies employ but refuse to honor when a buying group offers to purchase their elusive dollar or unit volume requirement. Drug companies employ several other methods of hiding the true cost of drugs to different buyers.
Shelf space allowances, eductional promotional allowances, site location allowances, advertising allowances, warehousing allowances, un-announced special buying periods,selective unit sizes and can manufacture new incentives as the need arise - of which retail pharmacies are excluded from.
page 77187-77188 - Upper limits for multiple source drugs.
11 digit NDC's are better than 9 because it limits the drug companies from 1 of their favorite methods of excluding retail pharmacies from the best prices available. This section does not
take into account the huge variations in prices between companies and
even the very large price variations by a single company using multiple allowances to reward different buyers. Drug companies may "play" with their prices but they always guard the final bottom line. Why not regulate them as much as you regulate retail pharmacies concerning prices? The size of the professional dispensing fee to cover the extremely large price differences in cost of product would have to be outrageously large. Due to the estimated acquistion cost being flawed - everything else is shifted to the absurd.
Pages 77190-77194 Impact analysis.
The impact of this loosely defined, poorly understood, ill advised method of determining cost will make Hurricane Katrina look like a picnic. There will be more pharmacies "killed" than Katrina by a 100 fold. The lost of jobs coupled with the lost of these pharmacies will never be recovered.

The lack of hard data and heads-in-the-sand by non-pharmacy administrators make even arguring this matter difficult.

Why must retail pharmacies who provide real savings and life saving heroic service pay for drug companies to become richer and reward those who are worse than used car salesmen.

In summary

1 Stop right now and gather real data.
2 Pay for what you get. Retail pharmacies provide more necessary
services. So they should get paid more. Mail order - well that
says it all - that is all they give and they should get paid less,
significantly less.
3 Rebates, kick backs, allowances, discounts and all other schemes
should be declared illegal OR not counted in A<P calculations.
4 The percentage of disparity should be less than 10% between the
lowest AMP and the next lowest AMP.
5 Every price should be determended on the 11 digit NDC and a maxium
of 7% between the lowest and the highest price.
6 48 hrs to correct below cost ..

Submitter : **Dr. Jason Turner** **Date: 02/13/2007**

Organization : **Moundsville Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Medicare Reimbursement May be Detrimental to ALL Pharmacies

Proposed cuts in Medicaid pharmacy reimbursement and inadequate state dispensing fees are threatening the health and safety of millions of Americans by driving independent community
pharmacies out of the Medicaid program, and even out of business.

In thousands of communities across the nation, the local community pharmacy is a vital, indispensable community health resource!

More than 50 percent of community pharmacies are located in an area with a population of less than 20,000. For the average independent pharmacy, 20 percent of prescriptions dispensed are for Medicaid recipients.

Pharmacies are being forced to operate below their costs!!!

In December, CMS proposed $8.4 billion in Medicaid cuts over the next five years. More than 90 percent of those cuts are expected to come from slashing pharmacy reimbursement for generic prescription medicines to Medicaid patients. A study released by the Government Accountability Office (GAO) on Jan. 22 found that basing reimbursement on a new Average Manufacturer Price formula, as dictated by CMS, will result in pharmacists being paid, on average, 36 percent less than their acquisition cost on Medicaid prescriptions.

On January 31, the Coalition for Community Pharmacy Action released a study on the cost to dispense a prescription, based on data from nearly half of all the retail pharmacies in the country. The study found it costs an average of $10.50 for a pharmacist to dispense a prescription, not including the cost of the medication itself.

The GAO report, together with the cost to dispense study, highlights the steep shortfall between pharmacy costs and the new pharmacy reimbursement proposed by CMS for the Medicaid program.

The Bottom Line for me, Jason Turner is the following&

AWP was not the most cost effective calculation to reimburse for prescription drugs, HOWEVER, AMP is not the step in the right direction. While the design may seem cost saving, the effects will be detrimental to the practice of pharmacy, all pharmacy, whether independent or chain pharmacies.

In order to most accurately and most cost effectively reimburse for prescriptions medications, there are two separate and equally important components which need to be addressed&the cost of the medication and the cost of dispensing the medication. To cost effectively reimburse for prescriptions, the cost of the medication should be reimbursed based on a fair and reasonable calculation based on the pharmacies cost of the drug PLUS a fair and reasonable DISPENSING FEE!

The current formula suggests a 150% markup (250% of cost) on the cost of the drug from the manufacturer. Does this seem like an appropriate margin??? The fact is, there are too many other factors which make even this extreme markup based on MANUFACTURER drug cost and a minimal dispensing fee of $1.00 a financially detrimental prescription to fill by any pharmacy.

IN ADDITION, the dispensing fee for most states is $4.00 per prescription, when studies have illustrated cost of dispensing of $10.50. With many states have a dispensing fee of only $1.00 or $1.50. Does this seem like an appropriate dispensing fee???

I request that the current plan be re-evaluated with a more reasonable mark-up determined, such as a reasonable and fair percentage markup on the PHARMACIES ACTUAL COST ON THE DRUG&PLUS A REASONABLE DISPENSING FEE OF $10.50.

Please share any comments or concerns&

Sincerely,

Jason Turner
Moundsville Pharmacy
115 N. Lafayette Ave
Moundsville, WV 26041
304.845.0390

CMS-2238-P-481

Submitter : **Miss. Shana Snook** **Date: 02/13/2007**

Organization : **Ohio Pharmacists Association**

Category : **Individual**

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. BLAKE GOWEN** **Date: 02/13/2007**

Organization : **PAYLESS PHARMACY**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

RE: CMS-2238-P "AMP CALCULATION PROPOSED RULE".

Collection of Information Requirements

Collection of Information Requirements

THE PROPOSED REGULATION IS ATTEMPTING TO REDUCE "NET" EXPENDITURES
OF THE MEDICAID PROGRAM THROUGH THE IMPLEMENTATION OF A NEW BASIS OF REIMBURSEMENT FOR PHARMACEUTICAL PRODUCTS PROVIDED TO BENEFICIARIES
BY TARGETING COMMUNITY PHARMACY PROVIDERS.

GENERAL

GENERAL

THIS PROPOSED LEGISTLATION IF MANDATED AS IS WILL HAVE A CATASTROPHIC
IMPACT ON INDEPENDENT PHARMACIES AND A NEGATIVE IMPACT ON THE
HEALTH CARE OF THE VERY BENEFICIARIES THAT MEDICAID IS SUPPOSED TO
PROTECT. THE AMP-FULS WILL BE CATASTROPHICALLY LOWER THAN THE AVERAGE RETAIL PHARMACY ACQUISITION COST THAT ARE PRESENTLY AVAILABLE. JUST LIKE THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
COMMUNITY PHARMACIES DEPEND ON MONEY TO BE ABLE TO CONTINUE TO PROVIDE STELLAR SERVICE TO THE PEOPLE THEY SERVE. THEREFORE I URGE
YOU TO CONSIDER THE COMMENTS MADE BY NCPA (NATIONAL COMMUNITY PHARMACY ASSOCIATION) IN REGARDS TO THIS PROPOSAL. SUCH AS
AMP MUST DIFFER FROM 'BEST PRICE', PBM TRANSPARENCY NECESSARY TO
ASSESS MANUFACTURER REBATES, AMP MUST BE REPORTED WEEKLY, AND
AMP MUST BE REPORTED AT THE 11 DIGIT NDC TO ENSURE ACCURACY.
THANK YOU FOR YOUR CONSIDERATION ON THIS VERY IMPORTANT MATTER. SEE ATTACHMENTS

CMS-2238-P-482-Attach-1.PDF

CMS-2238-P-483

Submitter : **Mr. Joseph Cross** **Date: 02/14/2007**

Organization : **Southwest Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a practicing independent community pharmacist with 20 years expierence.

