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.

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 : **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.

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.

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.

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!!!!!!!!!!!!!!!

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.

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.

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

Thc new regulations on AMP (Avcrage Manufacturer Price) sets the Fedcral 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 healthcarc 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 thc 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 thc 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

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 CPSI 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. Plcase 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

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

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.

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.

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.

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

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.

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.

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

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.

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.

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

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.

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

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.

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

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.

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

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

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

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

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

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

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"

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

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

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?

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

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.

Submitter : Mrs. Mary Ludlow **Date:** 02/14/2007

Organization : White Oak Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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.

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)

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

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.

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

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

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

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.

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

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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

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 correctly 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

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.

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

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

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

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

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?

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.

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

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

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

Submitter : Dr. FRANK SNYDER **Date:** 02/14/2007

Organization : SPRING CITY PHARMACY, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

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

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Sincerely,

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

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

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

Organization : **Olympia fields Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Leslie Norwalk, acting administrator.

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GENERAL

GENERAL

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see attachment

Submitter : Mr. A. gogh **Date:** 02/14/2007

Organization : walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachement, also
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.

CMS-2238-P-555-Attach-1.PDF

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

Organization : **Bienestar 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.

GENERAL

GENERAL

see attachement

CMS-2238-P-556-Attach-1.PDF

Submitter : **Ms. dominic palma** **Date: 02/14/2007**

Organization : **palma , dominic**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

we cannot afford to dispense drugs below our actual costs. the nmubers that you have are false and not what we pay for those drugs. we do not recieve any rebates or incentives for dispensing any drugs.
this will lead to my pharmacy no longer being able to care for many patients that we have cared for for 45 years in business. we will have to send them away and this may lead to the closing of our business and cause further unemployment.

Submitter : Mr. Corey Caillouet **Date:** 02/14/2007

Organization : University of Tennessee College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Pharmacy reimbursement rates set to below actual acquisition costs.

CMS-2238-P-558-Attach-1.DOC

Submitter : Dr. Betsy Miller **Date:** 02/14/2007

Organization : Dr. Betsy Miller

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-559-Attach-1.DOC

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

Organization : **PharmTri Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a registered pharmacist in the State of New Jersey, practicing for 26 years. I am very concerned that the latest round of cost-cutting by the Bush Administration and CMS is will cause local pharmacies to stop accepting Medicaid. The local pharmacy is the lifeline for many people in our area. We provide many value-added services for free, but will not be able to if the current cuts take effect. Our pharmacy is located close to retirement villages and assisted living facilities. The eldery who live there rely on us daily to provide many services including face to face counseling, free delivery to those who cannot drive, and ever increasing administrative assistance with the myriad of plans, prior authorizations, and other problems that arise due to the new Part-D plans. These people are the frail and old and rely on us daily to help them navigate the new systems, and then properly counsel them on their medications, then get their prescriptions out to the in a timely manner. Our customers rely on us more than ever, yet we do not get paid anything extra to to this. The GAO says we will be reimbursed 36% less than our cost, which will force me not to accept Medicaid. I WILL rest this responsibility on CMS and the Bush Administrations' budget cuts, as we have absorbed way too much already, including quadrupling my receivables due to slow payments from the Part-D plans. The senior citizens of our community are due more respect than this, and so are we. Cigna, United Healthcare, and Aetna have all reported record profits this year, but we have had our margin reduced by about 25%, yet our expenses just continue to grow, and administration more onerous for our patients and our organization.

Collection of Information Requirements

Collection of Information Requirements

AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer's rebates according to GAO-05-102. If AMP is to serve as the basis for pharmacy's true cost of goods, any and all rebates and price concessions CANNOT be included in the calculation, including rebates paid to the PBM's (eg-Medco, Caremark, etc.). An accurate definition of AMP will lead to increased generic dispensing, and lead to greater rebates to the states, which saves money for the entire system, while encouraging effective patient care.

Drug prices MUST be determined by 11-digit NDC codes, to ensure accuracy in packaging available and commonly used at the retail level, and to eliminate waste.

AMP MUST be reported weekly and accuracy must be guaranteed in the calculation, as our pricing fluctuates rapidly, sometimes on a daily basis. This is only fair, as we must pay bi-weekly or weekly in some cases, and would need this information for daily operation and purchases.

AMP must be kept to the retail class of trade only, as ours is the only one that is transparent and subject to audit. The PBM's are not subject to opening their books, so I feel their information will be at least stacked in their favor to increase their marketshare , and at worst, may show they do not share their rebates promised to their clients, as been seen in recent court cases.

All calculations of AMP MUST BE independently verifiable with full transparency to ensure accurate calculations. Underpayment will have dire consequences for patient care and access.

GENERAL

GENERAL

I hope that CMS will heed the GAO, NCPA, and others in regard to payments under the proposed AMP FUL rules.

The current formula will NOT cover pharmacy acquisition costs for multi-source generic medications.

AMP was never intended to serve as a basis of reimbursement.

To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by the pharmacy, which MUST exclude rebates and price concessions made by manufacturers which are NOT available to pharmacy.

Reporting AMP to an 11-digit NDC only

Excluding all mail-order facilities and PBM pricing form the calculations. These prices are NOT accessible to us.

Remember, we has our hands tied years ago when we were NOT ALLOWED to bargain with the PBM,s there is no other business in healthcare where a wholly-owned subsidiary can refer customers to itself. There is no transparency in the PBM business, which I believe grossly inflates the price of brand-name drugs. Remember how much the branded drugs cost in relation to generics, an incorrect AMP is a recipe for disaster, and is not conducive to generic dispensing.

I cannot and will not allow my business to participate in a program that had many liabilities in the normal course of business, and causes us to lose money. Denying access to vital medications and the delivery system itself will cause major increases in non-compliance resulting in increased emergency room use and hospitalizations.

The increases in prescription spending over the years has improved the quality of life and decreased hospitalizations, which saves money in the long run. Please do not be penny-wise and pound foolish.

I thank you in advanced for taking the time to read my comments, I can be reached at Kadamps@msn.com or Medicinetogo@msn.com

Response to Comments

Response to Comments

AMP must be regulated transparently to ensure correct and timely calculations so as not to place small pharmacies at a disadvantage after they have faithfully served their communities for many years in an ever-shrinking profit structure. I hope that CMS takes these thoughts into account, even if only for respect of our senior population.

Submitter : **Richard Boyd** **Date: 02/14/2007**

Organization : **Ohio Northern University**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

My name is Richard Boyd, and I am a pharmacy student at Ohio Northern University. I am interested in someday owning my own pharmacy. Recently, an issue has come to my attention that would affect my future as a community pharmacist.

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to community pharmacy. It is estimated that the reimbursement will be far below what it actually costs pharmacies to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what pharmacists 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.

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

Please consider all the students and community pharmacists who will no longer be able to operate if this is not resolved.

Sincerely,
Richard Boyd

CMS-2238-P-561-Attach-1.DOC

Submitter : **Dr. Jarrett Bauder** **Date: 02/14/2007**

Organization : **Uptown 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.

Submitter : **Miss. Christie Williamson** **Date: 02/15/2007**

Organization : **Pennsylvania Pharmacist Association**

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. I am a pharmacy student attending Duquesne University and I also work at The Medicine Shoppe 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,
Christie Williamson

Student Pharmacist

Submitter : Ms. Malinda Parman **Date:** 02/15/2007

Organization : University of Tennessee College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-564-Attach-1.DOC

Submitter : Dr. Walter Guice **Date:** 02/15/2007

Organization : Specialty HelathCare Partners, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

2-15-07

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,

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,

Walter Guice, Rph., BCNP
Specialthy HealthCare Partners, Inc.
Chattanooga, TN. 37421 (423-490-0166)

Submitter : Mr. Terry Griffith **Date:** 02/15/2007

Organization : Tennessee Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-566-Attach-1.DOC

Submitter : **Mr. Brian Deihl** **Date: 02/15/2007**

Organization : **APhA**

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. I am a pharmacy student attending Wilkes University.

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,

Student Pharmacist

Submitter : Mr. Tim Barrick **Date:** 02/15/2007

Organization : The Clinic Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Deficit Reduction Act of 2005 (DRA) that would change the Medicaid program's reimbursement for generic medications to a formula based onf 250% of the Average Manufacturers' Price (AMP) will have negative impact on retail pharmacies. Especially independent pharmacies and even more so independent pharmacies in "rural" areas who have a higher than average percentage of their patients who are medicaid eligible. In addition, at this point, no one knows what AMP will be. If Wholesale Acquisition Cost (WAC) had been designated as the standard, instead of AMP, as was recommended by many pharmacy advocate groups, this issue would be much clearer to everyone. Furthermore, how can group retail pharmacy as a group that includes mail-service pharmacies, hospital out-patient pharmacies, and outpatient clinics when these groups have access to rebate programs and price concessions that true retail pharmacies do not have access to? These price concessions drive the AMP down, therefore more drastically cutting in to profit margins for those pharmacies to do not have access to that type of preferential pricing.

Submitter : **Mrs. Patricia Keller** **Date: 02/15/2007**

Organization : **Newbern Discount Drug, LLC**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Your current definition of AMP will cause my retail pharmacy to lose money with each Prescription I fill for you.

Why would you ask me to to do this ????

We are in a rural area and provide free councelling to many of your patients. These people depend on us to solve their problems.

We have spent in excess of 1000 hours in solving medicare D problems.

We do the same each day with your medicaid / TnCare population.

This is free customer service directly for CMS and does not show as an expense on your budget.

Why kill the organizations who you are getting the largest return for your money.

Note the income statements of the third party benefit managers. Note the increasees in their profits from medicaid & medicare.
This is where the excesses are in the medical delivery system.

You are after the wrong pot of money.

CMS-2238-P-569-Attach-1.TXT

Submitter : **Dr. vicky noling** **Date: 02/15/2007**

Organization : **north florida pharmacy of mayo, inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I own a small independent pharmacy in a small town. Twenty percent of my prescriptions are paid for through Medicaid, with about 80% of these being prescriptions for children under the age of 18. If we have to discontinue accepting Medicaid due to the new proposed AMP pricing, these clients will have to drive at least 25 miles to the nearest city to have their prescriptions filled. This is a disservice to these underpriviledged children, whose parents often can't afford the gas to drive them out of town. A purpose of Medicaid is to help those who need it, and this proposal will negatively affect Medicaid clients, not to mention our local economy, as people will be forced to take their business out of town. Please reconsider this proposal, as I feel I am speaking for MANY small, independent pharmacies, not just myself. This proposal will negatively affect our business, possibly forcing us to close altogether!

Submitter : **Mr. Eric Amber** **Date: 02/15/2007**

Organization : **Medicine Stop Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-571-Attach-1.DOC

Submitter : Dr. Deborah Teague **Date:** 02/15/2007

Organization : IV Solutions Home Infusion Therapy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-572-Attach-1.DOC

CMS-2238-P-572-Attach-2.DOC

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

22222

Collection of Information Requirements

Collection of Information Requirements

222222

GENERAL

GENERAL

22222

Regulatory Impact Analysis

Regulatory Impact Analysis

222222

Response to Comments

Response to Comments

22222

Submitter : **Thomas Main** **Date: 02/15/2007**

Organization : **Main Drug Inc**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background '

AMP RULING Affecting Medicaid Reimbursement

Collection of Information Requirements

Collection of Information Requirements

AMP is to be the new benchmark for reimbursement for medicaid pharmacy products

GENERAL

GENERAL

On behalf of my employees and their families and myself I would like to oppose the current system for calculating AMP. Under the current system my reimbursement would be significantly less than I am able to purchase the product for. This is due to the fact that my reimbursement rate will be calculated based on what hospitals and other Huge suppliers pay for their medications. I think anyone in the world would agree that we should not be reimbursed based on what a huge hospital pays for their drugs when we can not physically buy the product for a fraction of the cost that these people can buy them for. The AMP should be calculated in a fair manner and it would be just as easily be possible to reimburse different pharmacies based on what their cost are. Thank You and I hope you will consider the lives of the the people this law would cause harm to by loss of access to care and putting pharmacies out of business.

Thomas Main Rph.

Submitter : Mr. WILLIAM PRATHER **Date:** 02/15/2007

Organization : GEORGIA BOARD OF PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

your proposed reimbursment schedules could quite possibly make needed drugs unavailable in rural, medically underserved areas where the Pharmacist may be one of the only sources of not only drugs but other important medical advice. any small business (mine included) cannot afford to fill prescriptions and lose money. mail order pharmacy or large big box stores, not located in many areas simply cannot fill these needs. Please reconsider your cuts and talk to some real small town Pharmacists concerning costs but talk to their patients about the service their Pharmacist provides. If you listen only to the Pharmaceutical Manufacturers and/or PBM industry you are not the whole story.

Thank you,
William Prather R.ph.
Member Georgia Board of Pharmacy
Owner, Blue Ridge Pharmacy
793 east main st
Blue Ridge, Ga.

Submitter : Gary Pettigrew **Date:** 02/15/2007

Organization : Gary Pettigrew

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to take this opportunity to express my concerns about the proposed changes in calculating prescription reimbursement that will affect retail pharmacy.

I have owned an independent pharmacy in rural West Tennessee since 1972; therefore I am not a stranger to change.

I am sure you will hear from many qualified individuals in our industry who have greater access to the relevant figures than I do so I will try to focus on other issues.

Reducing reimbursement to a level that is below cost for independent pharmacies will in the long run reduce the level of care many citizens receive. This will occur by either forcing many pharmacies to go out of business or causing them to curtail services. The closing of independent pharmacies will cause the loss of many jobs as well as reduce the support of local activities that many communities depend on. In other words, the destruction of a way of life that is invaluable to the survival of America.

There appears to be many flaws in the proposal. Although I do not claim to be an attorney, I believe I understand the bottom line of these proposals. Please be mindful of the fact that retail pharmacy cannot purchase at the level of mail order. Nor can mail order provide the level of pharmaceutical care community pharmacy does. Therefore, they should not be bundled together in determining drug cost.

Also, even though independent pharmacy has fought for years for transparency from PBM s, that is not the case. Therefore, any inclusion of PBM rebates or discounts should not be considered in the formulas.

Community pharmacy has provided an excellent delivery system for years despite the attacks by government, mail order pharmacies, and insurance companies. This is because independent pharmacist and their support staff want the best for their patients.

There have been many studies indicating the cost of filling a prescription (the governments 340B program is a good example). These figures should be considered when making a decision on a change in reimbursement philosophy.

Please be mindful of the information you will receive from people in our industry who are in the know about how inaccurate changes will affect our profession, therefore our nation.

Sincerely,
Gary Pettigrew D. Ph.

Submitter : Mr. HD HIGH **Date:** 02/15/2007

Organization : DELTA PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AS OWNER OF 2 INDEPENDANT PHARMACIES THIS REIMBURSEMENT FORMULA WOULD CAUSE US TO LOOSE MONEY- WE HAVE SERVED OUR COMMUNITY SINCE 1935-WE WOULD HAVE TO DISCONTINUE IN THE PROGRAM AND CAUSE LOSS OF MANY JOBS-THANKS

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

Submitter : **Date: 02/15/2007**

Organization : **St. Thomas Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

We are unsure that we will have the ability to do this with our current financial system. If we do have this functionality, it would take 3-6 months to update the NDC codes in the Pharmacy System and then take someone at least 4-6 hrs a week to maintain them. This would be about a $50,000 cost to us to update the NDC and about $300 a week to maintain them.