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP will likly be the basis of my reimbursement for my Medicaid customers and could serve as a template for all other third party benefits managers to set my reimbursement based on these new standards. I agree AWP does not acurately reflect the cost of generic drugs but this is irrelevent when looking at the aggressive MAC pricing used by most payers, including Medicaid.

GENERAL

GENERAL

Generic drug pricing changes drastically overnight. AMP imposed on community pharmacies needs to be realistically based on what community pharmacies can purchase at.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Using PBM rebates and mail order pricing discounts does not accurately reflect what I can buy drugs for. It is unfair to base my reimbursement using data that doesn't accurately reflect my cost.

CMS-2238-P-484

Submitter : **Mr. John Schipisch** **Date: 02/14/2007**

Organization : **Drake's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed reimbursement schedule based on AMP presents a major concern to rural pharmacies such as ours. Preliminary analysis indicates that after July 1, 2007, we will no longer be able to participate in the Medicaid program. Our situation in not unique, and we believe that many people throughout the country will lose access to pharmacy services.

CMS-2238-P-485

Submitter : **Rex Cramer** **Date: 02/14/2007**

Organization : **Quay Drugs**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

54 year independent retail pharmacy located in relatively rural, low income area of Ohio

GENERAL

GENERAL

The proposed extreme generic cost determination being proposed to be implemented this July would be a devastating blow to my operation, along with most pharmacy services. The people on these medicaid rolls have many special needs due to the socio-economic position that they are in. If pharmacy is asked to supply generic drugs at a loss, then these people will be left without available service, and the local pharmacy will be severely harmed financially also. It is totally reasonable for a pharmacist to expect to be fairly reimbursed for the products & services (home delivery, drug counselling) that that pharmacist provides. I request that this federal agency re-do this terrible cost determination formula to one that is going to allow us as pharmacists to continue to provide the services in our locale.

CMS-2238-P-486

Submitter : Sherry Schaffer **Date:** 02/14/2007

Organization : Ohio Pharmacists Association

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 no 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 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 comunity 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-487

Submitter : **Mrs. Lorna Danko** **Date: 02/14/2007**

Organization : **CVS/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.
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-488

Submitter : **Mr. David Upson** **Date: 02/14/2007**

Organization : **Palm Beach Pharmaceuticals Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

If CMS -2238-P aka AMP Calculation Proposed Rule is implemented I predict that numerous pharmacies will stop filling prescriptions for Medicaid Beneficiaries. Is this what you really want?

CMS-2238-P-489

Submitter : **Mr. Dan Fucarino** **Date: 02/14/2007**

Organization : **Mr. Dan Fucarino**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Leslie Norwalk Esq., 2-14-2007

Rather than both you with details that you surely have at your fingertips. Please consider that using AMP as a base for pricing third party prescriptions is nebulous, confusing, and open for entirely too much room for error. As presented, it will surely be the nail in the coffin of small community pharmacies throughout the United States. The impact that this will have on most patients will have a price tag the will dwarf any savings incurred by the new pricing. I beg you to consuider all these things before making this law.

Thank you for your consideration,

Dan Fucarino RPh

CMS-2238-P-490

Submitter : **Ms. Mary Riegle** **Date: 02/14/2007**

Organization : **MBR Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am a new pharmacy owner. I have spent many hours on the phone trying to resolve problems with third party payors for patients. If I were to price the time spent researching information for patients and deduct that from current reimbusement rates I would show no profit. Fortunately I am a pharmacist and do not have to pay a pharmacist or my doors would close. How can I suvive at a 36% reimbursement reduction based AMP? AMP does not reflect accurately pharmaceutical cost. It certainly does not reflect total dispensing cost AND patient counseling. In an effort to help more people obtain better medical care you are actually eliminating the one profession that they trust and have the most contact with, pharmacists. Please review your information and find a better resolution to the problems facing health care. Taking monies from pharmacies is the easy way, we have fewer lobbiest. Taking direct pharmacist contact away from patients is the most harmful way for patients. Please reconsider.

CMS-2238-P-491

Submitter : **Mr. robert kerek** **Date: 02/14/2007**

Organization : **Mr. robert kerek**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am an independent retail pharmacist/owner of a small community pharmacy. The proposed legislation regarding reimbursement to the pharmacist at Average Manufacturers Price will virtually drive me out of business. This pharmacy has provided health care for over 50 years to the community where it is located. There would be an immense negative impact on the local population if this business would be forced out. The only alternative I would have would be not to accept medicaid and medicare prescriptions. I would definitely implement that step in order to survive. Please do not pass this rule, for the sake of those living in this community. Thank you.

CMS-2238-P-492

Submitter : **James Turner** **Date: 02/14/2007**

Organization : **James Turner**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Mr. Leslie Norwalk-I have owned and operated an independent pharmacy for 25 years in Galesburg, Il. The formula for AMP, based on Federal upper limits (FULs) in the proposed rule, will not cover pharmacy acquicition costs for multiple source generic drugs. The GAO, in their latest report, found the price CMS would pay was, on average, 36% lower than I can buy the generic drugs for. How can anyone expect a business of any kind to sell it's product and loose 36% on each sale?! This is a formula for econimic and professional disaster! CMS obviously does not know much about retail pharmacy. When determining AMP, it includes price concessions by manufacturers and special prices to mail order facilities and PBMs. Guess what?? I don't get any of these special prices! How can I be held to pricing that I cannot get? Also, AMP should be reported at the eleven digit NDC level. My reimbursement should not be based on buying quantities that are impossible and unrealistic for an independent pharmacy. In conclusion, AMP, as it stands, is a formula for economic disaster. It holds me, and other independent pharmacies, to prices I cannot recieve and requires me to sell prescriptions far below cost. I don't want to walk away from 25% of my patients, but this formula leaves me little choice. Again, this is another example of government not knowing an industry and enacting laws that will cause it irreputable harm. I, for one, am getting sick of it! Don't tell me the Government cares about small business!! Jim Turner, RPh

CMS-2238-P-493

Submitter : **Mr. Jeremy Mable** **Date: 02/14/2007**

Organization : **University of Toledo**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This would effectively put nearly all pharmacies out of business. I work in a pharmacy as a pharmacy intern (I will be sitting for the boards in 17 months) in a low-income area and over 60% of our prescriptions are billed to Medicare/Medicaid. This would reduce our income by nearly 15% and would force use to eliminate MTM, and other services we provide to our patients free of charge. This will not fix the problem and is only a poorly researched band-aid.

CMS-2238-P-494

Submitter : **Dennis Chance** **Date: 02/14/2007**

Organization : **Taylor's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

If the bill concerning AMP is allowed to take effect it will bankrupt
most of the independently owned drugstores in this country. We have been bled dry by absurd contracts forced on us by insurance companies. All government officials think the only way to lower drug prices is screw the pharmacist. The amount spent by the drug industry bribing congressmen, excuse me the politically correct term is "lobby", exceeds the congressmen's annual salary. Medicare Part D
was written by the drug and insurance lobbyist and is tremendously profitable for both concerns. Pharmacy payments are TOO LOW and
TOO SLOW. A lot of press has been given to some congressmen being accused of corruption. HELL they are all corrupt. This mess and other garbage like mail order pharmacy would not exist if it weren't for the stupidity of pharmacists. If there are ANY reductions in our payments then the bankruptcies will begin. To show you how things in the real world are consider this. Today in Feb 14th. If I order a drug from my wholesaler today and sell it tomorrow on Medicare Part D I will have to pay my wholesaler for the drug on Feb. 25th. I will be lucky if Part D pays me for it by March 25th. You don't even need a high school diploma to know this bad business. But the pharmacists have been laughing stock of the business world for years.