Submitter : Dr. Dwight Weaver **Date:** 02/15/2007

Organization : Crain's Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the proposed AMP Regulation. As the owner of a small-town pharmacy in rural Tennessee I feel that the very existence of my business will be threatened if the CMS adopts the regulation. More than 95% of my income is from the sale of prescriptions and if I must accept reimbursement that results in a loss of 36% or more, as the GAO has determined, my business will not be able to survive.

Submitter : **Ms. Karen Hildebrand** **Date: 02/15/2007**

Organization : **Planned Parenthood of West Texas**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

GENERAL

GENERAL

I am the CEO of Planned Parenthood of West Texas. We are a small to mid-size family planning agency in rural West Texas. We serve 50 counties and over 14,000 patients. In this area, people have to travel great distances to access basic health care. For our patients, we are, many times, their only healthcare provider. Eighty two percent of our patients live at or below 150% of the federal poverty level; eighty nine percent live at 200% or below. The exclusion of my agency from receiving discounted pricing is devastating. Our patients are poor and it would be difficult for them if we increase what we charge them for their birth control and other pharmaceuticals. But we cannot continue providing pills and not cover the cost. We currently lose money on many of the drugs we provide and we cannot keep our doors open and continue to do this. My agency does not receive Title X funding so we are not eligible for 340b pricing. Although we receive Title XX funding from the state, which reimburses us after we see qualifying patients -those with incomes at or below 185% of the federal poverty level, this does not qualify us for 340b pricing. We are truly a safety net provider and need to be included as part of the approved group.

Submitter : Ms. Susan Melczer **Date:** 02/15/2007

Organization : Metropolitan Chicago Healthcare Council

Category : Health Care Provider/Association

Issue Areas/Comments

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

Response to Comments

Response to Comments

see attachment

CMS-2238-P-582-Attach-1.PDF

Submitter : Dr. Leslie Stuart **Date:** 02/15/2007

Organization : Tennessee Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-583-Attach-1.DOC

Submitter : Mr. James Kelley **Date:** 02/15/2007

Organization : Anderson County Discount Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Everything about the new pricing system proposed for pharmacies for Medicaid is absurd. We have been paid by the AWP system with a reimbursement fee. This has been so low, thousands of pharmacies around the country have went bankrupt and even the major chain stores are struggling. It is almost like the airline industry where we are being priced out of business. What is health care going to do when there are only 1-2 drug stores per town and they use 1 pharmacist and 20 techs. The Pharmacy Schools will close or we'll have less of them.

Everyone has to know that this new pricing system is absurd. Every year the reimbursement fees for pharmacies are going way down, especially over the last ten years, yet RX prices are going up. Doesn't everyone know why, because manufacturers are raising costs of drugs by great percentages. One bottle of medicine might cost $100.00 today, then cost $150.00 for the exact same bottle four months later. They have no conscience. A manufacturer will call with a new cough syrup that may cost between $40.00 - $60.00 for a 4oz. bottle, this is ridiculous! Something for a runny nose or allergies costing that much is ridiculous. Then you take something that cost the pharmacy $81.00 and you only pay $84.00 and act like you are going to reduce costs of health care by reducing pharmacy fees from $2.50 to $2.25 - Big Deal! Why not reduce the cost of the drug for pharmacies to $80.00 and save $3.00 - $4.00 per prescription. If you really wanted to reduce health care costs, this is the way to go. Also, several years ago, brand manufacturers saw that generics were too cheap. They then bought the generic companies and immediately raised the costs from $4.00 - $5.00 per 100 to $50.00 per 100 and thought that was OK. To save health care costs, what happened again, was remibursements to pharmacies were cut another 15 cents as if that made any sense. You would think that everyone alive would know where to control health care costs. It is not the drug store and everyone has to know that. Our profit margin is less and less each year but health care costs and RX prices are going up dramatically. Stop the manufacturer from pricing RX's so high and raising them so dramatically and you have accomplished what you are trying to do.

Submitter : Ms. robert logan **Date:** 02/15/2007

Organization : logan's discount drugs, inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : Mr. Steven Ciullo **Date:** 02/15/2007

Organization : Valley Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

As Corportate Director for Pharmacy Services at Valley Health System, I believe that these changes would create an undue hardship on our organization at this time based on the fact that the information requested would have to be provided manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources. Please note that will be doing further analysis to estimate the burden and cost to implement this proposal.

Thank you for your consideration of these issues.

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 15, 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,

Lewis Lowe, R.Ph.
Lowe s Pharmacy, Inc.

Submitter : Ms. Carol Steckel **Date:** 02/15/2007

Organization : Alabama Medicaid Agency

Category : State Government

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-588-Attach-1.DOC

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-589-Attach-1.DOC

Submitter : Mr. Larry Wilkinson **Date:** 02/15/2007

Organization : Terrace Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-590-Attach-1.RTF

Submitter : Mr. Philip Baier **Date:** 02/15/2007

Organization : Mr. Philip Baier

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-591-Attach-1.DOC

Submitter : Dr. Gary Louie **Date:** 02/15/2007

Organization : California Pacific Medical Center

Category : Pharmacist

Issue Areas/Comments

Background

Background

The regulation requires the pharmacies to submit the NDC code as part of its submission to CMS

GENERAL

GENERAL

This regulation poses undue hardship on the hospital as unless a hospital already has barcoding at the point of patient administration, the hospital information system will be unable to yield a 11-digit unique NDC number to submit to the State Medicaid agency. Majority of hospitals has yet to implement the bar code technology at point of care. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

The impact on workflow, staffing and financial resources of the hospital is quite dramatic, unrealistic and not justifiable given current fiscal and workforce constraints. I would disagree with the proposed rules comments that [W]e believe the cost of adding the NDC to each claim would be minimal. We are not able to estimate the cost to make this change. Just the opposite, we expect that this requirement would require tremendous amount of labor and other resources to implement. I estimate this to be minimally cost in the range of tens of thousands dollar annually. This is a cost that we are unable to absorb.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

This regulation poses undue hardship on the hospital as unless a hospital already has barcoding at the point of patient administration, the hospital information system will be unable to yield a 11-digit unique NDC number to submit to the State Medicaid agency. Majority of hospitals has yet to implement the bar code technology at point of care. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

The impact on workflow, staffing and financial resources of the hospital is quite dramatic, unrealistic and not justifiable given current fiscal and workforce constraints. I would disagree with the proposed rules comments that [W]e believe the cost of adding the NDC to each claim would be minimal. We are not able to estimate the cost to make this change. Just the opposite, we expect that this requirement would require tremendous amount of labor and other resources to implement. I estimate this to be minimally cost in the range of tens of thousands dollar annually. This is a cost that we are unable to absorb.

Submitter : Mark Byrd **Date:** 02/15/2007

Organization : Mark's Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-593-Attach-1.RTF

Submitter : Mr. Curtis Riley **Date:** 02/15/2007

Organization : Millry Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-594-Attach-1.DOC

Submitter : Mr. Antony Eason **Date:** 02/15/2007

Organization : TAS Drug, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

I represent TAS Drug, an independent pharmacy serving approximately 1,800 of your entity s beneficiaries in NC s western piedmont. I am writing to request that the finalization of legislation be delayed until more detailed information is made available.

Collection of Information Requirements

Collection of Information Requirements

****Federal Register Vol. 71, No. 246, 12/22/2006 page 77176 Section 447.502 Definitions **** AMP appears to provide reimbursement of acquisition costs only, without consideration of costs of doing business (dispensing costs, labor, packaging, rent, utilities &). TAS Drug, as well as, all other community pharmacies, could not even break even if we were to provide our products at cost . A minimum level of dispensing fee should be included as an alternative to the definition only position.

****Federal Register Vol. 71, No. 246, 12/22/2006 page 77178-77179 Section 447.504 Definition of Retail Pharmacy Class of Trade and Determination of AMP **

Regarding inclusion of mail order pharmacy prices in the definition of retail pharmacy class of trade for purpose of inclusion in the determination of AMP: TAS Drug, as well as, other independent pharmacies does not purchase pharmaceuticals at the same cost as mail order pharmacies and chain pharmacies. This is due in part to our inability to negotiate collectively with manufacturers, and our having to acquire products through wholesaler/distributors (who in turn must impose additional margins for the distribution of the products). The disparity between acquisition costs of mail order/chain pharmacy and independent pharmacy (such as TAS Drug) are very significant. Unfortunately, CMS s inadequate provision of data regarding AMP s to the retail pharmacy industry makes it difficult to respond definitively to this matter, therefore a final rule should be delayed until the CMS can provide more detailed/accurate information to allow a legitimate, valid evaluation of the AMP data.

I do not understand why PBM s rebates, discounts, etc. would be included in AMP calculations. TAS Drug has never received a share of any PBM s rebates. To the contrary, PBM s impose service fees to TAS Drug for the ability to provide service to the patients.

****Federal Register Vol. 71, No. 246, 12/22/2006 page77187-77188 Section 447.514 Upper Limits for Multiple Source Drugs ***** Regarding the request for comment on 11 digits v. 9 digits NDC calculation of AMP: A number of large bulk size products typically available to direct purchasers at discounted rates are not available for purchase by TAS Drug and other independent pharmacies. The 11 digit NDC should be utilized for FUL calculation to compensate for this disparity. Once again, independent pharmacies should not be asked to provide products and services below their acquisition costs.

GENERAL

GENERAL

In summary: 1. A minimum level of dispensing fee based on national annual independent analysis should be included in addition to the FULs for reimbursement determination. 2. Inadequate provision of hard data by CMS of AMP s to the retail industry hampers our ability to provided definitively accurate commentary on the matter. Therefore, the final rule should be postponed until adequate information is provided to allow for statistically significant evaluation. 3. If mail order is included in the definition of retail pharmacy class of trade, a significant additional increase should be provided to those entities that provide the more desirable mode of delivery of products and services, namely community pharmacies. 4. PBM s rebates, discounts, etc., should not be included in AMP calculations. 5. The 11 digit NDC should be utilized for FUL calculation

In closing, CMS should provide additional information to the industry related to the actual AMP and established FUL prior to implementation of a final rule. This will enable us to make a more educated commentary to help CMS and the legislature meet the intent of the legislation.

Response to Comments

Response to Comments

****Federal Register Vol. 71, No. 246, 12/22/2006 page 77190-77194 Section 447.514 Impact Analysis **** The statement we believe that these legislatively mandated section 6001 savings will potentially have a significant impact on some small, independent pharmacies should be changed to read &will have a catastrophic impact on most independent pharmacies if your entity s proposed changes are ruled on as-is.

Another possible development from the rule changes as-proposed, would be the refusal of pharmacies to accept the reimbursement offered, leaving significant gaps in providers for your entity s beneficiaries.

Submitter : **Beverly Guy** **Date: 02/15/2007**

Organization : **Millry Drugs**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-596-Attach-1.DOC

Submitter : **Date: 02/15/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

February 15, 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 Rite Aid Pharmacy.

I. 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,

Lindsey Klish

Student Pharmacist

Submitter : **Dr. Brent Dunlap** **Date: 02/15/2007**

Organization : **Plateau DrugCenter**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-598-Attach-1.DOC

Submitter : Dr. Don Dehart **Date:** 02/15/2007

Organization : Mcintosh Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-599-Attach-1.DOC

CMS-2238-P-599-Attach-2.DOC

Submitter : **Deborah Ann Whisenhunt** **Date: 02/15/2007**

Organization : **Mcintosh Drugs**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-600-Attach-1.DOC

Submitter : Mr. DONALD JOHNSTON **Date:** 02/15/2007

Organization : HIDEG PHARMACY INC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

IT IS VERY IMPORTANT THAT CMS NOT IMPLEMENT THE PROPOSED CUTS TO THE PRICES PAID TO RETAIL PHARMACISTS FOR THEIR DRUGS AND SERVICES. OUR PATIENTS NEED THE ABILITY TO SEE A NEIGHBORHOOD PHARMACIST FOR ALL THEIR MEICAL NEEDS AND ANY PRICE CUTS WILL HINDER THAT AVAILABILITY.
PLEASE WORK WITH THE NATIONAL PHARMACY GROUPS TO HELP SAVE COSTS IN THE COMPLETE COST OF MEDICAL CARE, QUALITY PHARMACEUTICALS CAN SAVE MORE MONEY IN THE LONG RUN. INCREASED GENERICS WITH A FAIR DISPENSING FEE AND FAIR COST OF GOODS IS NEEDED.THESE DRASTIC CUTS WILL PUT MANEY STORES OUT OF BUSINESS WHICH WILL HUT HEALTHCARE, COST JOBS, CUT TAXES,AND HURT MANY PEOPLE.....

THANK YOU FOR YOUR TIME....

Submitter : Keith Boyett **Date:** 02/15/2007

Organization : Mt. Vernon Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-602-Attach-1.DOC

Submitter : **Dr. Brent Dunlap** **Date: 02/15/2007**

Organization : **Scott County Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-603-Attach-1.DOC

Submitter : Joyce Walker **Date:** 02/15/2007

Organization : Mt. Vernon Pharmacy

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-604-Attach-1.DOC

Submitter : **Dr. Bill Dunlap** **Date: 02/15/2007**

Organization : **Plateau DrugCenter**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-605-Attach-1.DOC

Submitter : Dr. Caye Renager **Date:** 02/15/2007

Organization : Mcconaghy Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-606-Attach-1.DOC

Submitter : Mr. Trevor Williams **Date:** 02/15/2007

Organization : Smith Drug Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Ms. Norwalk,

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

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

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medication. This does not consider the recently released report from the accounting firm Grant Thornton LLP "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies" in which it is reported that the median cost of dispensing a prescription for a pharmacy is $9.86.

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.

My pharmacy and others have already been hit hard by many factors including poor(pathetic) reimbursements from PBM's who administer the Medicare Part D plan. These companies such as Humana,Caremark,Express Scripts, Medco and many others are ripping off Medicare, the American people, as well as the community pharmacy.
These same companies are FORCING millions of employees of companies to obtain their prescriptions through mail order. This takes business away from my store on a weekly basis. These many factors along with AMP pricing may very well drive me out of business. MY DRUGSTORE HAS BEEN SERVING OUR COMMUNITY FOR ALMOST 100 YEARS!!!!!

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,

Trevor Williams, RPh

Submitter : Mr. ERNIE RIDDLE **Date:** 02/15/2007

Organization : RIDDLE EXPRESS PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

Submitter : **Date: 02/15/2007**

Organization : **Mark's Family Pharmacy**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-609-Attach-1.RTF

Submitter : **Mr. Stephen Griffin** **Date: 02/15/2007**

Organization : **Griffin Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I,m Steve Griffin, RPh. owner of Griffin Pharmacy with 2 locations in the Birmingham, Al. area and our original location in the small town of Sipsey, Al. We have 36 full time employees and have been
in business 26 years.