Dennis Chance R.Ph.
Taylor's Pharmacy
508 High School Ave
Columbia, MS 39429
601-736-2271
mdubone5@bellsouth.net

CMS-2238-P-495

Submitter : Mr. Jerry Duren **Date:** 02/14/2007

Organization : Duren Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The implementation of AMP will be an in-justice to those that use this service and to those that pay for the service. The end result will BE that many pharmacies will have to discontinue serving this population group since the cost of the medication is greater than the reimbursement. Generics save money for Medicaid, this will just cause a shift from generics to brand name drugs, which will result in significant additional cost to the taxpayers. If AMP IS TO BE USED UNDER THE PRESENT TERMS, THEN A DISPENSING FEE OF $25.00 MUST BE IMPLEMENTED, so that pharmacies can continue to deliver this integral part of the health care delivery system.

CMS-2238-P-496

Submitter : **Mr. Gabriel Stapleton** **Date: 02/14/2007**

Organization : **Mr. Gabriel Stapleton**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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.
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-497

Submitter : Mr. John Johnson RPh **Date:** 02/14/2007

Organization : Mr. John Johnson RPh

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a registered pharmacist with over 25 years of hospital pharmacy experience, and also do some local (independant) retail work as well.
The proposed CMS changes, as currently written, may cause a terrible strain on the abilities of retail pharmacies, especially independant (non-chain stores such as WalGreens or WalMart) to continue to survive. I would like to suggest a few modifications of the current proposal that might help prevent the closing of retail pharmacies, especially in small-town rural America.

Collection of Information Requirements

Collection of Information Requirements

CMS proposes to allow the states to set the dispensing fee instead of having a federal guideline.

Also, CMS's definition of "average manufactorer's Price" is a calculation of 250% of the Federal Upper Limit of the lowest price drug in that class instead of a more scientificlly sound review and average of the costs that retail pharamcies are actually paying.

I suggest (comments below) that there are better alternatives to these proposals.

GENERAL

GENERAL

CMS proposes to allow the states to set the dispensing fee, which might vary widely from state to state. It has been suggested that this will drop from perhaps an average of $10.00 to $4.00. This drastic decrease is un-warrented, and draconian in nature. If the new average is $4.00, then this means that there will be some pharmacies that will get less than $4.00 which is not fair.

Regarding the definition of "average manufactorer's Price" CMS's proposal to use a calculation of 250% of the Federal Upper Limit of the lowest price drug in that class may penalize local retail pharmacies that do not have access to this lowest price drug(s), and cause their acquisition fees to be higher than the reimbursement cost.
A more scientificlly accurate review of the prices that retail pharmacies are actually paying would in my opinion be more fair to the pharmacies that are actually providing medications to the public.

I urge you to consider these and other points brought forward by pharmacists and organized pharmacy groups before these proposals are finalized. Please do no penalize local retail pharmacies for trying to continue to be independant employeers in their home towns. Having "big-box" chain drug stores across America is just not warrented. Thank you.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The American Pharmacists Assoc. (APhA) has information available to the CMS to support suggested changes to the regulations.

Regulatory Impact Analysis

Regulatory Impact Analysis

See general comments

CMS-2238-P-498

Submitter : Mr. Everet Lewis, Jr **Date:** 02/14/2007

Organization : Dallas Express Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

regarding CMS-2238-P

I am writing to express my displeasure with the proposed reimbursement for Medicaid using the AMP price guidelines.

I am afraid that you are putting a hardship on independent community pharmacies that may forever affect prescription assessibility for program beneficiaries. Still struggling with decreased revenues from the implementation of Medicare Part-D, now we are faced with the continual erosion of profitibility of our stores. It is true that independent pharmacies may not have the buying power of chains, government agencies and mail order pharmacies (which are usually operated by the large chains or PBMs.)

AMP prices do not reflect a true cost that pharmacies may have in the purchase of prescription drugs. We are unable to purchase either through unavailability or exclusion certain drugs that may have an AMP at a reasonable cost.

A recent article I read stated the average cost of dispensing an Rx is now $10.50. I am not stating that we need that as a reimbursement level. I understand that is not reasonable to expect. It would be nice to however have a level that allows reasonable profit and return on investment. I became a pharmacist to help provide a needed service for my customers and became a store owner in order to give better customer service than I could provide as a chain pharmacist. It was also to hopefully make a reasonable profit.

Independent pharmacies have always provided services that chain were not always willing to provide. Many are also located in rural areas which may not be serviced by the chains. If independent pharmacies fail (due to financial reimbursement or too little of) it will make a void in prescription availability to some of the program beneficiaries.

Thank you for your time in reading my viewpoint. Please protect the future of pharmacy and the accessibility of services to the people that need them.

CMS-2238-P-499

Submitter : **Miss. Linda Graf** **Date: 02/14/2007**

Organization : **Miss. Linda Graf**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Linda Graf, and I am a pharmacy intern at Kroger Pharmacy #16315 in Columubus, Ohio. My pharmacy is located in an urban area, and our patient demographic consists primarily of Ohio Medicaid and Medicaid/Medicare dual eligible patients. The proposed AMP definition under CMS-2238-P "Prescription Drugs" will not only cause great harm to pharmacies in urban areas with a similar patient demographic, but also independent and chain pharmacies as a whole.

It is estimated that the reimbursement rate for generic drugs 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 my pharmacy and other chain and independent pharmacies actually pay for these drug products. If reimbursements do not cover costs, many independent pharmacies may have to turn away their Medicaid patients, and urban pharacies such as mine may have to do the same.

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 much freedom 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 independent and chain pharmacies. 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 who already have trouble accessing adequate health care, especially in rural and urban communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs. Unles AMP is defined to cover acquisition costs, an incentive will be created to dispense more brand drugs which could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price (AMP) that covers independent and chain pharmacy costs. The definition should be issued as soon as possible, before AMP takes effect.

Sincerely,

Linda Graf
Pharmacy Intern
4th year PharmD candidate
The Ohio State University

CMS-2238-P-500

Submitter : Mr. Eric Graham **Date:** 02/14/2007

Organization : Red Crown Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Re: CMS proposed AMP reimbursement for pharmacies.

I am an indepedent pharmacy owner located in Kalamazoo, Michigan. My pharmacy takes great care in providing pharmacy care to all of our patients including those on Michigan Medicaid. We have been reluctant to speak out with regards to the lack of reimbursements and dispensing fees from insurance companies for fear of audits by the insurance companies or even cancellation of our contract if we don't accept their 'take it or leave it' negotiation tactics. Therefore, pharmacies reluctantly continue to sign and accept lower reimbursements and dispensing fees because we don't have a collective voice to help us combat this practice. We are now faced with CMS and proposed AMP based reimbursements.

Each year is another year that reimbursements become smaller and we have to fill more prescriptions in order to stay in business.
Independent pharmacies continue to be targeted as a means to help reduce budgets by reducing pharmacy reimbursement and dispensing fees. I hope CMS and others understand when pharmacies lose money we also fire employees who rely on small business for employment. CMS should be reminded that such decrease in pharmacy reimbursements will also cause higher unemployment. These situations are easily documented, but as a pharmacy we do not see the pharmacy benefit managers (PBM's) being aggressively assaulted year after year like community pharmacy.