GENERAL

GENERAL

I want to express my concern with the proposed rule (CMS-2238-P) regarding the pharmacy providers based on the AMP model as set forth in the Deficit Reduction Act of 2005. If the pharmacvy reimbursements utilizing AMP as outlined in this rule are implamented I will be forced to discontinue service to medicad patients due to the fact that my reimbursement would be below my aquisition cost for the drugs.
Even a report by the GAO states that community pahrmacies such as mine would lose an average of 36% on each generic prescription filled for a Medicaid beneficieary.
A recently relased report from the accounting firm Grant Thornton LLP indicated the median cost for dispensing a prescription is $10.51.

Pharmacist were here when CMS instituted the Medicare Part D Prescription Drug and they took care of the patients by allowing them to have their medications while trying to work through all the new reimbursement mechanisms. During that time due to all the confusion my pharmacys payments were delayed for over 90 days. this is only one example when pharmay came through. Please consider the importance of community pharmacies when debating the AMP pricing model.

Sincerely,

Stephen H. Griffin, R.Ph.

Submitter : **sally slusher** **Date: 02/15/2007**

Organization : **NC Association of Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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,

Sally J. Slusher
NC Association of Pharmacists

GENERAL

GENERAL

February 18, 2007

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

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

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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 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,

Sally J. Slusher
NC Association of Pharmacists

Submitter : **Wilbur Price** **Date: 02/15/2007**

Organization : **McConaghy Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-612-Attach-1.DOC

Submitter : Dan McConaghy **Date:** 02/15/2007

Organization : McIntosh drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-613-Attach-1.DOC

Submitter : **Ms. Stephanie Capron** **Date: 02/15/2007**

Organization : **Ritzman Pharmacies, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

Background

Background

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Collection of Information Requirements

Collection of Information Requirements

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Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

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Regulatory Impact Analysis

Regulatory Impact Analysis

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Response to Comments

Response to Comments

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CMS-2238-P-614-Attach-1.TXT

Submitter : **Dr. John Kessler** **Date: 02/15/2007**

Organization : **Dr. John Kessler**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

February 15, 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

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 The North Carolina Association of Pharmacists 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, the North Carolina Association of Pharmacists 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 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,

John M Kessler, Pharm. D. BCPS
President and Chief Clinical Officer
SecondStory Health, LLC
919.621.8973
jkessler@secondstoryhealth.com

Submitter : Aubrey Bryan Higdon **Date:** 02/15/2007

Organization : Mt. Vernon Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-616-Attach-1.DOC

Submitter : **Brightman B. Coker** **Date: 02/15/2007**

Organization : **McConaghy Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-617-Attach-1.DOC

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Hello I am an independant pharmacist trying to make a living just like everyone else. I understand the proposed changes to pharmacies reimbursement is about to change. The proposed changes are very flawed and if implemented as they stand will force many individuals such as myself out of business and greatly reduce our patients access to care.
The AMP calculation you are attempting to use has many flaws:
1)including mail-order pharmacies in the calculation.
Mail-order pharmacies have special prices not available to retail pharmacies.
2)Rebates to PBM's.
This has nothing to do with retail pharmacy. It is out of our control. And we do not see any of this money. If CMS wants it go after the PBM.
3)Pricing updates happen daily in this trade. This means I can by a drug today for more than CMS is willing to reimburse. CMS will update 30 days after the month end. That means we will be reimbursed much less than our cost for 60 days. This in my mind is just stealing from pharmacies to help CMS budget. The standard in this industry is that PBM's update their data DAILY!!!!
4)NDC is going to be 9 digits not 11. The standard is 11. Why change? Again to steal rightful money owed to pharmacies to put back into CMS budget. This is not right. The last 2 digits are necessary to insure correct pricing. Different package sizes cost different amounts. If CMS reimbursement is based on a bottle of 5000 Which would be the cheapest, And I by a bottle of 100 my cost is a whole lot higher per tablet than the price that was based on 5000 units.)
5)GAO finds AMP will be 36% below invoice price. How will stay in business. The answer we will not. Decreasing patients access and quality of care. So if that is your goal to save monet here to spend more later, I assure you will accomplish that.
6)CMS does not account that we are professionals. Requireing 6 years of professional education. We are the most accessable base of knowledge. Patients walk in the store all the time with questions or problems that we fix at no charge. How is this accounted for? When you go to the doctors you need an appointment which is billed for their time. CMS definition must account for pharmacists time dispensing, counseling, time on the telephone,fax,email with Medicaid agencies,PBMs,billing information, real costs like rent,utilities, mortages etc. CMS is treating us like retailers. We do not just resale goods. We provide an irreplaceable service, which is being jepordized.
Thank You for your time.
Brian Bryk

Submitter : Norman John McConaghy **Date:** 02/15/2007

Organization : McConaghy Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-619-Attach-1.DOC

Submitter : **Mrs. June Adams** **Date: 02/15/2007**

Organization : **Adams Pharmacy and Home Care Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am a small business owner that services over 250+ medicaid patients. I do not have access to the pricing this AMP is based on. My cost to dispense to patients is $10.50+ since many of the patients require special packaging. This is so very unfair to put my business out of business. I cannot operate my business with these unfair practices. What other business in the country operates with the margins pharmacies are forced with?? I know of none that have not gone out business. These patients will lose access to their medications and the pharmacist that takes the time to explain it to them. Sincerely, June Adams

CMS-2238-P-620-Attach-1.WPD

CMS-2238-P-620-Attach-2.WPD

Submitter : Ms. Laura Lanman **Date:** 02/15/2007

Organization : APhA-ASP

Category : Health Care Professional or Association

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 : **john mcconaghy** **Date: 02/15/2007**

Organization : **john mcconaghy**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-622-Attach-1.DOC

Submitter : Ms. Nancy Kachel **Date:** 02/15/2007

Organization : Planned Parenthood of Arkansas and Eastern Oklahom

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-623-Attach-1.DOC

Submitter : Mr. Jeffrey McCloud **Date:** 02/15/2007

Organization : McCloud Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a pharmacist and co-owner of McCloud Family Pharmacy in Huntington, WV. I have been a pharmacist for 12 years and opened my own establishment in 2005.

Collection of Information Requirements

Collection of Information Requirements

The government will reimburse using the AMP schedule for generic drugs beginning in July 2007. The effect of this will be for 36% of Medicaid rx's we fill, we will take a loss, thus making it impossible to be profitable as a business taking Medicaid recipients.

GENERAL

GENERAL

See attachment.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

We calculated our cost to dispense a prescription to break even to be $10.50 in addition to cost of the drug.

Regulatory Impact Analysis

Regulatory Impact Analysis

We are against the induction of AMP due to its adverse effect on our business as a whole.

Response to Comments

Response to Comments

The impact of this bill could lead to our dissolution.

CMS-2238-P-624-Attach-1.DOC

CMS-2238-P-624-Attach-2.DOC

CMS-2238-P-624-Attach-3.TXT

CMS-2238-P-624-Attach-4.DOC

Submitter : Mr. Lynn Connelly **Date:** 02/15/2007

Organization : Medicine Mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The government cannot expect ANY business to sell prescription drugs below cost and stay in business. Each class of trade should be separated. For instance, retail, mail order, and long term care pharmacies all purchase at different cost levels and the same AMP figures should not be used for every class of trade.

We are only asking the government to be reasonable and fair.

Submitter : **Mr. Don Waldron, Jr.** **Date: 02/15/2007**

Organization : **Mr. Discount Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 15, 2007

Centers for Medicare and Medicaid Services
Attention: CMS 2238-P Mail Shop C4-26-05
7500 Security Blvd.
Baltimore, MA 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 s 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 _____. We are a major provider of pharmacy service in the community and your consideration of these comments in essential.

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

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

2. Calculation of AMP- Removal of Rebates, Concessions to PEMs and Mail Order Pharmacies

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize the 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 and avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns the Mississippi Independent Pharmacies Association proposed 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 dispense by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules of the package size most commonly dispense 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 filled by the Mississippi Independent Pharmacies Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,
Don Waldron, Jr.
Mr. Discount Drugs
4832 Poplar Springs Drive
Meridian, MS 39305

Submitter : **Mr. Joel Amundson** **Date: 02/15/2007**

Organization : **Allina Hospitals & Clinics**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing pharmacist since 1972, and plan to continue to practice for another 8-10 years. I read in the Feb issue of Drug Topics that reimbursements for generics under Medicaid would be less than acquisition by an average of 36%. How can a pharmacy, or any business, continue when we can't cover our costs? Over 85% of our activity is dispensing RX medication and counseling patients, which is free. If we do not get sufficiently get reimbursed, most pharmacies will not even be around when payors decide to provide Medication Therapy Management (MTM) reimbursement to pharmacist providers. Pilot projects are years away in getting data and agreement that pharmacist's provide valuable services for patients and help assure their medications will be safe, effective, and cost effective. In both hospital and retail settings, pharmacists have significant value to patients and other health care providers. If the current reimbursement strategy continues, the only pharmacies left will be the big box retailers and mail order. Patient access to pharmacists will be much more limited, and patients will have a much less effective outcome following their medication use. It is important to remember that medications are not a commodity like groceries. Medications are powerful and can do a lot of good, or they can do a lot of bad. Pharmacists are a key resource to the public and to other health care professionals in assuring the appropriate use of medications for the patient. We can easily show annual savings in health care costs for patients that exceeds every pharmacist's annual salary. Physicians and nurses rely on pharmacists every day to assure the right thing happens regarding medication. So until pharmacy reimbursement, either through dispensing, or through patient counseling (MTM) when it is in place, you cannot expect good results if you beat up on pharmacies until they are forced to close. Please come up with a better plan. Note that the primary reason drug prices are high are due to pharmaceutical companies and the lack of an effective negotiation to achieve better pricing of pharmaceuticals. Targeting the local pharmacy is missing the mark completely. Pharmacists regularly do what they can to help patients find ways to save money on their medications. Most people who visit their local pharmacy already know that.
Like many pharmacists, I have enjoyed my role in serving patients and helping them use medications appropriately for better health. We are there because we enjoy helping people. The reimbursement needed to keep the pharmacy doors open is our only key issue. Please make the changes needed by targeting the drug companies and insurance companies....those that are only business-focused. Right now there is too much focus on decreasing reimbursement to health care providers! You are very welcome to contact me if you wish. Joel Amundson 763/559-0974

Submitter : Mr. Kevin Hartman **Date:** 02/15/2007

Organization : Nashville Pharmacy Services, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-628-Attach-1.RTF

Submitter : Mr. Mark Lowry **Date:** 02/15/2007

Organization : Lineville Clinic Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I have owned my own pharmacy for 7 years, my wife & I invested several thousand $ to do this and ever since we bought this pharmacy we have seen our business gross increase greatly but due to 3rd party insurance and fed and state medicaid and medicare we have literally almost gone broke. We cannot take any cuts in reimbursement at all. Please do not lower our reimbursements.

GENERAL

GENERAL

Please do not lower the retail pharmacy's reimbursements by lowering the cost factor of the reimbursement. My profit is shrinking daily and if you pass this lowering of the amp then most all retail pharmacies will be forced to close. I have over $300 thousand dollars invested and can't hardly pay the bills. Do not ruin this business as small business is what made this country great.

Submitter : Mr. Michael Smathers **Date:** 02/15/2007

Organization : SCPA, and Return Solutions, Inc

Category : Drug Industry

Issue Areas/Comments

Background

Background

Servicing pharmacies in the Southeast since 1979 in the service sector.

GENERAL

GENERAL

I have been working with pharmacies in the Southeast, in particular South Carolina, since 1979. Over the past 7 to 8 years, I have unfortunately seen many community pharmacies either being bought out or closed because of the continued lack of reinbursement for their time, effort, education, investment in the community, and having to compete in an unlevel field of business. These men and women daily tell me they don't know how long they can hold on because of lack of profits and continued cuts in reinbursements.

It's a sad day when I tell these professional pharmacists that "it can't get any worse", and then it does. Why is it that each time there is a program to supposedly save the consumer on the price of their prescriptions, it is always the independant pharmacists who have to pay for it? Where is the free enterprise?

Submitter : Mr. Lemuel Boyett **Date:** 02/15/2007

Organization : Family Health Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medications. 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 dispening a prescription for a pharmacy is $9.86.

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 a 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.

Submitter : **Mr. Fred Calcaterra** **Date: 02/15/2007**

Organization : **Family Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I operate an independent pharmacy in Southern Illinois and struggle to care for Medicaid and Medicare patients. The pricing that we are subjected to is not sufficient to give quality prescription service. Many patients need delivery, which is a huge expense for use. Our electric utility is Ameren CIPS and they have recently been allowed to increase rates up to 100%. How are we to receive lower rates and stay profitable? Also in Illinois we have had a minimum wage law that increased wages to $7.50 an hour. I cannot continue to have expenses increase and not be able to increase my prices. How do you suppose I can continue or do you not want individuals who are small business owners to continue to have employees and be the "Backbone of America!" Please do not allow the Deficit Reduction Act pertaining to the Medicaid program to happen.

Sincerely,
Fred Calcaterra

Submitter : Mr. Dave Campana **Date:** 02/15/2007

Organization : Alaska Department of Health and Social Service

Category : State Government

Issue Areas/Comments

Background

Background

Comments on the CMS-2238-P.

GENERAL

GENERAL

See Attachment

CMS-2238-P-633-Attach-1.DOC

Submitter : **Dr. Blake Dunlap** **Date: 02/15/2007**

Organization : **Plateau DrugCenter**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-634-Attach-1.DOC

Submitter : Dr. Derek Quinn **Date:** 02/15/2007

Organization : Westlake Drug, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed reimbursement system associated with this regulation is one of many options to control the cost the Medicaid program. Two concerns, however, present themselves readily with this regulation. First, regardless of the basis for reimbursement, pharmacists must be fully reimbursed for the cost of the drug to their pharmacy as well as for the overhead and professional service associated with dispensing the prescription. This regulation does not have a provision to ensure that pharmacists are at least reimbursed for the acquisition cost of the drug and for the professional service provided. Second, generic reimbursement has always included an incentive to use generic drugs by giving a higher percentage margin than brand name reimbursement. This incentive contributes to an overall lower healthcare cost through the use of low cost generic drugs. Without this incentive and with reimbursements being potentially less than acquisition cost, the number of providers choosing not to accept Medicaid reimbursement will begin to skyrocket and leave patients without access to their prescription drugs.

First, please consider the addition of a minimum reimbursement mandate that guarantees coverage of both the acquisition cost as well as the professional service being provided. Second, require the use of therapeutic alternatives when an alternate product in the same class has a generic available and in this way control the use of expensive brand-name medications.

Respectfully submitted,

Derek J. Quinn, Pharm.D., R.Ph.
Pharmacist

Westlake Drug, Inc.
8822 Portage Road
Portage, MI 49002
269.327.3049
www.westlakedrug.com

Submitter : Dr. Blake Dunlap **Date:** 02/15/2007

Organization : Scott County Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-636-Attach-1.DOC

Submitter : Dr. Mike Baker **Date:** 02/15/2007

Organization : Scott County Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-637-Attach-1.DOC

Submitter : David Hueter **Date:** 02/15/2007

Organization : David Hueter

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-638-Attach-1.PDF

Submitter : **Mrs. Wanda Dunlap** **Date: 02/15/2007**

Organization : **Scott County Pharmacy**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-639-Attach-1.DOC

Submitter : William Arrington **Date:** 02/15/2007

Organization : University of Tennessee Memphis

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-640-Attach-1.DOC

Submitter : Mr. William Holt **Date:** 02/15/2007

Organization : Jones Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

You will drive the smaller independent pharmacies out of business. This is a small store in a small elderly town. There is not a larger store for 25 miles in any direction. The nations elderly will suffer from this!!!

Submitter : **Ms. Paula Gianino** **Date: 02/15/2007**

Organization : **Planned Parenthood of the St. Louis Region**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

Regarding File Code CMS-2238

Dear CMS Administrator,

I am the CEO of Planned Parenthood of the St. Louis Region (PPSLR) and Reproductive Health Services (RHS) of PPSLR in St. Louis Missouri. We are a 75 year old non profit health care oranization that provides gyecologic and reproductive medical services to over 34,000 women, men and teens each year.

Two thirds or more of our patients are poor, with no insurance, living at or below 200% of the fedcral poverty level. We operate six family planning centers and one fully licensed ambulatory surgical center; in all of our locations we provide various medications, the majority medications dispensed are oral contraceptives. All of our locations sell and/or dispense for free medications at far below local retail pharmacy rates; retail pricing is beyond the reach for the super majority of our patients.

All of our centers operate on a sliding fee scale in order to serve those in need; we participate in Medicaid and other sources of funding to subsidize the comprehensive care we provide. These sources of funding do not fully cover the costs for all patients.

In some of the counties where our facilities are located, we are the only provider of services on a sliding fee schedule, or witout other restrictions that cause barriers for our clients. We provide approximately $150,000 a year in charity care at RHS, our surgical center.

Our ability to serve our clients, especially at our centers which do not receive 318 or 340b status, is totally dependant upon our ability to continue to purchase pharmaceuticals at nominal pricing, from willing companies. Without nominal pricing, we will no longer be able to purchase and provide low cost contraception to our patients. This will have a dramatic impact on their ability to access contraception, which will lead to further unintended pregnancies, increased numbers of children, increased abortions, increased human, financial and social costs to the patient, our community and society.

We know that we save taxpayers close to $4.00 for every dollar we allocate for family planning services--multi billions of dollars are saved. And nominally priced pharmacueticals are the foundation of the success of family planning providers in non Title X or 340b or 318 entities.

We have just learned as of 2/14/07 that two of our four 340b registered health centers may lose this status within the next two months when our Title X contracts are renewed. This is devastating news; we have not even completed an impact analysis, while we await clarification and final decision. This is a real and perfect example of why nominal pricing is so critical and of why public health entities such as ours--those dedicated to servind impoverished and underserved populations--are in such tenuous/vulnerable states given this dynamic regulatory envorinment.

We are in desperate need for stability in these regulatory areas so that we can plan, serve, and even expand services to more individuals in need. We are the safety net providers for our community and for the country, all of us are needed because the numbers of individuals grow each year.

I urge CMS to use its authority to authorize "safety net providers" for eligibility for nominal pricing. We are the front line providers, the non profit entities, such as PPSLR and RHS, whose mission it is to serve low income and uninsured women, men and teens, and who provide services on a sliding scale.

The future of four of our current family planning centers, and our surgical center may be dependent upon nominal priced pharmaceuticals; this will have an impact on over 26,000 patients in our region.

Respectfully submitted,

Paula M. Gianino
President and CEO
Planned Parenthood of the St. Louis Region and
St. Louis, MO
RHS of PPSLR

Submitter : Dr. Frank Fariello **Date:** 02/15/2007

Organization : Dr. Frank Fariello

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

a few major issues with the AMP (average manufacturer price) rule.
1. pharmacy acquisition costs for multiple source generic medications are not covered in the formula for AMP based Federal Upper Limits.

2. Average Manufacturer Price was never intended to serve as a basis for reimbursement, in order for AMP to be used it must be redefined to reflect the ACTUAL COST PAID BY RETAIL PHARMACY (not PBMS!!!!)

to redefine (AMP) 3 things must happen
1.all rebates and price concessions made by manufactures which are not available to retail pharmacy MUST BE EXCLUDED!!!!!!
2. exclude all mail order facilities and PBM pricinf from AMP calculations (mail order facilities and PBMs are extended special prices from manufacturers and they ARE NOT PUBLICLY ACCESSIBLE IN THE SAME WAY THAT RETAIL PHARMACIES ARE PUBLICLY ACCESSIBLE
3. the reporting of AMP at the NDC number level to ensure accuracy

Submitter : Mr. Bob Dufour **Date:** 02/15/2007

Organization : Wal-Mart Stores, Inc.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mrs. Kim Custer **Date:** 02/15/2007

Organization : Planned Parenthood of North East PA

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

While we, Planned Parenthood of North East Pennsylvania, are not an affected provider, we serve the same patients. We are a safety net provider, serving 37,000 patients annually with low-to-no cost birth control and reproductive exams. The low-income, uninsured and underinsured women we serve would have no other access to birth control, if they were not able to receive them from an agency such as this at little to no cost. Although we currently receive the funding that allows us to provide contraception at a low cost, there is no guarantee that we will not be affected in the future. Therefore we ask you to create a designation that protects all safety net providers so we may ensure all women are treated and served with dignity.

Submitter : Mrs. keisha brown **Date:** 02/15/2007

Organization : Bergen Point Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

WE, AS AN INDEPENDENT PHARMACY, ARE OPPOSED TO THIS PROPOSED RULING BECAUSE THERE ARE MANY THINGS THAT DOESNT MAKE SENSE FOR BUSINESS, MUCH LESS PATIENT CARE. FIRST, THE FORMULA FOR AMP(AVERAGE MANUFACTURER PRICE) BASED FULS(FEDERAL UPPER LIMITS)IN THE PROPOSED RULE WILL NOT COVER ACQUISITION COSTS FOR MULTIPLE SOURCE GENERIC MEDS.(IF OUR COSTS CAN'T BE COVERED WE CANNOT SERVE PATIENT AND WITHOUT SUFFICIENT REIMBURSEMENT WE CANNOT PAY OUR EMPLOYEES MUCH LESS LIVE!!!) SECONDLY, AMP WAS NEVER INTENDED TO SERVE AS A BASIS FOR REIMBURSEMENT. THIRDLY, AMP MUST REFLECT ACTUAL COST PAID BY RETAIL PHARMACY TO BE AN APPROPRIATE BENCHMARK. THIS ACCOMPLISH THIS ONE MUST EXCLUDE ALL REBATES AND PRICE CONCESSIONS MADE BY MANUFACTURERS WHICH ARE NOT AVALIBALE TO RETAIL PHARMACY. ONE MUST EXCLUDE ALL MAIL ORDER FACILITIES AND PBM PRICING FROM AMP CALCUATION. (MAIL ORDER FACILITIES AND PBMS ARE EXTENEDED SPECIAL PRICES FROM MANUFACTURERS AND THEY ARE NOT PUBICLY ACCESSIBLE IN THE WAY THAT BRICK AND MORTAR PHARMACIES ARE PUBLICALY ACCESSIBLE.) ONE MUST ALSO REPORT AMP AT THE 11 DIGIT NDC LEVEL TO ENSURE ACCURACY.
BOTTOM LINE USING AMP IS NOT REALISTIC FOR RETAIL PHARMACIES BECAUSE WE DON'T BUY AT AMP. WE DON'T BUY DIRECTLY FROM THE MANUFACTURERS SO WE DONT SEE REBATES AND PRICE CONCESSIONS. THE WHOLESALERS, MAIL ORDER HOUSES, AND PBMS SEE THESE BREAKS IN PRICE. WE ONLY SEE WHAT THE WHOLESALERS WANT TO CHARGE US AFTER THEY HAVE MARKED UP THERE LOW COST. SO IT WOULD BE AN INJUSTICE TO RETAIL PHARMACIES TO IMPOSE SUCH A RULE AND ESSENTIALLY PENALIZE US FOR DOING BUSINESS AS USUAL. WE WILL NOT BE ABLE TO PAY OUR BILLS WITH PAYMENTS FROM MEDICAID, OR ANYONE FOR THAT MATTER, GIVING US BELOW COST WITH A EXTREMELY LOW REIMBURSEMENT. THEREFORE NOT BEING ABLE TO SERVE OUR MUTUAL PATIENTS.

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Center for Medicare and Medicaid Services
Attn: CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

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

I am pleased to submit the following comments to the Centers for Medicaid and Medicare 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.

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 most Medicaid patients have their prescriptions filled. PBMs and mail order pharmacies do not dispense prescriptions to the general public.

2. AMP should reflect prices paid by retail pharmacies, without including rebates , concessions to PBMs and mail order pharmacies.

3. Including Medicaid data in AMP calculation does not recognize that Medicaid pricing is heavily regulated by state and federal governments.

4. By allowing Manufacturer to report date used for the calculation of tha AMP will create a template for market manipulation and fraud, due to the increased risk involved in both price fluctuations and market manipulation due to timing of manufacturer reporting and the extended ability to revise reported data under this proposes structure.
There ought to be a trigger mechanism to address severe price fluctuations by CMS.

5. We believe that CMS should use the 11 digit AMP value for the most commonly dispensed package size by retail pharmacies to calculate 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 regulation 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 appreciate your consideration of the above comments and ask that you please contact us with any questions.

Sincerely,

Kafi Agboola

cc: Rep Albert Wynnn

Submitter : William Brown **Date:** 02/15/2007

Organization : W.R.B. Enterprises, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : William Brown **Date:** 02/15/2007

Organization : S.S. Brown Enterprises, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-649-Attach-1.DOC

Submitter : William Brown **Date:** 02/15/2007

Organization : W.R.B. Enterprises, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-650-Attach-1.DOC

Submitter : Rose Baran **Date:** 02/15/2007

Organization : Rose Baran

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-651-Attach-1.DOC

Submitter : Mr. Joseph Roney **Date:** 02/15/2007

Organization : New Jersey Pharmacists Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-652-Attach-1.DOC

Submitter : Mr. Matthew Leonard **Date:** 02/15/2007

Organization : CVS/pharmacy Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-653-Attach-1.PDF

Submitter : Mr. GLENN KOSIROG **Date:** 02/15/2007

Organization : KOSIROG REXALL PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

INDEPENDENT PHARMACY

Collection of Information Requirements

Collection of Information Requirements

CMS-2238-P: IMPLEMENTING THE MEDICAL DRUG REBATE PROGRAM PROVISIONS OF THE DEFICIT REDUCTION ACT OF 2005

GENERAL

GENERAL

I am clearly against the proposed regulation of the Deficit Reduction Act, as it will have a devastating impact on our business. No independent pharmacy can stay in operation while experiencing a 36% loss on each transaction. Especially our business which is located in a low income area and is mostly dependent on income from Medicaid.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

CMS.HHS.GOV WEBSITE

Response to Comments

Response to Comments

devastating

Submitter : Mr. NICK HOLLAND **Date:** 02/15/2007

Organization : JONES DRUG STORE

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

WE ARE LOCATED IN A RURAL AREA SOME 20 TO 25 MILES FROM ANY MAJOR TOWN.MANY PATIENTS ARE POOR..MANY LACK TRANSPORTATION TO OTHER
TOWNS FOR PHARMACY SERVICES.IF THE PROPOSED RULE (CMS-2238-P)REGARDING REIMBURSEMENT TO PHARMACIES IS APPROVED THE NEEDY WILL
SUFFER BECAUSE WE'LL BE UNABLE TO FILL MEDICAID PRESCRIPTIONS OR
WILL CEASE TO EXIST.

Submitter : Mr. Bradford Sturgis **Date:** 02/15/2007

Organization : College City Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-656-Attach-1.TXT

Submitter : Mr. Anthony Warford **Date:** 02/15/2007

Organization : Corner Drug Store of Sturgis

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mr. Tom Frazer **Date:** 02/15/2007

Organization : Sturgis Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-658-Attach-1.DOC

Submitter : Mr. Tony Warford **Date:** 02/15/2007

Organization : Corner Drug Store of Sturgis, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-659-Attach-1.DOC

Submitter : Mrs. Kathy Holladay **Date:** 02/15/2007

Organization : College City Drugs

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-660-Attach-1.TXT

Submitter : Mr. Jeffrey Hons **Date:** 02/15/2007

Organization : The Planned Parenthood Trust of San Antonio

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

see attachement

CMS-2238-P-661-Attach-1.RTF

CMS-2238-P-661-Attach-2.RTF

Submitter : Mrs. Adele Fondren **Date:** 02/15/2007

Organization : College City Drugs

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-662-Attach-1.TXT

Submitter : Mr. BILL ALLEN **Date:** 02/15/2007

Organization : AmeriMed Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-663-Attach-1.TXT

Submitter : David Rueter **Date:** 02/15/2007

Organization : Thrifty White Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-664-Attach-1.DOC

Submitter : Ms. Betty Hoover **Date:** 02/15/2007

Organization : Planned Parenthood Center of ElPaso

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-665-Attach-1.DOC

Submitter : **Bruce Dunkin** **Date: 02/15/2007**

Organization : **Dunkin's Pharmacy**

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 one of the most efficient and influential accesses for the recipient.

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

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

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

Sincerely,

Bruce Dunkin, RPh/Owner
Dunkin s Pharmacy

Submitter : Mr. JON MARCACCINI **Date:** 02/15/2007

Organization : JON'S DRUG

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Why are you doning this? Have not all of you had contact with a rural independent pharmacy like mine. Or perhaps your parents or grandparents drug store. As a kid don't you have fond memories of these places. Well we are not dead so don't try to bury us. As you all moved to Metropolis we still serve the folks back home, everyday and usually on the holidays we try to take off. We don't lobby we don't have any power, all we do is take care of people. I don't know who you listen to or how this proposal to kill us got this far but we are not crying wolf. We have been beat up by Part D which without our help on day one would of crashed an burned and the continued ability you have given gaint PBM's to dictate take it or leave it contracts have just about done us in. Not everyone can be serviced at a gaint store or by mail. Ask around those with real pharmacy needs seek us out and need us the Independent phamacy because we still take care of them the old fashioned way with service and respect. Please give us the same.

Sincerely Yours

Jon Marcaccini

Submitter : **Mr. Theodore Beatty** **Date: 02/15/2007**

Organization : **Coborn's Pharmacy Office**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Coborn's is a family owned grocery combo chain of some 31 pharmacies. We are located in mostly rural Minnesota.

Collection of Information Requirements

Collection of Information Requirements

Enact the rule that requires Medicaid generic prescriptions to be paid at AMP.

GENERAL

GENERAL

This regulation will negatively impact 10% of our pharmacy business. The Medicaid prescriptions, if AMP were implemented would result in almost a $3.6 million drop in our gross profit, based upon our sales and margins. We would certainly have to consider discontinuing service to Medicaid patients. Implementing this reimbursement would result in the loss of jobs in the rural markets. The AMP must be such that the drug cost our pharmacies pay are reimbursed for. We cannot survive on reimbursements that allow for only 64% os our drug cost.

Submitter : **Dr. Joey Banks** **Date: 02/15/2007**

Organization : **Dr. Joey Banks**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 15, 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.