CMS has proposed that community pharmacies be reimbursed based on AMP. It concerns me that CMS will not listen to the experts in reimbursement policies, such as pharmacists, pharmacy organizations, and congressional parties with understanding.

Community Pharmacies provide exceptional care and benefit to people and this time spent with each person is expensive. If CMS continues on the path to reimburse community pharmacies based on AMP and insignificant dispensing fees, I foresee a majority of pharmacies no longer supporting Medicaid programs because it will cost them money to fill prescriptions. Furthermore, it's only a matter of time before community pharmacies band together to stop such practices as this and I look forward to supporting such action. Remember, in order to stay in business I have to make a profit. We fight each day to survive and I hope CMS will find the courage to support community pharmacy and help us to thrive and not struggle with decisions over humanity. Stop bleeding local community pharmacies and start looking into PBM's and Drug Manufacturers!

Warmest Regards,
Eric M Graham, RPh.

Submitter : **Mr. Robert Bimeal R.Ph.** **Date: 02/14/2007**

Organization : **Value Health Center Pharmacy 18**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

DRA requires reduction in Medicaid spending and is intent on taking 90% of the savings cost out of 3% of the program cost. This is to be done by using the term Average Manufacturer Cost (AMP) to be defined and implemented in determining the Federal Upper Limit (FUL) price reimbursement to pharmacies for multiple source generic medications. Following are some things that must be considered in determining AMP to arrive at a viable sane definition. Please go to the general comment field.

GENERAL

GENERAL

For a retail pharmacy to provide medications to the medicaid population it must be able to purchase meds at a price that is less than the reimbursement it is to receive including the cost of electronic transmission to the pharmacy benefit manager (PBM), labeling, container, Pharmacists time spent to counsel the patient to ensure positive outcomes, delivery costs, and packaging. PLAINLY SAID, AMP MUST BE DEFINED AS IT RELATES TO THE RETAIL PHARMACY CLASS OF TRADE.

The government accounting office (GAO) itself acknowledges that as defined AMP will cause retail pharmacy to be reimbursed at a rate of 36% less than even the cost of the medication.

You must understand that several considerations must be made in defining AMP if medicaid patients are going to get medication from retail pharmacies which is quality personal care and more cost effective than what will happen when these patients would turn to hospital emergency rooms for care and in deteriorated conditions as a result of pharmacies not being able to participate in the program because the government determined to steal medications and services.

AMP was not ever intended to be a baseline for reimbursement. However if it is to be used for this purpose it must be accurate for the retail pharmacy cost of medication. For it to be determined accurately; following are some of the considerations that must be made:
> PBM rebates and discounts cannot be included. These are not available to retail pharmacies and access to these entities is not open to the public.
> CMS must require PBM transparency. PBMs have fought in both national and state arenas to keep their tactics a secret from review by the government and its clients. Their contracts are not subject to audit except in some very rare cases and then only where the client is allowed to select an auditor the PBM approves. Several PBM have paid multiple fines of millions of dollars each for violations of government regulations and yet are still allowed to participate in government contracts.
> Drug wholsaler bona fide service fees cannot be deducted. These are not passed through to the pharmacy.
> Manufacturers must report at least monthly.
> Manufacturers must report using the 11 digit NDC number.
> CMS must reject AMPs that have low market volumes as an outlier to the regulation. Any medication with an AMP that has less than 40% of the total market should not be considered.
> Individual pharmacies including mail order pharmacies operated by PBMs must not be classified as wholesalers.
> Long Term Care (LTC) facilities and the pharmacies that serve them do not sell to the general public and therefore their pricing should not be included in AMP determination.
>The final Rule needs to clarify, by the inclusion of a parenthetical after the term cash discounts that only those cash discounts that fail to qualify as wholesaler customary prompt pay discounts are to be deducted when AMP is calculated

Please finalize the definition of AMP using these considerations. Don't implement a cost metric that will cause the retail pharmacy to drop participation in the medicaid program or even go out of business completely when the commercial PBMs begin to use the AMP as their reimbursement metric. An AMP that is not calculated based on retail pharmacy product cost will jeopardize the health of the medicaid population, cost more for patient hospitalization, and ultimately cause the program to fail. Neither of us should advocate that.

CMS-2238-P-502

Submitter : **Mr. Orin Smith** **Date: 02/14/2007**

Organization : **Mr. Orin Smith**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I own a small independent pharmacy and have been in business for over 30 years at the same location. My son is a pharmacist and I was hoping to have a business to pass down to him. It seems CMS is not going to allow that because of the implementation of AMP. President Bush is looking to save billions of tax payers money, I m all for that. But I don t think this all of this saving should come out the pockets of the retail pharmacies in the United States. Everyone included in the distribution of prescriptions should share in this.

Collection of Information Requirements

Collection of Information Requirements

AMP calculation

GENERAL

GENERAL

see attachment

CMS-2238-P-502-Attach-1.DOC

CMS-2238-P-503

Submitter : Mr. Evan Luksic **Date:** 02/14/2007

Organization : University of Cincinnati College of 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.
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-504

Submitter : Mr. Thomas Temple

Date: 02/14/2007

Organization : Iowa Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-504-Attach-1.PDF

CMS-2238-P-505

Submitter : **Mr. Bert Smith** **Date: 02/14/2007**

Organization : **My Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Community Pharmacist 36 years.

GENERAL

GENERAL

see attachment

CMS-2238-P-505-Attach-1.DOC

Submitter : **Mr. Tim Heimann** **Date: 02/14/2007**

Organization : **Ohio Northern University- Pharmacy Student**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

As a soon to be pharmacist this new legislation involving AMP makes me very nervous about my future in the profession. The rates of community pharmacy profit are as low as 2-4% which makes it very difficult to make a profit currently. If this new legislation goes into effect in July it will be very tough for retail pharmacies to stay in business. Once this starts pharmacies are going to have to start turning away prescriptions that they know they are going to lose money on, or if they continue to fill every script they won t be able to stay in business. This could result into a lot of bankrupt pharmacies and lot of lost jobs for pharmacists and technicians. I believe a lot more research needs to be done before the government makes these legislative moves. If you look at the profit margin in the profession of pharmacy, the actual pharmacy makes minor profits compared to drug companies. If legislation is going to be made to save money, look at aspects of pharmacy/health care where it is actually possible. The current legislation does not do this, and in fact does the complete opposite. I think there are ways to save money, but decreasing reimbursements to the already low profit pharmacies is not the way to do it. Thank you very much for your time, and please feel free to contact me.