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,

Darlene Chaykosky
Student Pharmacist

Submitter : **Miss. Aimee Hightower** **Date: 02/15/2007**

Organization : **University of Tennessee College of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-671-Attach-1.TXT

Submitter : **Dr. Robert Ott** **Date: 02/15/2007**

Organization : **Ott Drug Store Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 15, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacy owner located in Deer River Minnesota. 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 the Minnesota 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 and would result in FULs that are lower than a retail pharmacy s acquisition cost.

3. Removal of Medicaid Data

Including these data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. The inclusion of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

4. Manufacturer Data Reporting for Price Determination Address Market Lag

The risk of price fluctuations due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns, the Minnesota Pharmacists Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the Association comments on the lack of clarity on claw back from manufacturer reporting error.

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. 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 submitted by the Minnesota Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,
Robert Ott Pharm.D.

cc. Rep. James Oberstar

Submitter : Theresa Gerst **Date:** 02/15/2007

Organization : Theresa Gerst

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Regarding the reimbursement of pharmacists for generic drugs: this new regulation will not take into account the community pharmacy's dispensing fee. The community pharmacist spends time with the patient both face to face as well as via telephone and even e-mail anwering questions and helping the patient with their treatment. By law, pharmacists are required to counsel the patient regarding their medications also taking valuable time. Pharmacists should be allowed to get payment for these services.
To not properly reimburse pharmacists for these services (the dispensing fee) could result in patients not receiving their medication. Therefore, I hope that you revisit the purposal and consider increasing the pharmacy dispensing fee. Just think who you would call if you had a question about your medication.

Submitter : **Mr. Eric Esterbrook** **Date: 02/15/2007**

Organization : **Brunner's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I appreciate the oppurtunity to submit comments to CMS about CMS' 12-20-06 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 West Reading PA. We are a major provider of pharmacy services in the community and your consideration of these comments is very important.

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 date 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 fluctations 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

I 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 taht you please contact myself of PPA with any questions.

Sincerly,
Eric R. Esterbrook R.Ph.
532 S Park Rd
Wyomissing, PA 19610
Brunner's Pharmacy
301 S. 7th Ave
West Reading, PA 19611
610-376-6542

Submitter : Mr. Ketan Patel **Date:** 02/15/2007

Organization : The University of TN Healtch Sci. Center, Memphis

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-675-Attach-1.DOC

Submitter : **Date: 02/15/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As an independent pharmacy owner, I would like to comment and ask that the definition of AMP for reimbursement of medicaid generics be reconsidered. According to the GAO study,the AMP reimbursement formula as it now stands would on average leave us being paid about 36% less than our acquisition cost of the medication. The CCPA study found that the average cost to dispense a prescription is $10.50, and that is before we even take into consideration the cost of the medication. If this definition of AMP stands, I will have to be forced to reconsider dispensing any medications to medicaid patients. As an independent pharmacy, 92% of my business comes from prescription sales--I am not a walmart who can make up the losses in front end sales--we need to AT LEAST have the definition of the AMP cover the cost of the medication if we are to continue to serve this vital population who already falls through the cracks with other health services. Pharmacists are a vital link with medicaid patients in the community--especially independent pharmacists who take the time to help and counsel them. Independent pharmacists are a crucial resource for the medicaid patients that is taken for granted. I do not want to stop servicing these individuals, but if it means that i will lose money on every generic prescription that i fill for a medicaid patient (and most of these patients receive generics due to state formularies), i cannot afford that. I am a small business owner that helps to keep our community the community that it is, and i think that is very unfair of the government to make a determination of what AMP should be on their own without any knowledge of the subject. I urge you to listen to NCPA, CCPA, APHA, and all the Pharmacy lobbyists who know that your definition of AMP is off base and will cause detriment to the pharmacy community.

Let's remember who was there and stepped up to the plate in January 2006 when Medicare D debuted with all of its mass confusion. The community pharmacists were the ones out there advancing patients medication and going not paid from insurance companies for months at a time wondering if we were going to get reimbursed so that we could help patients and not let them go without medications.(Remember that many pharmacists were forced to close their doors then due to low and slow reimbursements from the PBMS). We were there for you when your system failed, and now the thanks we get from you is that you think we make too much money and are taking 90% of the $8.4 billion in medicaid cuts from pharmacists.

Please redine the definition of AMP to reflect pharmacists actual acquisition cost of the medication. And this acquisition cost is for community pharmacists, not the mail order and big PBMs of the country that get special rebates and price concessions from maufacturers that retail pharmacies do NOT get!

I would think that the medicaid system could save more money if they mandated the use of generic drugs and not brand name drugs--this would be significant savings for the medicaid system while promoting effective patient health care.

The loss of money that we would experience due to this definition cannot be overcome by the community pharmacists by aggressive purchasing practives, rebates, generic rebates or even adequate dispensing fees. Unfortunately it will be the government who forces small business out of business. Please listen to us--we have real concerns that should be addressed!!Listen to NCPA, CCPA, APHA, NACDS, we have data to back up our concerns. Don't let pharmacists down now after all we have done for CMS!

Submitter : **Mr. Tremain Cooper** **Date: 02/15/2007**

Organization : **South Carolina Pharmacy Association**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

I grew up a poor little boy whose parents' accounts receivable fell short of their notes payable over and over again. More times than not however they had just enough income to pay bills and buy unhealthy but good food to feed me so I wouldn't starve to death. This was the routine for years and years. Well, before age 21 I lost both of my parents to death within 4 years of each other. I could see that they were tired and out of energy in their last days of life before going on to glory. They couldn't continue any longer with robbing Peter to pay Paul then sticking up Peter and Paul to pay Barthalamul. I could see the hurt in their eyes in their last days of life because they wanted to be here for me and provide for me everything I needed to have a successful life. Well, since their deaths I've gone on to become a successful young man with a great education and future in the profession of pharmacy. Similarly pharmacies provide everything patients need to have a healthy and prosperous quality of life. Patients go on to live long lives through their interactions about the pharmacy and medications they receive from the pharmacists. Like my parents pharmacies have been for so many years fighting to stay above water and it seems as if it is getting worse. We are not being adequately reimbursed for the services we provide that prevents and corrects so many medication errors that could cost our country billions of dollars annually. I am in agreeance that their is a need to lower health care expenditures over the next 8 or 9 years but I'm asking that pharmacist and pharmacies are adequately reimbursed simultaneously. I think it should be mandated that pharmacies only pay AMP to acquire prescription drugs to dispense to Medicaid patients and a dispensing fee of $15.00 be included in the remimbursement calculation. I want to be able to serve my Medicaid patients 20, 30, 40, years from now. I'm sure their is some fair agreement would could make that benefits our government, our pharmacy providers, and most of all our patients. I'm a pharmacy student graduating officially on May 11, 2007, with community pharmacy in my heart and the community in my soul please make my graduation present one to be proud of.

Submitter : Dr. John Douglas **Date:** 02/16/2007

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

Background

Background

February 15, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist for Walgreens, a community retail pharmacy located at 530 Cool Springs Blvd, Franklin, Tennessee. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

Collection of Information Requirements

Collection of Information Requirements

Definition of Retail Class of Trade Removal of PBMs and Mail Order Pharmacies

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

GENERAL

GENERAL

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy [OR the pharmacy in which I work], where over 65% of our business comes from prescription drugs. What the other sales in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

Regulatory Impact Analysis

Regulatory Impact Analysis

Removal of Medicaid Data

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

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

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

Use of 11-Digit NDC versus 9-Digit NDC

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

Response to Comments

Response to Comments

Submitter : Mr. Bob Parks **Date:** 02/16/2007

Organization : Mississippi Discount Drugs

Category : Pharmacist

Issue Areas/Comments

Background

Background

I have been practicing pharmacy for 42 years.....almost entirely as an independently owned community pharmacy.

Collection of Information Requirements

Collection of Information Requirements

The proposed regs on AMP are outragous. This is an insult to the local pharmacists of this nation. The profit margins for retail pharmacy have been decreasing since I first started practicing, however, these narrow margins have reached the point where it will be impossible for MANY stores to stay in business with your newest legislation. You are barking up the wrong tree when attacking pharmacies. The big profits are being made by the manufacturers and the PBM's. In trying to save on health care costs, that is where you should be looking. You must put a stop to the destruction of health care via eliminating local pharmacists across our nation.

GENERAL

GENERAL

The proposed regs on AMP are outragous. This is an insult to the local pharmacists of this nation. The profit margins for retail pharmacy have been decreasing since I first started practicing, however, these narrow margins have reached the point where it will be impossible for MANY stores to stay in business with your newest legislation. You are barking up the wrong tree when attacking pharmacies. The big profits are being made by the manufacturers and the PBM's. In trying to save on health care costs, that is where you should be looking. You must put a stop to the destruction of health care via eliminating local pharmacists across our nation.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. (My pharmacy is located at 224 Clinton Blvd. Clinton, Mississippi. 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 Mississippi Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions

Regulatory Impact Analysis

Regulatory Impact Analysis

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. (My pharmacy is located at 224 Clinton Blvd. Clinton, Mississippi. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

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Response to Comments

Response to Comments

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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 the Mississippi Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions

Submitter : Dr. Andrew Hart **Date:** 02/16/2007

Organization : Fairview Pharmacy Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like 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 pharmacist employed in Minneapolis, Minnesota. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Remove PBM and Mail Order from Retail Class of Trade
(i) Creates consistency in the Regulation
(ii) Conforms definition with market reality

2. Implement a Trigger Mechanism
(i) Addresses severe price fluctuations
(ii) Mitigates Risk of Pricing Lag

3. Use of 11-Digit NDC versus 9-Digit NDC
(i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely,
Dr. Andrew Hart, PharmD. RPh.
email: ahart1@fairview.org

cc. All Members of Congress

Submitter : **Date: 02/16/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I believe the provisions in Docket: CMS-2238-P are ill-advised and need to be revised to reflect adequate payment for services especially in the retail class of trade. From the information I have evaluated the definitions of AMP put forth discourage the use of low cost medications and will force many retail pharmacies(the ones that have the most exposure to Medicaid patients)either to withdraw from their State Medicaid programs or to go out of business altogether. As documented by the GAO,the proposed rule will set AMP at 36%on average below the community pharmacy acquistion cost from the examples used. In addition, the Cost of Dispensing Study conducted by Grant Thornton for the Coalition for Pharmacy Action set the average community pharmacy cost of dispensing(average overhead cost per RX) to be $10.50. Unless some measure is implemented to bridge this huge gap, this discrepency will be next to impossible to overcome. Part of the problem with using the proposed AMP model is that the retail trade does NOT have access to the rebates and discounts that would be available to the Mail order/PBM industry and therefore should be considered a different class of trade with a different re-imbursement model and dispensing fee.

I understand that the purpose of this process is to implement the provisions of the Deficit Reduction Act of 2005.However, I don't believe that those responsible for drafting this particular legislation truly understood the dynamics of the current pharmacy marketplace and which segments contribute most to the high cost of prescription medications. Since the Manufacturing and Pharmacy Benefit Manager (PBM)sectors really control the marketplace they have put tremendous pressure on the distribution sector to become extremely efficient or go out of business as many smaller community pharmacies have. That is why the only remaining places to reduce prescription costs are in the manufacturing and PBM sectors. The AMP legislation is flawed because it attempts to reduce costs, once again, at the expense of the distribution or community pharmacy sector: the sector least able to afford the cuts while providing a direct and valuable service to the Medicaid as well as other patient populations. I believe that the regulation of the PBM industry-particularly the practice of referring prescriptions to their own mail order companies for non-shared rebates and discounts as well as requiring transparency for all aspects of their operations will offer the most value towards reducing prscription costs at this time.

Thank you for considering my comments

Submitter : Dr. Robert Rashti **Date:** 02/16/2007

Organization : Planned Parenthood of Southeastern Virginia

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-682-Attach-1.DOC

CMS-2238-P-682-Attach-2.DOC

Planned Parenthood of Southeastern Virginia
Health Centers
910 West Mercury Blvd., Hampton, VA 23666
425 West 20th Street, Suite 6, Norfolk, VA 23517
5441 Virginia Beach Blvd., Virginia Beach, VA 23462

February 16, 2007

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

RE: File Code CMS-2238-P
Request for Inclusion as Safety Net Provider

Dear Administrator Norwalk:

I am greatly concerned about the omission of defining Planned Parenthood affiliates such as our in the Deficit Reduction Act of 2005. The effect of this legislation at present is to exclude our affiliate from eligibility to purchase contraceptive medications at nominal pricing.

Planned Parenthood of Southeastern Virginia (PPSEV) is a non-profit 501 (c) 3 organization, serving the Hampton Roads area and Southeastern portion of our state for 42 years. Our three health centers provide women and men needed services that focus on family planning but include Emergency Contraception, diagnosis and treatment of sexually transmitted infections, prenatal care and breast and cervical cancer screening.

PPSEV provides these services primarily to low income and disadvantaged women with no health care coverage. Last year our three health centers provided such services to 11,000 unduplicated women. For most of these women, we are their only source of affordable reproductive health care.

Sixty-eight percent (68%) of the women we serve are between 20 and 34 with no health care coverage. They are working poor. Our remaining patients include 26% below age 20 and 6% above age 35. Fifty-six per cent (56%) of our patients provided financial information that places them at or below 150% of the poverty level. The total number of indigent women we served increases to 68% if 2,243 patients without financial information are representative of those surveyed.

Planned Parenthood of Southeastern Virginia represents an important community resource and work in concert with other agencies and organizations. We provide colposcopy and LEEP services to one of the local health departments. We provide area abused women's shelters free contraceptive services to their clients. This year we have launched new services to reach an

underserved Latino community, the fastest growing segment of the population. Our prenatal program is possible through collaboration with the Eastern Virginia Medical School.

Many of PPSEV's Planned Parenthood sister health centers across the country are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. Our affiliate participated in the Title X program until April 1982 when politics dictated all future Title X funds would be utilized by State Health Departments.

For the past 25 years, PPSEV has qualified for nominal pricing as a safety net provider. This fact has allowed us to provide critical contraceptive services to low income working women and disadvantaged women, some of the most vulnerable people in our community. Without nominal pricing for our affiliate contraceptive services will no longer be available for these women. Last year PPSEV provided over 16,000 packs of contraceptives in addition to other forms of contraception such as Depo, NuvaRing, Patches, IUDs and Essure. It would be hard to believe that disenfranchising these women was ever the intent of the Deficit Reduction Act of 2005.

Without our inclusion as a safety net provider, we do not qualify as a 340B covered entity. Unless PPSEV is included within the CMS definition as a safety net provider, our patients will be adversely affected. Those who can purchase their contraceptives elsewhere it will create a greater financial burden; the majority of our patients who cannot will face the increased risk of unintended pregnancies. Without access to nominal pricing, our affiliate would be required to purchase pills at higher cost than we currently charge our patients. Patients would be unable to purchase these pills even at our cost let alone at retail prices in some store. ***Nominal pricing is critical tour providing contraceptive services to women in our community with the greatest needs and fewest resources.***

Unfortunately, like many other small safety net providers, we do not qualify for the three categories; 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. None the less, PPSEV serves as an important safety net provider to our community. PPSEV sincerely hopes that the Centers for Medicare and Medicaid Services (CMS) will exercise its authority to name "other safety net providers" that will included affiliates such as our.