A very concerned PharmD. Candidate,

Tim Heimann
Ohio Northern University
t-heimann@onu.edu

Submitter : **Mr. Robert Marckioli** **Date: 02/14/2007**

Organization : **Royal Palm Drug**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Retail pharmacy 38 years

GENERAL

GENERAL

see atttached

CMS-2238-P-507-Attach-1.DOC

CMS-2238-P-508

Submitter : Mr. Jack Polk

Date: 02/14/2007

Organization : Mr. Jack Polk

Category : Pharmacist

Issue Areas/Comments

Background

Background

Community pharmacy

GENERAL

GENERAL

see attachment

CMS-2238-P-508-Attach-1.DOC

CMS-2238-P-509

Submitter : **Mr. Jason Smith** **Date: 02/14/2007**

Organization : **My Pharmacy Coral Reef**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

retail pharmacist

GENERAL

GENERAL

see attached

CMS-2238-P-509-Attach-1.DOC

CMS-2238-P-510

Submitter : **Mr. Sid Margolis** **Date: 02/14/2007**

Organization : **Mr. Sid Margolis**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

pharmacist

GENERAL

GENERAL

see attached

CMS-2238-P-510-Attach-1.DOC

CMS-2238-P-511

Submitter : Joe Patterni

Date: 02/14/2007

Organization : Joe Patterni

Category : Pharmacist

Issue Areas/Comments

Background

Background

retail pharmacy

GENERAL

GENERAL

see attached

CMS-2238-P-511-Attach-1.DOC

CMS-2238-P-512

Submitter : **Ms. Jennifer Roby** **Date: 02/14/2007**

Organization : **Pennsylvania Pharmacists Association**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacy student attending University of the Sciences in Philadelphia (Philadelphia College of Pharmacy) and I also work at CVS Pharmacy.

1. Remove PBM and Mail Order from the 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 Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Jennifer Roby
Student Pharmacy Intern

CMS-2238-P-513

Submitter : **Mr. antonio sellecchia** **Date: 02/14/2007**

Organization : **RUBINO'S PHARMACY**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed changes to pharmacy reimbursement will be extremely detrimental to my business and to my medicaid recipients. Serious concearns have been raised about how the DRA will affect reimbursement.

Collection of Information Requirements

Collection of Information Requirements

Current provisions of the DRA require medicaid dispensing pharmacies to accept AMP as the formula for reimbursement.

GENERAL

GENERAL

Accepting AMP here at my pharmacy means that I will loose money on each generic prescription that I fill. Major changes must be made to make the formula fair. Recent reports from the goverment accountability office have shown that my above comments are indeed true. The centers for Medicare (CMS)have doubts about the validity of the the GAO report, however after reading the report I find that it is precise in its findings. CMS has stated that the GAO did not account for rebates paid on the back end of drug sales. Such a statement is not only ridiculos but insulting to our industry. Rebates from manufactures or wholesalers account for less than 1%
of my actual drug cost. AMP pricing as curent will reduce reimbursement on average 36%. One does not have to be genius to figure out that the rebate portion of CMS's concearns just do not add up.
To correctly reimburse pharmacies, the following must happen:
1. Calculate AMP based on a "retail class of trade", exlude mail order pharmacy, hospital and nursing homes, they can buy drugs at deeply discounted prices. These discounts are not available to retail settings.
2. Update pricing at least weekly, drug prices can increase on a daily basis.
3. Employ a minimum dispensing fee for pharmacies. The current cost to dispense a prescription is approximately $9.00
4. Exlude rebates paid to wholesalers and mail order houses, this will further drive AMP down, thus hurting my business even more.

In order for me to continue my excellent service to my community and medicaid recipients the above points must be met or I may have to turn those recipients away and/or close my doors altogether. A system that uses wholesale acquisition as a basis would mute AMP concearns altogether. Please fix AMP because AMP= "ain't my price".

CMS-2238-P-514

Submitter : Mr. Craig Burridge

Date: 02/14/2007

Organization : Pharmacists Society of the State of New York

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-515

Submitter : **Mr. Tom Whiston** **Date: 02/14/2007**

Organization : **Whiston Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The development of AMP has arisen out of the manufacturers pricing basis of AWP that became completely unrelated to the actual cost basis of a prescription medication. The same has occurred with hospital billing that is overly inflated. The rational to utilize a sound cost basis is a good one.Due to discriminatory pricing that is still tied up in Federal Court since 1994 the development by CMS for cost basis is flawed and will result in detrimental effects on the current retail pharmacy dispensing marketplace.

Collection of Information Requirements

Collection of Information Requirements

The provisions regarding AMP are valid in the basis to define a true cost basis. The fact that it is not tied to a concomminant increase in dispensing or professional fee is disappointing. The basis of reimbursing below acquisition with CMS full well knowing this and ignoring data generated by OMB is of grave concern. There are no provisions to understand the short and long term effects on Pharmacy.
The secrecy utilized and lack of input by pharmacy alludes to the fact that this is not a good process.

GENERAL

GENERAL

I have followed the process of implementation of AMP by CMS and found the senitment of "We are from the government and we are here to help" to be completely accurate. This further validates that there is no common sense approach to implementing new policy and only beancounter mentality. Our pharmacy has been here over 100 years. We have survied world wars and depressions. We have grown continuously and been able to give back to the community. This plan by CMS is wrong and evil. I have listened to every pharmacy group and participant in this process and the only one that is for it is CMS. The fact that they refute GAO data further validates the danger of this plan. I will not belabor the issue. I could go on. My comments will garner little note nor impact any change. That is the greatest danger of even offering to have input. CMS has no plans to listen nor to alter their plans. That is most unfortunate for America. The loss to the country will be far more than the paltry savings touted by CMS. My prayers will be that somehow the process will be stopped and tragedy averted.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The collection of information would have been nice but we were never contacted. I am not sure where CMS decided to model this program after.We

Response to Comments

Response to Comments

We have four pharmacies in our county. This CMS generated initiative will close two of those pharmacies within one month leaving patients without access to medication or health information. The effect to the economy will be negative as well.

CMS-2238-P-516

Submitter : **Bryan Gobin** **Date: 02/14/2007**

Organization : **Alert Pharmacy Services, Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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 Mt Holly Springs, PA. 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 Pennsylvania 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, Pennsylvania 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 Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Bryan R Gobin, RPh
President
Alert Pharmacy Services, Inc
7174868606

CMS-2238-P-517

Submitter : **Miss. Nicole Woersching** **Date: 02/14/2007**

Organization : **Duquesne University**

Category : **Individual**

Issue Areas/Comments

Background

Background

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 student attending Duquesne University.

Collection of Information Requirements

Collection of Information Requirements

1. Remove PBM and Mail Order from the 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

GENERAL

GENERAL

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

Sincerely,

Nicole Woersching

CMS-2238-P-518

Submitter : dale schultz **Date:** 02/14/2007

Organization : pickerington pharmacy llc

Category : Pharmacist

Issue Areas/Comments

Background

Background

we have been serving needs of medicaid patients for over 16 years at our current location and, i believe, have gone out of our way to meet the needs of our patients

Collection of Information Requirements

Collection of Information Requirements

the new reimbursment will mean that our pharmacy looses money on nearly every generic medication under that system
it is only reasonable that we be provided with our cost plus a fair dispensing fee. why should pharmacists loose money on these medications when drug manufacturers and pbm's make a profit?

CMS-2238-P-519

Submitter : Mrs. CAROLYN BOLAND **Date:** 02/14/2007

Organization : Mrs. CAROLYN BOLAND

Category : Pharmacist

Issue Areas/Comments

Background

Background

I AM AN OWNER OF 2 SMALL INDEPENDENT PHARMACIES: BOLAND PHARMACY IN BOWMAN, SC 29018 AND BOLAND PHARMACY IN ST MATTHEWS, SC 29135.
WE PROVIDE PHARMACY SERVICES IN 2 RURAL AREAS. WE SERVICE A LARGE PERCENTAGE OF MEDICAID RECIPIENTS, ESPECIALLY IN OUR BOWMAN, SC LOCATION.

Collection of Information Requirements

Collection of Information Requirements

MEDICAID PROGRAM:PRESCRIPTION DRUGS; AMP REGULATION
CMS 2238-P RIN 0938-AO20

GENERAL

GENERAL

I SUPPORT THE MORE EXTENSIVE COMMENTS THAT ARE BEING FILED BY THE SOUTH CAROLINA PHARMACY ASSOCIATION REGARDING THIS PROPOSED REGULATION. I WOULD APPRECIATE YOUR CONSIDERATION OF THESE COMMENTS. THANK YOU AGAIN FOR YOUR TIME. SEE ATTACHMENT.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

THE PROPOSED REGULATION WOULD PROVIDE A REULATORY DEFINITION OF AMP AS WELL AS IMPLEMENT THE NEW MEDICAID FEDERAL UPPER LIMIT PROGRAM FOR GENERIC DRUGS.

Regulatory Impact Analysis

Regulatory Impact Analysis

I DO NOT THINK THAT IT IS FAIR TO INCLUDE PBM, HOSPITAL, AND MAIL-ORDER ACQUISITION PRICES WHEN DETERMINING THE AMP. AS AN INDEPENDENT PHARMACY OWNER, WE CANNOT PURCHASE DRUGS AT THE SAME PRICE AND THIS AMP WILL MORE THAN LIKELY BE BELOW MY COST. I THINK THAT THERE SHOULD BE A HIGHER ACQ PRICE SET FOR RETAIL STORES.

THERE ALSO NEEDS TO BE FREQUENT PRICE UPDATES. IF A PRICE GOES UP AND IT IS NOT UPDATED IMMEDIATELY IN THE SYSTEM, WE COULD BE REIMBURSED EVEN FURTHER BELOW OUR COST.

THE MOST COMMON PACKAGE SIZE DISPENSED BY RETAIL PHARMACY INVOLVES AN 11-DIGIT NOT 9-DIGIT NDC NUMBER. I HOPE THAT THIS WILL BE THE NUMBER THAT WILL CONTINUE TO BE USED FOR BILLING.

Response to Comments

Response to Comments

IF THE AMP REGULATIONS GO INTO EFFECT AS WRITTEN, IT WILL PROBABLY PUT BOTH OF MY STORES AND MANY OTHER INDEPENDENT PHARMACIES OUT OF BUSINESS. THIS MEDICARE PART D HAS CUT MY PROFIT BY ABOUT 30%. I CANNOT STAND ANOTHER BIG CUT. THERE ARE MANY PATIENTS, ESPECIALLY IN THE RURAL AREAS THAT WE SERVICE, THAT DEPEND ON US. THEY DO NOT UNDERSTAND MEDICARE PART D, MAIL ORDER, ETC. THEY DEPEND ON US FOR MORE THAT JUST THEIR PRESRIPTIONS. WE ARE ALSO THEIR SOURCE FOR INFORMATION ON ALL OF THESE NEW PROGRAMS. PLEASE, HELP US!!! THERE MUST BE A BETTER WAY TO DETERMINE AMP OR COME UP WITH ANOTHER ACQ PRICE FOR RETAIL STORES!!!!!!!!!! THANK YOU FOR YOUR TIME. CAROLYN BOLAND, RPH BOLAND PHARMACY PO BOX 398 BOWMAN, SC 29018 AND BOLAND PHARMACY PO BOX 235 ST MATTHEWS, SC 29135. MY PHONE NUMBER IS 803-829-2547 IF YOU WOULD LIKE TO CALL ME.

CMS-2238-P-519-Attach-1.TXT

CMS-2238-P-520

Submitter : **Mr. David Acconcia** **Date: 02/14/2007**

Organization : **Center Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

independent retail pharmacy owner

Collection of Information Requirements

Collection of Information Requirements

AMP formula for rx pricing

GENERAL

GENERAL

please reconsider this formula as it is just not workable or fair! No business can provide products and services below or even at actual cost. We, as many retail pharmacies, are in a rural area with no other local alternatives. Please issue an accurate and fair definition of what WE pay for pharmaceuticals. Thank you

CMS-2238-P-521

Submitter : **Warren Friedman** **Date: 02/14/2007**

Organization : **Hillcrest Atrium Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated (by the GAO,no less)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.

I have heard that the CMS response to this question is a wait-and-see attitude. That is, let's wait and see if pharmacies do close before we change anything. This would be a disaster, not just for the pharmacies, but for the Medicaid patients as well.

CMS-2238-P-522

Submitter : **TIMOTHY Monahan** **Date: 02/14/2007**

Organization : **Pennsylvania Pharmacist Association**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

February 14, 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 student attending Temple University Pharmacy School and I also work at Walgreen.

1. Remove PBM and Mail Order from the 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 Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Timothy Monahan

Student Pharmacist

CMS-2238-P-523

Submitter : **Mrs. Kelly Ann Perkins** **Date: 02/14/2007**

Organization : **Mrs. Kelly Ann Perkins**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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 student attending Lake Erie College of Osteopathic Medicine, School of Pharmacy and I also work at Eckerd Drug.

Collection of Information Requirements

Collection of Information Requirements

1. Remove PBM and Mail Order from the 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 Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

CMS-2238-P-524

Submitter : Mrs. Mary Ludlow

Date: 02/14/2007

Organization : White Oak Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-525

Submitter : **Jill Reinhardt** **Date: 02/14/2007**

Organization : **First Choice Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I would just like to let you know that I am very supportive of Associated Pharmacies, Incorporated view on prescription drugs and payment. Please help the independent pharmacies stay alive. It is very difficult right now, and we help A LOT of people.

CMS-2238-P-526

Submitter : **Miss. Christine Chmielewski** **Date: 02/14/2007**

Organization : **Miss. Christine Chmielewski**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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 student attending Wilkes University: Nesbitt School of Pharmacy and I also work at CVS/pharmacy.

1. Remove PBM and Mail Order from the 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 Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Christine Chmielewski (Student Pharmacist)

CMS-2238-P-527

Submitter : **Dr. Cecily DiPiro** **Date: 02/14/2007**

Organization : **South Carolina Pharmacy Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 14, 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 pharmacist employed in Charleston, South Carolina. 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,

Cecily V. DiPiro
1886 Omni Blvd.
Mt. Pleasant, SC 29466

CMS-2238-P-528

Submitter : **Mr. felix szymkowiak** **Date: 02/14/2007**

Organization : **roadway pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS suggestion of AMP will put many pharmacies out business, I myself included. We service many rural seniors and low income people. This will jeopardize their health. It will also put 10 people in our business out of work whose families rely on this job. Please consider a fair reimbursement for pharmacy services. It is essential.

Thank you,

Felix Szymkowiak, R.Ph.

CMS-2238-P-529

Submitter : **Mr. Andrew Charter** **Date: 02/14/2007**

Organization : **Haggen, Inc.**

Category : **Health Care Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-529-Attach-1.DOC

CMS-2238-P-530

Submitter : **Mrs. Darlene Gardiner** **Date: 02/14/2007**

Organization : **Medicap pharmacy 8334**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I have been a full time registered pharmacist since 1978. I beleive we do more than amp can cover to help medicare and medicaid patients

GENERAL

GENERAL

Please do not let the amp legslation go through

CMS-2238-P-531

Submitter : **Mr. Jeffrey Biddle** **Date: 02/14/2007**

Organization : **Village Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-531-Attach-1.DOC

CMS-2238-P-532

Submitter : Mrs. Samantha Smith **Date:** 02/14/2007

Organization : Mrs. Samantha Smith

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

If we allow this legislation to pass, then the kind of quality that customers have come to expect from the pharmacy would not be. In order for a pharmacy to have good customer service, there needs to be a reasonable amount of staff on hand. If this legislation is passed, then profit would in fact go down and that would lead to payroll to go down. If we value good, quality service, then we must be able to employe people that are exceptional at what they do. That takes money. Please say "no" to this legislation.