They need us, we need you. It's that simple. It's that profound!

Respectfully submitted,

Robert A. Rashti, M.D.
President & CEO
Planned Parenthood of Southeastern Virginia
Hampton, VA 23666

Submitter : **Rosemary Rosdahl** **Date: 02/16/2007**

Organization : **Watertown Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 2007

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

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

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

1. Remove PBM and Mail Order from Retail Class of Trade
(i) Creates consistency in the Regulation
(ii) Conforms definition with market reality

2. Implement a Trigger Mechanism
(i) Addresses severe price fluctuations
(ii) Mitigates Risk of Pricing Lag

3. Use of 11-Digit NDC versus 9-Digit NDC
(i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely,

Rosemary Rosdahl
Watertown Pharmacy
204 Lewis Ave. S
Watertown, MN 55388
phone 952-955-2153

cc. Members of Congress
Norm Coleman
Amy Klobuchar

Submitter : **Mr. william wimmer** **Date: 02/16/2007**

Organization : **goodrich pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

our pharmacy has spent countless hours of unpaid time to try and help seniors navigate the new medicare part d plans. our thanks has been a lower reimbursement by the medicare plans and to top it off cms is looking to squeeze us further. amp and ful will without a doubt decrease the count of pharmacies in this country. does cms really think mail order companies can give patients the access they need. in the long run health cost will increase because local pharmacist will no longer be there for the senior population because of the goverments short sightedness .

Submitter : Mr. Russ Spivey **Date:** 02/16/2007

Organization : Middle Tennessee Pharmacy Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-685-Attach-1.DOC

February 15, 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

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy, where over 95% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Russ Spivey
5519 Cavendish Dr.
Murfreesboro, TN 37128

cc: Senator Lamar Alexander
Senator Bob Corker
Bart Gordon

Submitter : Ms. Margherita Giuliano **Date:** 02/16/2007

Organization : Connecticut Pharmacists Association

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

i.e. See Attachement

CMS-2238-P-686-Attach-1.TXT

CMS-2238-P-686-Attach-2.RTF

CONNECTICUT PHARMACISTS ASSOCIATION
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March 8, 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

The Connecticut Pharmacists Association (CPA) is 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 the Average Manufacturer's Price (AMP) as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

CPA continues to support federal efforts that are designed to improve the affordability of and access to prescription drugs and healthcare professionals. While we support these efforts, we are compelled to offer the following comments on the CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510. §447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. §447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed in §447.510 creates some areas of concern: (i) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (ii) the reporting system itself creates an artificial price lag in the reimbursement basis; (iii) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (iv) the suggested time for record retention is overly burdensome. Additionally CPA offers comments on the use of the 11-Digit NDC code rather than the 9-Digit NDC code. The following comments will address these concerns.

§447.504 Determination of AMP

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This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect.

Defining Retail Pharmacy Class of Trade

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

This comprises an overly inclusive definition of "retail class of trade." The proposed regulation correctly assumes that long term care (LTC) pharmacies do not dispense to the general public, and therefore, should not be included in the definition of "retail class of trade". The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discount, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption.

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded until their impact on AMP is determined because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006 report entitled: *"Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,"* the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not met by mail order pharmacies as they are not open to the public and **require unique contractual relationships** for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available or passed on to traditional retail pharmacies. Also, the majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs due to the challenges and special needs they require.

Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP for medications dispensed to the Medicaid population.,

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

CPA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. CPA is unaware of any state that licenses PBMs as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

We believe section 447.504(e) should be amended at this time to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade until such time that the impact of including these operations can be determined.

CPA also contends that excluding mail order and PBM pharmacies from the AMP calculations will help to provide greater certainty and reliability in pricing data. The complexities of discount, rebates and other forms of price concessions with these entities can easily lead to misstatements and errors in accounting - particularly between quarters – creating pricing volatility and fluctuations in AMP values. Until CMS can determine the impact this will have on AMP it is best to exclude it.

It is critical to understand that traditional community pharmacies that currently care for the Medicaid population do not purchase medications at AMP. Community pharmacies are for profit businesses that need to have their product cost covered with a return on investment. The current definition of AMP does not address these concerns.

Inclusion of Medicaid Sales

It is our belief that 447.504(g)(12) should exclude Medicaid from AMP Data. Unlike Medicare Part D and non-Medicaid SCHIP, which have private party negotiators on formularies and reimbursement rates, Medicaid participates in a rebate as provided in OBRA 90. Some states received additional rebates from manufacturers based on formulary choices stemming from a preferred drug list mechanism similar to PBMs as noted above. Moreover, the inclusions of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

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Given the above statements it is clear that counting Medicaid will have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

Discounts, Rebates and Price Concessions

CPA contends that certain discounts, rebates and price concessions found in §447.504(g)(6) and (9) should not be included in the AMP calculation. Price concessions provided by drug companies to PBM and mail order pharmacies in the form of rebates, chargebacks or other contractual arrangements which, by their very relationship are not available to out-of-pocket customers or third party private sector parties. While discounts, rebates, price concessions, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. Since PBM and mail order pharmacies have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade, they are clearly distinguishable from the community retail pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to reconsider the inclusion of mail order pharmacy rebates, chargebacks and other price concessions until the impact on AMP can be determined.

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP.

On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to

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the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions.

Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] **The impact of these findings cannot be ignored.** When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation. **It is critical that CMS do a comparison of AMP with and without these concessions to determine the impact before it is implemented.**

§447.510 Requirements for Manufacturers.

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

'Claw-back'

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

Pricing Lag

Under the proposed regulation, the AMP first reported to CMS could be as many as 30 days old. As such, the data will be out of date prior to dissemination to the states and the general public, a process potentially taking another 30 to 60 days. Additionally, the flexibility given the

[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[2] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

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manufacturer to report discounts employed and the restatement figures will add significant variability to this lag. Material lag in AMP degrades transparency and places an undue burden upon the retail pharmacy class of trade. The technical difficulties and associated overhead burdens of limiting or eliminating this structural lag may prove to be insurmountable. Therefore, CMS should provide guidance to the states and other users of AMP on the proper method to address any issues resulting from the structural lag.

Severe Price Shifts

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

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

Record Keeping

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

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Additional Comments

Use of the 11-Digit NDC Rather Than the 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

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

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

Sincerely,

Margherita R. Giuliano

Margherita R. Giuliano, R.Ph., CAE
Executive Vice President

cc: Connecticut Congressional Delegation

Submitter : **Ms. David Brown** **Date: 02/16/2007**

Organization : **Middle Tennessee Pharmacy Services**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-687-Attach-1.DOC

February 15, 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

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

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

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

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

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

Sincerely,

David Brown
114 Riverbend Rd.
Shelbyville, TN 37160

cc: Senator Lamar Alexander
Senator Bob Corker
Bart Gordon

Submitter : **Mr. John Duncan** **Date: 02/16/2007**

Organization : **Med-Surg Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please carefully consider the ramifications of this. We can not and will not continue on Medicaid if CMS-2238-P is implemented.
Thank you.
John Duncan, R.Ph.

CMS-2238-P-688-Attach-1.WPD

2-15-2007

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
John Duncan
Med-Surg Pharmacy
2828 Hiway 31 South

Decatur, Al 35603

Submitter : STAN BRITTEN **Date:** 02/16/2007

Organization : AMARILLO DIAGNOSTIC CLINIC PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

THE IMPLEMENTATION OF CMS-2238-P WOULD HAVE A VERY NEGATIVE IMPACT TO MY PHARMACY. THE CURRENTLY THE AVERAGE COST PER PRESCRIPTION IS $13.20. WE ALSO PROVIDE HOME DELIVERY TO OUR PATIENT AT NO ADDITIONAL CHARGE AND FOR MANY THIS IS THE ONLY WAY THEY CAN GET THEIR PRESCRIPTIONS IN OUR RUAL COMMUNITY. IF THESE CHANGES ARE IMPLEMENTED, WE MAY BE FORCED TO DISCONTINUE GENERIC BRANDS AND ONLY DISPENSE NAME BRAND PRESCRIPTIONS WHICH COULD BE MORE COSTLY TO THE STATE.

Submitter : Mr. Doug Snider **Date:** 02/16/2007

Organization : Snider's Discount Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-690-Attach-1.RTF

2/16/2007

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 $9.86.

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,

Doug Snider

Submitter : Mr. Mark Hobbs **Date:** 02/16/2007

Organization : Hobbs Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Generic Drug reimbusement for Medicaid has been set BELOW cost for retail pharmacies

Collection of Information Requirements

Collection of Information Requirements

AMP has been defined to include outlets that get prefferential pricing (mail order and PBM's) that are not available to retail pharmacy

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Data has been clooected by the GAO that shows reimbursemnt wil be 36% below costs

Regulatory Impact Analysis

Regulatory Impact Analysis

AMP was never intended as a basis for reimbursement. It MUST be based on the price that at which retail pharmacies can obtain medications

Response to Comments

Response to Comments

Idependent pharamcies will lose money on every generic dispensed. Many will not be able to paticipate or go out of business. The result will be higher utilization of Brand medications and higher costs to the Medicaid system

Submitter : Mrs. Beth Spivey **Date:** 02/16/2007

Organization : Middle Tennessee Pharmacy Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-692-Attach-1.DOC

February 15, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist at Middle Tennessee Pharmacy Services, a community retail pharmacy located at 101 Public Sq West, Shelbyville, TN 37160. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy, where over 95% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Beth Spivey
5519 Cavendish Dr.
Murfreesboro, TN 37128

cc: Senator Lamar Alexander
Senator Bob Corker
Bart Gordon

Submitter : AMANDA MORRISON **Date:** 02/16/2007

Organization : AMARILLO DIAGNOSTIC CLINIC PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

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THE IMPLEMENTATION OF CMS-2238-P WOULD HAVE A VERY NEGATIVE IMPACT TO OUR PHARMACY. CURRENTLY THE AVERAGE COST PER PRESCRIPTION IS $13.20. WE ALSO PROVIDE HOME DELIVERY TO OUR PATIENT AT NO ADDITIONAL CHARGE AND FOR MANY, THIS IS THE ONLY WAY THEY CAN GET THEIR PRESCRIPTIONS IN OUR RUAL COMMUNITY. IF THESE CHANGES ARE IMPLEMENTED, WE MAY BE FORCED TO DISCONTINUE GENERIC BRANDS AND ONLY DISPENSE NAME BRAND PRESCRIPTIONS WHICH COULD BE MORE COSTLY TO THE STATE.

Submitter : BRENT MORGAN **Date:** 02/16/2007

Organization : AMARILLO DIAGNOSTIC CLINIC PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

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Submitter : Dr. Leslie King **Date:** 02/16/2007

Organization : Marcrom's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-695-Attach-1.DOC

February 15, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of Marcrom's Pharmacy, a community retail pharmacy located at 1277 McArthur St., Manchester, TN 37355. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

3. Removal of Medicaid Data

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

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

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

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

Sincerely,

Leslie Marie King
3024 Runabout Dr.
Nashville, TN 37217

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Jim Cooper

Submitter : Mark Whittier **Date:** 02/16/2007

Organization : Canby Drug & Gifts

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am submitting comments to Centers for Medicare and Medicaid Services (CMS) regarding CMS 12/20/2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new FUL program on generic drugs. I am a pharmacist owner located at Canby Drug & Gifts in Canby, MN. We are the only provider of pharmacy services in the community and your consideration of my comments is crucial in my pharmacy being able to continue to provide these services.

Definition of Retail Class of Trade - Removal of PBMs and Mail Order Pharmacics.

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed.
2) Calculation of AMP- REMOVAL OF REBATES , CONCESSIONS TO PBMS AND MAIL ORDER PHARMACIES
AMP should reflect prices paid by community pharmacies. Including these elements results in a below cost FUL.

Why do mail order pharmacies pay less for drugs anyway? Why not allow communtiy pharmacy the same rebates and pricing to save money?

3) REMOVE MEDICAID DATA
in calculating AMP. Including these elements does not recognize that Medicaid pricing is heavily regulated by state and federal govts.

4)MFG Data reporting for price Determination-address market lag
Implement a trigger mechanism to address severe price fluctuations and mitigate risk of pricing lag.

5) Use 11-digit NDC verses 9 digit NDC- most common package size dispensed by community pharmacies.

I support the comments filed by the MN Pharmacists ASSN regarding this proposed regulation. I appreciate your consideration of these comments and ask that you contact us with any questions.

THANKS,
MARK WHITTIER
CANBY DRUG & GIFTS
CANBY, MN 56220
PH 507-223-5955

E-MAIL canbyrx@frontiernet.net

cc. Sen Norm Coleman
& Rep. Collin Peterson

Submitter : Lynn Rolston, CEO **Date:** 02/16/2007

Organization : California Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-697-Attach-1.DOC

californiapharmacistsassociation

One Profession, One Voice

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

Re: File code: CMS-2238-P (42 CFR Part 447)

Dear CMS:

The California Pharmacists Association (CPhA) is the largest state pharmacy association in the nation, representing over 5000 members. CPhA is pleased to be able to offer these comments on the proposed rule to define Average Manufacturer Price (AMP) and implement provisions of the Deficit Reduction Act of 2005 (DRA).

OVERVIEW

In reviewing the proposed rule, CPhA believes it is important to take a step back and remember how and why AMP came about: to ensure that prescription drug programs paid for by taxpayers receive prescription drug products at the lowest available price. Thus, as part of the OBRA 90, two new concepts were established: Average Manufacturer Price and Best Price. As conceived, pharmaceutical manufacturers would be required to pay rebates to Medicaid programs to ensure that the net cost to those programs for prescription drugs did not exceed the best price offered to other purchasers. The amount of the rebate was calculated by comparing AMP and Best Price. The difference between the two determined the amount of the rebate owed. In order for the calculation to be fair, several factors were taken into consideration to ensure that manufacturers were not excessively charged and that "double rebates" were avoided. Thus, over time, AMP has evolved based on its pure use as a standard in determining rebates ("rebate function") under the "best price" provisions of the federal law.

As mandated by the Deficit Reduction Act of 2005, AMP will now be used for an additional purpose – as a factor in determining the reimbursement paid to pharmacies for multiple source generic drugs dispensed under Medicaid programs ("payment function"). This payment function of AMP unfortunately does not fit "hand in glove" with its traditional rebate function. In fact, in many ways, it conflicts with the role AMP plays in determining rebates to arrive at Best Price.

CPhA believes the best method of resolving any conflict between these two functions of AMP is to examine the basic purposes of the statutes and craft the definition and use of AMP to better fit those purposes. We do not believe the proposed rule deals with these purposes adequately. In these comments, CPhA proposes several changes that we believe will bring the definition of AMP more into line with Congressional intentions for both rebates and reimbursement. We also believe these changes will result in the use of AMP in a manner that is more fair and more reasonable both as a basis for pharmacy reimbursement as well as in the application of the Best Price provisions of federal law.

BACKGROUND FOR CPHA'S COMMENTS

The payment function for AMP is founded in a desire by Congress to more accurately identify the Estimated Acquisition Cost (EAC) of multiple source generic drugs dispensed in Medicaid programs. For many generically available drugs, states have set a maximum limit for the EAC based on the Federal Upper Limits (FUL), which until now have been based on the lowest published cost of the generic drugs included on the FUL list.