CMS-2238-P-533

Submitter : **Ms. Shannon Carr** **Date: 02/14/2007**

Organization : **Pennsylvania Pharmacists Association**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

February 14, 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 student attending Wilkes University and I also work at Walgreens.

1. Remove PBM and Mail Order from the 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 Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Shannon Carr
Student Pharmacist

CMS-2238-P-534

Submitter : **Melissa Sweigart** **Date: 02/14/2007**

Organization : **Melissa Sweigart**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacy student attending Wilkes University and I also work at Weis Pharmacy

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

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

Sincerely,

Melissa Sweigart

Student Pharmacist

CMS-2238-P-535

Submitter : **Dave Healy** **Date: 02/14/2007**

Organization : **Medicine to Go pharmacies**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Community pharmacy: We are located in an area with a large senior citizen population. They require and are entitled to good care including face to face consultations (necessary for avoiding dangerous drug reactions). They also require pick-up and delivery as many cannot drive . This vital service is provided free of charge and requires proper reimbursement to continue. We also provide administrative help at no charge which can be very time-consuming and confusing to seniors.

Collection of Information Requirements

Collection of Information Requirements

AMP-based FUL calculations will NOT cover aquisition costs for multiple-source generic drugs becausse AMP was never intended to serve as a basline for reimbursement. If CMS is to implement AMP, it must be done correctly to ensure community pharmacy is not underpaid.
An accurate definition of AMP must reflect actual cost paid by retail pharmacy, and exclude all other classes of trade, including PBM's.
Also, transparency is paramount for correct calculations. I believe that retail pharmacy should have the right to review the calculations before they are law, and updates should be done weekly, as prices sometimes change rapidly. It would also be correct to exclude mail-order pharmacy from the class of trade, as they collect rebates from manufacturers, but are not subject to audit!! There is no way to tell if their figures are correct, or will they under report to undersell us, or not have to share rebates with their sponsors.
Also, AMP must be reported as an 11-digit number, so as not to skew the figures for independant pharmacies.

An accurate definition of AMP would lead to greater and accurate rebates for state Medicaid programs, and encourage generic dispensing at the retail level.

According to the GAO, (report GAO-07-239R p.4), at the present calculation, we would bee paid 36% lower than our acqusition costs.
This would force many pharmacies out of the Medicaid business, annd increase emergency room visits many times. I am sure that this would cost mmore than a correct AMP calculation.

GENERAL

GENERAL

Please take the time to include all parties and correctlly calculate AMP pricing. Also, all rebates paid to outside sources that are not available to community pharmacy have to be excluded from AMP calculations, including rebates paid to PBM's.

It's easy to be penny-wise and pound foolish, I hope CMS can see past politics and give community pharmacy a reasonable deal. Many people will miss us in the system if we are priced out.

Thank you for your time

CMS-2238-P-536

Submitter : **Derrick Wall** **Date: 02/14/2007**

Organization : **Wall Drugs of Johnsonville, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I own an independent pharmacy in a rural area of Florence county. I have 8 employees who help run my business. We service a large number of medicaid patients.

Collection of Information Requirements

Collection of Information Requirements

The new plan for reimbursing generics with a Federal Upper Limit(FUL) is 250% of the Average Manufacturer's Price (AMP).

GENERAL

GENERAL

I understand that we have to find a way to save money. This just isn't it. We should be pushing people towards taking cost effective generics. The only thing that will happen with this plan is to cause pharmacies to have to close thus limiting access to the patients. Thank you for your time. Allan Wall

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

A report by the Government Accountability Office (GAO) shows that the new plan will result in an average 36% reduction in pharmacy reimbursement for generic medications.

Regulatory Impact Analysis

Regulatory Impact Analysis

If this plan goes into effect my pharmacy would lose money on every generic prescription filled. Studies by Pfizer show that the average cost to dispense is around $10. The new plan would have my pharmacy dispensing generics below cost.

Response to Comments

Response to Comments

At the very least this proposal would cause me to have to reduce my staff. People will lose their jobs. I would also have to stop taking Medicaid insurance. Being in a rural area, this is going to hurt the people who can least afford it. (The medicaid patients.) Also the pharmacies who still take medicaid will be more inclined to push patients to more expensive brand drugs.

CMS-2238-P-537

Submitter : **Mr. Kevin McCloud** **Date: 02/14/2007**

Organization : **McCloud Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The use of AMP based FUL's to define generic drug reimbursements to pharmacies and its devastating impact on not only the pharmacies but the patients who depend on them for daily living.

Collection of Information Requirements

Collection of Information Requirements

The proposed regulation would base all pharmacy generic drug reimbursements off the AMP based FUL's. AMP calculations would be based off of 30 day data that once collected and implemented would then be approximately 60 days behind the actual costs that the pharmacies have to pay.

GENERAL

GENERAL

See attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

In a recent GAO accounting report, the federal government has found that pharmacies will be paid an average of 36% below acquisition cost for the 77 drug sample group from the month of December 2006. It should also be noted that medicaid patients make up 20% of a pharmacies total volume and that 56% of all medications dispensed in an independent pharmacy are generics.

Regulatory Impact Analysis

Regulatory Impact Analysis

From this report, it is easy to see that pharmacies, especially independently owned smaller pharmacies, will not be able to maintain their business while still accepting state medicaid plans. AMP was never intended to be used to set pharmacy reimbursements, but only to help determine manufacturer rebates back to the states. Since the pharmacy does not receive these rebates, they should not be used in the determining of reimbursements to said pharmacy.

Response to Comments

Response to Comments

Pharmacies, esp. smaller independently owned ones, will have to stop accepting medicaid and may be forced to close due to lack of reimbursement.

CMS-2238-P-537-Attach-1.DOC

CMS-2238-P-538

Submitter : **Miss. Jennifer Heasley** **Date: 02/14/2007**

Organization : **Miss. Jennifer Heasley**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

[February 14, 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 student attending Duquesne University and I also work at Med-Fast Pharmacy.

1. Remove PBM and Mail Order from the 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 Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Jennifer Heasley, Student Pharmacist

CMS-2238-P-539

Submitter : **Mr. Joe Miles** **Date: 02/14/2007**

Organization : **Main Street Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

2/14/2006

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 on 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,

R.J.Miles
Main Street Pharmacy

CMS-2238-P-540

Submitter : **Dr. Michael West** **Date: 02/14/2007**

Organization : **Super Discount Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As it stands AMP will end my ability to serve this rural area in Tennesse. I fill 90% medicare & medicaid prescriptions, 64% of which are generic. I cannot stay in business at 36% below net. I cannot negotiate as mail order pharmacies (antitrust) or Walmart can. I serve a small aged community that cannot drive to the next town in order to get care, but if AMP goes through as planned, I will not be here to serve them

CMS-2238-P-541

Submitter : Dr. DANA WOODS **Date:** 02/14/2007

Organization : WOODS PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a Pharmcist and Pharamacy owner in Mountain View Arkansas- a rural community or around 3,000 people and a county with around 11,000. i have been a Pharmacy owner for over 21 years.

Collection of Information Requirements

Collection of Information Requirements

AMP is simply not a reflection of it's intended purpose. Ill advised policy designed to ultimately rid our society or the rural and small Pharmacies which have served our nation continously for decades.

GENERAL

GENERAL

The fedearl government imposing unreasonable rules should be unlawful. IT is certainly anti-competitive and the ultimate result would not be good for the consumer. A network of Pharmacies is essential in the event of a disaster. Rural Pharmacies provide services not found or offered by the chain Pharmacies . These services help the recepients remain independent. We also extend extra help in medication advise.
AMP would certainly encourage the use of more expensive brand drugs-resulting in a net increase cost to the drug program instead of a decrease. This increase could be extremely significant

Response to Comments

Response to Comments

The GAO in their own analysis agrees that AMP would force Pharmcies to either quit participating in medicaid or lose money. What a choice?

CMS-2238-P-542

Submitter : **Mr. Naren Desai** **Date: 02/14/2007**

Organization : **Desai Pharmacy/AIPhA**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

We are a Medicaid provider in state of Illinois. Almost 90% of our business is Medicaid. We would like to submit comments about the proposed AMP based reimbursment for Medicaid to go into effect on July 01, 2007.

Collection of Information Requirements

Collection of Information Requirements

The proposed ruling will make AMP as a basis for FUL(Federal Upper Limit) in the Medicaid program. According to GAO(Goverment Accountablity Office)these FULs will be 36% below average acquisition cost of most pharmacies.

GENERAL

GENERAL

1. If many independents are forced out of Medicaid business, the quality of care will suffer in rural and inner city area. This will increase the medical expenses of the state as many Medicaid recipients will end up with bigger problems requiring hospitalization.
2. If AMP based reimbursment should go into effect, it should reflect the actual acquisition cost of the pharmacy.
3.The dispensing fee should be increased to $12.50 to reflect the increased cost of filling a prescription.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

A study done by Grand Thornton LLP on behalf of NCPA and NACDS determined the cost of dispensing at $10.50 per prescription on average. This study was concluded on August 2006 that included data from 24,400 pharmacies. This cost of doing business is increasing every day.

Response to Comments

Response to Comments

The average dispensing fee being so low, if this AMP based reimbursment goes into effect many independents will stop filling Medicaid prescriptions and some who do much of their business with Medicaid will be forced out of business.

CMS-2238-P-543

Submitter : **Roberta Aber** **Date: 02/14/2007**

Organization : **Planned Parenthood of Summit, Portage & Medina Cou**

Category : **Other Health Care Provider**

Issue Areas/Comments

Background

Background

Planned Parenthood of Summit, Portage and Medina Counties is a non-profit organization providing family planning health care and contraceptive services to over 15,000 unduplicated clients at five sites in three counties in Ohio. Three of our sites are part of a Title X supported project. The other two sites receive no government funds, yet serve many low-income, uninsured clients nonetheless. Over half of the clients at these two sites have incomes below 50% FPL and at least 80% have incomes below 200% FPL. Most of the clients at these sites are young adults who are particularly vulnerable to the adverse social and economic impact of unintended pregnancy. Young adults are the most likely age group to be uninsured. These sites are "safety net providers" to the communities they serve.

We have been able to provide affordable contraceptive supplies to clients at these sites because, in the past, we have purchased these supplies at nominal prices. Without nominal pricing, many of our clients will not be able to afford their contraceptive supplies. Their only recourse will be to travel 20 miles or more to a Title X family planning site.

Collection of Information Requirements

Collection of Information Requirements

test

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed regulations do not include a definition of "safety net providers." In the absence of such a definition that includes non-Title X family planning providers, many low-income and uninsured individuals served by these providers will no longer be able to afford the contraceptive supplies they seek.

Submitter : **Allen Jordan** **Date: 02/14/2007**

Organization : **The Medicine Chest**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 14, 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 on 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,

Allen H. Jordan, R.Ph., MBA
The Medicine Chest
210 South Jackson Street
PO Box 69
Grove Hill, Al 36451

CMS-2238-P-545

Submitter : **Mr. Burke Langham JR.** **Date: 02/14/2007**

Organization : **Stacey Drug Store**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-545-Attach-1.DOC

CMS-2238-P-546

Submitter : **David Kohll** **Date: 02/14/2007**

Organization : **Kohll's Pharmacy and Homecare**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Please see attached letter regarding my views on Medicaid generic reimbusement changes.

GENERAL

GENERAL

See attachment

CMS-2238-P-546-Attach-1.DOC

Submitter : **Dr. STANLEY NUSBAUM** **Date: 02/14/2007**

Organization : **S & J DISCOUNT DRUGS**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

ATTACHMENT

Submitter : **Steve Lee** **Date: 02/14/2007**

Organization : **Steve Lee**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

02/14/07

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

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Sincerely,

Steve Lee
1299 E. Morgan St.
Martinsville, IN 46151

CMS-2238-P-549

Submitter : Dr. FRANK SNYDER

Date: 02/14/2007

Organization : SPRING CITY PHARMACY, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-2238-P-550

Submitter : TERRY ROARK **Date:** 02/14/2007

Organization : ROARK'S HEALTH MART PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

MY WIFE AND I HAVE OWNED AND OPERATED A PHARMACY IN RURAL TENNESSEEE FOR SOME 18 YEARS. WE HAVE CARED FOR AND ABOUT OUR PATIENTS FOR ALL OF THOSE YEARS. WE ARE THE MOST ACCESSIBLE HEALTH CARE PROFESSIONAL TO OUR PATIENTS IN AN AREA WITH A HIGH PERCENTAGE OF MEDICAID PATIENTS. WE FEEL THAT THIS PROPOSED CHANGE IN HOW PRESCRIPTION DRUGS ARE PAID WILL FORCE US TO STOP TAKING OUR STATE MEDICAL ASSISTENCE PROGRAM AND WOULD FORCE A HARDSHIP ON OUR FRIENDS AND PATIENTS. THESE REIMBURSEMENTS ARE BASED ON PRICES THAT ARE NOT AVAILABLE TO PHARMACIES SUCH AS OURS THAT SERVICE THE MEDICAID POPULATION. THE RESULT OF THIS PROPOSED REGLUATION WOULD BE THAT WE WOULD LOOSE 25% OF OUR BUSINESS. I DON'T THINK WE CAN SURVIVE AMP IN IT'S PROPOSED FORM.

Submitter : **Dr. Melanie Lee** **Date: 02/14/2007**

Organization : **Ede Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

02/14/07

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,

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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,

Melanie Lee
1299 E. Morgan St.
Martinsville, IN 46151

CMS-2238-P-552

Submitter : **Mr. James Floyd** **Date: 02/14/2007**

Organization : **Tennessee Pharmacist Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-552-Attach-1.TXT

Submitter : **Dr. Akil Ghoghawala** **Date: 02/14/2007**

Organization : **Bienestar Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Leslie Norwalk, acting administrator.

I cannot stress enough the importance of our entire community expressing our outrage over this ruling. AMP will have a devastating effect on our industry if there are not changes made. Quite simply, business cannot expect to operate at a loss to service medicaid patients.

Give yourself some time to go over this information. The attachment is 7 pages...and is quite a bit to digest. However, we cannot put this aside and forget about it. Come July, when AMP rolls out, you will be kicking yourself for not spending 1 hour to try to improve this ruling.
see attachment

CMS-2238-P-554

Submitter : **Dr. a gogawa** **Date: 02/14/2007**

Organization : **Olympia fields Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Leslie Norwalk, acting administrator.

I cannot stress enough the importance of our entire community expressing our outrage over this ruling. AMP will have a devastating effect on our industry if there are not changes made. Quite simply, business cannot expect to operate at a loss to service medicaid patients.

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GENERAL

GENERAL

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see attachment