The DRA unfortunately requires FULs to be based on AMP as of January 1, 2007. This statutory requirement limits the options available to CMS in crafting an approach that can serve as a basis for both the rebate and payment functions for AMP. Many in the pharmacy industry are asking CMS to adopt an alternative basis for FULs; however, this is not an option under the DRA and is an issue properly referred to Congress. CPhA appreciates this limitation on the authority CMS has in dealing with the task at hand. As a result, our comments propose that CMS re-evaluate the bases for its proposed rule and shift to a system that more equitably balances the marketplace realities faced by retail pharmacies while preserving the traditional rebate function provided by the use of AMP. In our view, the proper "fix" is to modify the way three key components are interpreted in the proposed rule:

1. What should be included in AMP
2. What should be included in Best Price and
3. How the "retail pharmacy class of trade" is defined.

These three components are addressed more fully later in these comments. We turn first, however, to policy issues involved in promoting the appropriate use of multiple source generic drugs in medicaid programs.

POLICY ISSUES IN USING AMP-BASED FULS

Of significance in the historical use of FULs is the fact that Congress believed that the use of cost effective generic drugs should be encouraged and, in fact, incentivized. Thus, the EAC of generic drugs on the FUL list was not set at the lowest published wholesale cost, but rather was set at 150% of the lowest published wholesale cost. This was done, in part, to ensure that pharmacies across the nation would be able to purchase the drugs at the FUL price or less, but also to create a financial incentive (in the form of profit on the "spread" between what the drug cost and what the pharmacy was paid) to encourage pharmacists to use generic drugs when they are available.

Even though the DRA sets FULs at 250% of AMP, the impact of shifting to FULs based on AMP ***as defined in the proposed rule*** will be to eliminate the financial incentive for generic drug use and will result in FULs that may be below the actual cost of the drug product to retail pharmacies. Unless the proposed definition is revised, the change to AMP-based FULs will create financial incentives for pharmacists to promote the use of single source branded drugs in many therapeutic drug groups instead of alternative drugs for which generic versions are available. This incentive will be very strong in many cases because shifting to a single source branded drug may be the only way for the pharmacy to make a profit when filling the prescription.

This effect of using AMP to calculate FULs has been documented in a report from the Government Accountability Office (GAO) to the House Committee on Energy and Commerce.[1] In that report, the GAO found that FULs established using the then current AMP data would be,

[1] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office, December 22, 2006.

on average, 36% below the average cost of the medication to retail pharmacies. More importantly, for 43 of the 77 drugs reviewed, ***the AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies***. To state this latter finding more succinctly, for the drugs involved, NO retail pharmacy (as determined by GAO) could buy the drug product at or below the AMP-based FUL

CMS disagrees with the findings put forth by the GAO in their report, and CMS' argument has some merit. Until the new FULs are established, no one can say exactly how they will compare with the actual acquisition costs paid by retail pharmacies. In addition, adjustments in purchasing practices may improve the situation for retail pharmacies. However, the GAO report quite clearly raises the likelihood that AMP-based FULs, ***as defined in the proposed rule***, will result in many situations where the average retail pharmacy is unable to purchase the medications at or below the FUL price.

The scenario presented by this likelihood cannot have been the intent of Congress and it certainly cannot financially benefit Medicaid programs. If the financial incentives presented to pharmacies drive them to use single source branded drugs instead of generic alternatives, the fiscal impact will be much greater than the savings that are anticipated from the shift to AMP-based FULs. Regardless of the scope of the fiscal impact, there is no doubt that the prediction made by CMS that the change ". . . will drive retail pharmacies to fill more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs – thereby reducing these pharmacies' acquisition costs" will prove to be inaccurate.

Establishing AMP-based FULs that reflect reimbursement levels that are below actually attainable acquisition costs raises greater issues than just the loss of financial incentives. It is impossible to find that such FULs will reflect anything approximating "appropriate reimbursement for estimated acquisition costs" for multiple source generic drugs, an analysis CMS encourages States to make. The proposed rule also suggests that the states examine the market realities and adjust dispensing fees to compensate. While this is an important correction to the current reimbursement system, this does not solve the underlying problem presented by an unreasonable system for calculating AMP.

If AMP is to accurately fulfill both its rebate and payment functions, it must reflect the actual prices available to retail pharmacies. While all rebates and price concessions are appropriately included in "Best Price," they should not be included in AMP.

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

§447.504 DETERMINATION OF AMP: WHAT SHOULD BE INCLUDED IN AMP?
In §447.504, the rule details the process and transactions used in determining AMP. In its background, CMS details its consideration of whether the applicable transactions should be viewed broadly or narrowly and rationalizes its decision based on its view of the retail pharmacy marketplace (addressed below) and on past agency policy regarding AMP. We believe this approach is overly broad, in that past policy reflects a different focus on the use of AMP (i.e. rebate function) and the agency's interpretation of the marketplace does not provide adequate consideration of the obvious inconsistencies that occur when FULs based on AMP as defined in the proposed rule are used as approximations of EAC.

In our view, the transactions included in AMP should be based on a more narrow view of what is meant by the "retail pharmacy class of trade" but should also consider more significantly the link between FULs and EAC. To do otherwise will create a system that favors purchasers who, in fact, operate in a market environment that is not accessible either to the general public or to the retail pharmacies that serve that public. As noted elsewhere in these comments, these purchasers should be included in the determination of Best Price in order to preserve the rebate function of AMP, but to incorporate them into the payment function of AMP is unreasonable and patently unfair.

The proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. By including these discounts and concessions, the proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers have contracted to pay to other entities. While these discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. These manufacturer payments should be considered to be outside the realm of transactions used to calculate AMP. **Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with third parties**

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade. CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA).

CMS should also exclude rebates paid to PBMs from the AMP calculation but include them in the calculation of Best Price. PBM rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive. Neither does the retail pharmacy class of trade have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from the AMP calculation.

CPhA supports basing AMP on sales to retail pharmacies that dispense drugs to the general public and excluding from AMP any sales that reflect rebates or discounts that are not reasonably available to these pharmacies. We acknowledge that this will result in a higher AMP, but we believe this approach represents a more rational approach that will yield fair AMPs and FULs that truly approximate the "estimated acquisition cost" experienced by retail pharmacies that serve Medicaid beneficiaries. The rebate function of AMP is preserved by including PBM rebates and other discounts in the calculation of Best Price.

§ 447.505 DETERMINATION OF BEST PRICE: WHAT SHOULD BE INCLUDED IN BEST PRICE?
Section 447.505 addresses the determination of Best Price. For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater.

CPhA believes the determination of Best Price in the proposed rule is appropriate. We agree that Best Price should be determined on sales to any entity and not just on those in the retail pharmacy class of trade. However, in determining AMP, only those entities in the retail pharmacy class of trade should be considered. Best Price is the most appropriate vehicle in which to include all the manufacturer rebates, discounts and other price concessions extended to other entities as well as Direct-to-Patient sales and manufacturer coupons.

Combined with our suggested changes to AMP, this definition of Best Price will result in an improved determination of rebates due to state Medicaid programs. A higher AMP for multiple source generic drugs will result in higher rebates based on the requirements of 42 USC 1396r-8. For single source branded drugs, the net cost to Medicaid programs will be unchanged, as any increase in payments to pharmacies will be offset by larger rebates from manufacturers. The result, however, will be a system that more accurately places the costs of rebates on the entities that enjoy the benefits of the discount policies. Such an approach is fair and reasonable.

§447.504(E): HOW THE "RETAIL PHARMACY CLASS OF TRADE" IS DEFINED

The area in which we have the greatest disagreement with the proposed rule is in the area of what entities should be included in the retail pharmacy class of trade. In the discussion of the proposed rule, "Retail pharmacy class of trade" is described as: "any entity that purchases prescription drugs from a manufacturer or wholesaler for dispensing to the general public." We generally agree with this description; however, we strongly disagree with the provisions of proposed section 447.504(e) that interprets this description to include mail order pharmacies and PBMs.

PBMs are Not Pharmacies. CPhA has never found that PBMs either "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public. In order to do either, PBMs would need to be licensed as pharmacies under applicable state law. No PBM is licensed as a pharmacy under California law and we are not aware of any state that licenses PBMs to purchase, receive or dispense drugs to the general public. While PBMs do function as middlemen in the arrangement of pharmacy services, these entities literally never touch the drugs. To equate this to being a retail pharmacy is completely and utterly unjustifiable. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

Public Access Defines Retail Pharmacy Class of Trade. CMS is correct to exclude nursing home pharmacies from the retail pharmacy class of trade for two reasons. First, these pharmacies are extended prices not available to retail pharmacy. Second, nursing home pharmacies are not deemed to be "publicly accessible."

The case for including mail order pharmacies in the retail pharmacy class of trade is likewise not justified. In our view, most mail order pharmacies, like nursing home pharmacies, are not publicly accessible. Their clientele are usually restricted to members of a particular health plan or group; in fact, membership in a particular plan or group may result in a mandate on the consumer to utilize a mail order pharmacy to obtain insurance coverage. This level of coercion clearly distinguishes these pharmacies from those that are truly accessible to the general public. In addition, a member of the general public typically cannot walk into a mail order pharmacy, present a prescription to be filled and have it dispensed on the premises.

Mail order pharmacies are much more like the pharmacies that service nursing homes and are excluded in the proposed rule from the retail pharmacy class of trade. Both types of operations are "closed door" in that they sell only to facilities or plans with which a contractual relationship

exists. As with nursing home pharmacies, discounts and rebates that are available to mail order pharmacies rely greatly on the ability of the pharmacy to play a significant roll in determining which medications are dispensed. These same types of discounts are not available to traditional retail pharmacies.

As with nursing home pharmacies, mail order pharmacies that operate as a closed door operation should not be included in the retail pharmacy class of trade. As such, we believe section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to pharmacies in the retail pharmacy class of trade.

Excluding mail order pharmacies and PBMs from the definition of the retail pharmacy class of trade would offer numerous benefits to pricing data and regulatory oversight, including reduced recordkeeping requirements, reduced risk of price fluctuations, and limiting the need for additional regulatory burdens. Since there would be fewer transactions, fewer records will need to be maintained by manufacturers and reported to CMS, thus reducing the reporting requirements of manufacturers. Since mail order pharmacies are most likely to participate in discounts, rebates and other forms of price concessions, the nature of these complex contractual arrangements are more likely to lead to misstatements and errors in accounting and the need for re-statement of pricing information – particularly between quarters - creating pricing volatility and fluctuations in AMP values. Excluding mail order and PBM pharmacies from AMP calculations thus assists to provide greater certainty and reliability in pricing data. Vertical integration between manufacturers and mail order pharmacies creates transactions that are not arm's length and thus afford opportunities for market manipulation. In the future, CMS would likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

OTHER AREAS OF CONCERN

Pricing Lag

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

AMP Should Be Reported At the 11-Digit NDC to Ensure Accuracy

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

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential. Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. CPhA supports the use of the 11- digit NDC when calculating the FUL.

CMS Must Employ a Complete Definition on Cost to Dispense
The definition of "Dispensing Fee" found in §447.502 does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

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

The definition of "Dispensing fee" in the regulation should reflect all these additional costs and states should be required to include these costs in their consideration of appropriate dispensing fees.

Sincerely,

Lynn Rolston
CEO
California Pharmaicsts Association

Submitter : Mr. Jon Fiume **Date:** 02/16/2007

Organization : Ritzman Pharmacies Inc.

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-698-Attach-1.DOC

CMS-2238-P-698-Attach-2.DOC

February 15, 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

1. You have the comments and suggestions filed by the National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA) regarding this proposed regulation. We agree with and support the positions represented by NCPA and NACDS.

2. Generic medications average roughly 1/6th of the brand name cost. AMP as currently defined means that pharmacies are much better off dispensing brand name medications rather than losing money on generics. Instead of saving, there is a great chance of spending more. What a waste of tax payer dollars, when governmental policy is only focused on an aspect of cost savings that will ultimately cost more money in total.

3. Can CMS really ignore the report of the General Accounting Office (GAO) and proceed with releasing of AMP as currently defined?

4. The very existence of community pharmacy is at stake by the Federal Government setting such an irresponsible and inaccurate benchmark for community pharmacy cost of goods such as AMP currently is defined

5. The level of customer service and within rural and urban communities is seriously threatened when the AMP being used does not even cover wholesale cost of medication, let alone the cost of filling a prescription.

Please do the right thing for Medicaid Patients to be able to continue to get the medication they need.

Please do the right thing when spending tax payer dollars.

Please do the right thing for community pharmacy.

Sincerely,

Jon A. Fiume
Vice-President Retail Operations
Ritzman Pharmacies, Inc.

Submitter : Dr. Meegan Schaeffer **Date:** 02/16/2007

Organization : Clinic Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-699-Attach-1.RTF

March 8, 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 Brainerd, Minnesota. We are an independent pharmacy with a large Medicare and Medicaid patient base and are very concerned about the impact of the proposed regulations on our financial stability. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. **Remove PBM and Mail Order from Retail Class of Trade**
   (i) Creates consistency in the Regulation
   (ii) Conforms definition with market reality

2. **Implement a Trigger Mechanism**
   (i) Addresses severe price fluctuations
   (ii) Mitigates Risk of Pricing Lag

3. **Use of 11-Digit NDC versus 9-Digit NDC**
   (i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely,

Meegan Schaeffer, Pharm.D.

cc. Members of Congress(Rep. Peterson, Rep. Bachman, Rep Oberstar, Rep. Kline, Rep. Ramstad, Rep McCollum, Rep. Ellison, Sen. Coleman, Sen. Klobuchar)

Submitter : Mr. Kyle Skidmore **Date:** 02/16/2007

Organization : Phi Delta Chi Professional Pharmacy Fraternity

Category : Other Health Care Professional

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Hi, I am a fifth year pharmacy major @ Ohio Northern University, and will be making the transition into the workforce within the next year. The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my future in pharmacy. It is estimated that the reimbursement will be far below what it actually costs pharmacies 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.

Thanks for your time and consideration on this important matter.

KYLE W. SKIDMORE

Submitter : Mr. Joseph Reycraft **Date:** 02/16/2007

Organization : Maple Plain Drug

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a pharmacist in a small town providing pharmacy care for 40 years. I have seen our profits deminish over the last few years to a point that our cash flow have been severely affected. We cannot take another hit on reimbursements and expect to remain in business providing healthcare to this community with your suggested plan. Please revisit your decision so we can survive in the market place.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

We continue to loose money on many RX's and have to wait for our money and find it impossible to survive.

Submitter : Mr. Jeff Myers **Date:** 02/16/2007

Organization : Cephalon, Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-702-Attach-1.DOC

Cephalon
deliver more

February 16, 2007

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

Dear Ms. Norwalk:

Cephalon, Inc. is a biopharmaceutical company specializing in drugs intended to treat and manage neurological diseases, sleep disorders, cancer, and pain. Our corporate headquarters is in Frazer, Pennsylvania, and we have facilities in a number of other locations in the United States and around the world.

Cephalon appreciates the opportunity to comment on the proposed regulations for implementation of the Medicaid prescription drug provisions of the Deficit Reduction Act of 2005, P.L. 109-171 (DRA), which President Bush signed into law on February 8, 2006. These provisions focus primarily on the calculation and reporting of Average Manufacturer Price (AMP).

Definition of Retail Pharmacy Class of Trade and Determination of AMP

The proposed rule refines the definition of retail pharmacy class of trade for the purposes of calculation of AMP; however, a few key entities are not addressed by the rule. In particular, the physician class of trade could represent a significant portion of sales transactions for a particular product, yet it is not addressed by the proposed rule. Cephalon would appreciate guidance from the Centers for Medicare and Medicaid Services (CMS) on this point.

In addition, DRA provides that direct sales to Health Maintenance Organizations (HMOs) and hospitals are excluded from AMP calculations, since these entities are not in the business of providing drugs to the general public. Cephalon requests that CMS provide additional guidance with regard to the issue of HMOs. Not all HMOs function in the same way. Just as Long Term Care (LTC) facilities and pharmacies do not serve the general public (i.e., are not part of the retail pharmacy class of trade) and are now excluded from AMP calculations, some HMO-operated pharmacies may provide drugs only to their enrollees; thus, they do not serve the general public in the way that other retail pharmacies might. As a result, Cephalon requests clarification that these entities should also be excluded from AMP calculations. Conversely, Cephalon suggests that HMOs that simply reimburse enrollees for their drug purchases at retail pharmacies (without themselves purchasing or taking possession of the drugs) should be included in the calculation of AMP.

Patient Coupons

In the rule, CMS proposes to include coupons redeemed by any entity other than the consumer in the calculation of AMP while coupons redeemed directly to the manufacturer by consumers would continue to be excluded from calculation of AMP. Direct redemption by the consumer, CMS reasons, is not part of the retail pharmacy class of trade. However, in instances where a third party vendor is used by the manufacturer to administer a coupon program on its behalf, Cephalon suggests that the coupon be considered redeemed directly to the manufacturer by the consumer. Similarly, coupons redeemed by the consumer at a retail pharmacy should be excluded from calculation of AMP. In either case, the *consumer*, not the third party vendor or retail pharmacy, is realizing the full value of the coupon, and the transaction should be excluded from calculation of AMP. Only when the third party or retail pharmacy retains some value from the transaction should the value be included in AMP.

If, notwithstanding the above comments, CMS nonetheless decides that third party transactions of the type described above are to be included in calculation of AMP, Cephalon respectfully requests that CMS offer additional guidance regarding the basis that CMS will require for the valuation of such coupon transactions (e.g., wholesale acquisition cost (WAC), retail cost, or some other method).

Further, Cephalon requests clarification from CMS as to the definition of "coupon." Does CMS intend the term to refer only to paper coupons, or is the term to be interpreted more broadly to include patient assistance discount cards and other media provided to consumers?

Customary Prompt Pay Discounts

DRA specifically excludes from the calculation of AMP any customary prompt pay discounts made to wholesalers; however, CMS in this rule proposes that customary prompt pay discounts be included in calculation of Best Price (BP). Cephalon asks CMS for clarification as to why, for purposes of calculating BP, CMS is requiring reporting of customary prompt pay discounts that have been specifically excluded from calculation of AMP and guidance as to how manufacturers are to report customary prompt pay discounts to CMS, since such discounts are typically deducted by the purchaser, not the manufacturer.

Authorized Generic Drugs – Section 447.506

In the rule, CMS "propose[s] to interpret the language of section 6003 of the DRA to include in the BP and AMP calculations of the branded drugs, the authorized generic drugs that have been marketed by another manufacturer or subsidiary of the brand manufacturer (or NDA holder)."[1]

Cephalon respectfully submits that the proposed rule provides insufficient guidance as to how the required pricing information is to be gathered, shared and calculated. Neither the preamble of the statute nor the text of the proposed rule addresses whether the branded-product manufacturer must incorporate raw sales data into the branded product calculations to derive the

[1] 71 Fed. Reg. 77,174 at 77,183 (Dec. 22, 2006).

blended AMP and BP figures, or whether it can rely on an authorized-generic manufacturer to provide the authorized-generic AMP-eligible units and dollars to derive the blended AMP. The proposed rule also does not sufficiently address how to comply in light of potential competitive concerns under the antitrust laws. Ordinarily, branded manufacturers are prohibited from receiving proprietary sales data and best price information from the manufacturer of the authorized generic.

Beyond the antitrust concerns, Cephalon also questions whether the branded manufacturer can safely rely on the quality of the pricing data received from the manufacturers of the authorized generics. If the branded manufacturer receives the calculated AMP figures without the backing data, the branded manufacturer can not discern whether the calculations are either complete or accurate. Differences in how individual manufacturers calculate AMP (Class of Trade determinations) may complicate calculation of a blended AMP. Among other problems, since false or inaccurate certifications to government entities can result in serious and substantial penalties, the certification requirements for manufacturers proposed by CMS in the rule and discussed below would seem to have the inequitable effect of requiring and then punishing branded manufacturers for warranting information that is not within their control.

Requirements for Manufacturers – Section 447.510

Recalculation of Base Date AMP

Cephalon requests clarification from CMS that the recalculation of base date AMP may take into account all changes to the definition of AMP as proposed by CMS, including changes to the definition of retail pharmacy class of trade and the exclusion of customary prompt pay discounts from the calculation of AMP.

Further, Cephalon suggests that, following publication of the final rule, manufacturers be allowed to recalculate their base date AMPs retroactive to January 1, 2007.

Calculation of Monthly AMP

CMS indicates that manufacturers will now be required to submit AMP calculations on a monthly basis; however, unlike quarterly AMPs, monthly AMPs will not be subject to revision. Current law provides that a manufacturer whose AMP calculation is negative for the current quarter may use a positive AMP from the previous quarter. If a manufacturer is faced with a negative monthly AMP, should the manufacturer report a previous month's positive AMP?

Also, Cephalon has concerns about the general timeliness of data submissions from generic manufacturers to branded manufacturers for the calculation of AMP for authorized generics. Cephalon requests further guidance from CMS as to how timeliness of monthly and quarterly submissions will be enforced so that branded companies will not run afoul of the law due to late submission of data by generic manufacturers.

Finally, manufacturers have no way of knowing whether coupons or other price concessions will be redeemed in a given month. In the rule, CMS proposes that manufacturers

estimate possible redemption in a given quarter and allocate the rebates over the three months of the quarter. Implementing this policy would skew manufacturers' monthly submissions without the benefit of restatement. Although CMS suggests the possibility of allowing manufacturers to use a 12-month rolling average for the purpose of reconciling lagged data, it is not clear whether CMS proposes to include the month for which calculations are being made or whether CMS intends that the manufacturer use the prior 12 months. Cephalon would appreciate clarification of this point and, in light of the new certification requirements for manufacturers (discussed below), Cephalon requests additional guidance as to how CMS envisions implementing this policy.

Certification Requirements

DRA provided for penalties for manufacturers that provide false information or fail to provide timely information to CMS. Now CMS is proposing to require manufacturers to certify all pricing reports submitted pursuant to this proposed rule. CMS would require that all pricing reports be certified by a manufacturer's "Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO."[2] Cephalon notes that reporting structures vary from one manufacturer to the next and suggests that the individual designated as being responsible for reporting of pricing information be the one accountable for certification purposes.

Further, Cephalon is concerned about how the proposed certification requirements would be enforced. As noted previously, Cephalon has serious reservations regarding the certification of data from other manufacturers or data submitted based on the company's best estimates regarding the price concessions that may be redeemed in any given month. Given that the proposed requirement makes no mention of whether a manufacturer "knowingly" or "willfully" submitted false information or made an untimely submission, Cephalon would appreciate further elaboration by CMS as to how the proposed certification requirements would be enforced.

FFP: Conditions Relating to Physician-Administered Drugs – Section 447.520

CMS proposes state requirements for submission of claims for physician-administered drugs (as defined by the proposed rule). The requirements mandate that submitted claims provide specific information so that manufacturers may be billed for the proper Medicaid rebates, and States would be required to adopt the reporting requirements in order to qualify for Medicaid Federal Financial Participation (FFP), the Federal share of Medicaid costs paid to the State.

Cephalon is disappointed that CMS chose not to address a related issue in the proposed rule – the pro-rating of Medicaid rebates when Medicaid is the secondary payor. Senator Charles Grassley (R-IA), former Chairman of the Senate Finance Committee, clarified congressional intent with regard to this matter in a letter to CMS dated August 14, 2006.[3] In the letter, Chairman Grassley stated:

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[2] *Id.* at 77,186.

[3] Letter from Senate Finance Committee Chairman Charles Grassley (R-IA) to CMS Administrator Mark McClellan (Aug. 14, 2006).

> To assure that this provision of the DRA is implemented properly, I request that CMS issue specific guidance stating that the rebate due for physician-administered drugs furnished to dual-eligibles and Qualified Medicare Beneficiaries is limited to that portion of the Medicaid allowable payment that the state actually pays as a copayment or deductible on the claim paid by Medicare as primary payor.[4]

Cephalon encourages CMS to initiate a notice and comment period with regard to this matter and to give proper deference to the stated intent of Congress prior to rendering permanent the current CMS interpretation of the statute.[5]

Effects on Drug Manufacturers

While the proposed rule concludes that the new reporting requirements would result in minimal burden for manufacturers, Cephalon respectfully disagrees. Although manufacturers are currently required to make quarterly AMP submissions to CMS, the proposed rule not only institutes monthly reporting of AMP calculations, but it changes the way that manufacturers calculate AMP. Thus manufacturers are required to implement new methodologies while quickly implementing monthly reporting of AMP and quarterly reporting of both customary prompt pay discounts and best price. Additionally, manufacturers will continue to be responsible for calculating AMP under existing methodologies. In a letter to pharmaceutical manufacturers, Jimmy Mitchell, Director of the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration, admonished manufacturers that, despite the changes to AMP effectuated by DRA, manufacturers will continue to report AMP to the Public Health Service's 340B program using traditional methodologies.[6] Thus, at minimum, manufacturers will be required to maintain dual calculations for AMP. Add to this the possibility of recalculating baseline AMP, and the burden begins to grow significantly.

Cephalon appreciates the opportunity to comment on these proposed regulations, and looks forward to publication of the final rule on or before July 1, 2007. If you have any questions, please do not hesitate to call me at (202) 772-4440.

Respectfully Submitted,

Jeff M. Myers
Vice President, Government Affairs

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[4] *Id.*
[5] As indicated in a Letter from Acting CMS Administrator Leslie Norwalk to Senate Finance Committee Chairman Charles Grassley (R-IA) (Dec. 15, 2006).
[6] Letter from OPA Director Jimmy Mitchell to Pharmaceutical Manufacturers (Jan. 30, 2007).

Submitter : **Mr. davdid warshofsky** **Date: 02/16/2007**

Organization : **Mr. davdid warshofsky**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Ind. Pharmacy

Collection of Information Requirements

Collection of Information Requirements

Proposed regs AMP would be detremental to retail pharmacy.

GENERAL

GENERAL

see attached

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

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

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

Submitter : Mr. DESAK HICKS **Date:** 02/16/2007

Organization : VILLAGE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am the owner/pharmacist of the ONLY pharmacy in the small rural town of Coffeeville Alabama. It is 26 miles to the next nearest pharmacy. Please believe me when I say, that I will NOT be able to fill prescriptions for my medicaid patients (30% of my patient population) if the new AMP guidelines are put into effect. I will probably have to close my doors, since I will either be loosing money on every prescription I fill, or will be loosing 30% of my customers when they are forced to travel elsewhere. I won,t bore you with repeating all the figures that I am sure you have already heard. Please understand that many of my patients will not have the means to travel to other towns to get their medications, and many do not have the mental capacity to go through the whole mail order process.
I have put 13 years of my life (every since I got out of pharmacy school) into taking care of these people, and building relationships with them. It is extremely unfair to these people and myself to now make them try to find a new pharmacy.

please call me if I can answer any questions for you.
Desak Hicks
251-276-3400
desakhicks@yahoo.com

Submitter : **Dr. Jennifer Burch** **Date: 02/16/2007**

Organization : **Central Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 18, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy(s) is located in Durham, NC. We are a major provider of pharmacy services in the community and have been since 1978. Medicare Part D has had a huge effect on my business and we are still taking a hard look to see if we are profitable. With the cost to fill a prescription over $10 the current reimbursement strategies are hard to make ends meet. 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,

Jennifer L Burch, PharmD, CDE
Vice President

cc: David Price

Submitter : **Date: 02/16/2007**

Organization : **Trenton Indian Service Area**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

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

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

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

Submitter : **Dr. julian maddox** **Date: 02/16/2007**

Organization : **glover pharmacy #3 inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-707-Attach-1.RTF

02/15/2006

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,

Julian D. Maddox R.Ph.
02/15/2006

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.

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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,

Julian D. Maddox R.Ph.

Submitter : Harold Cooley **Date:** 02/16/2007

Organization : Cooley Apothecary Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-708-Attach-1.DOC

CMS-2238-P-708-Attach-2.DOC

COOLEY APOTHECARY INC.
128 NORTH LAKE DRIVE
PRESTONSBURG, KY 41653
606-886-8106

February 16, 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-A020

Thank you for the opportunity to comment to the Centers for Medicare and Medicaid Services regarding December 20. 2006, proposed regulations that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit program for generic drugs. My pharmacy is located in rural Eastern Kentucky in the City of Prestonsburg. Our pharmacy is a major provider of pharmacy services in the community which is heavily dependent on Medicaid for health care services. Your consideration of these comments is essential for our pharmacy to continue to service these patients.

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 he vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the "general public." The Kentucky Pharmacists Association has submitted extensive comments addressing 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 are unfair to retail pharmacies and counter to Congressional intent.

3. Removal of Medicaid Data

Including these data elements is skewing negatively 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, Kentucky Pharmacists Association proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, there is a 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 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.

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

Sincerely,

Harold W. Cooley, R. Ph.
hwcooley@setel.com

Submitter : **Sara Buchanan** **Date: 02/16/2007**

Organization : **North Carolina Association of Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 18, 2007

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

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

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

Sara Buchanan, PharmD

cc. Members of Congress (Virginia Foxx)

Submitter : **Miss. Annalise Jencson** **Date: 02/16/2007**

Organization : **University of Toledo Pharmacy Student**

Category : **Individual**

Issue Areas/Comments

Background

Background

hc 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. Martha Renfro** **Date: 02/16/2007**

Organization : **Mountain States Health Alliance**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

My comment is in an attachment. Please See Attachement.

CMS-2238-P-711-Attach-1.PDF

Johnson City Medical Center
400 N. State of Franklin Road
Johnson City, Tennessee 37601

Mountain States Health Alliance

February 16, 2007

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

Dear Sir or Madam:

I am replying with comments to your proposal in the proposed rule dated December 22, 2006 on file code CMS-2238-P. This is the proposed rule in the Federal Register to implement certain provisions in the Deficit Reduction Act of 2005 that would require hospitals to provide an 11-digit unique NDC number on the billing submission to State Medicaid agencies for outpatient drug administration to enable the state to bill manufacturers for rebates.

This requirement would create a massive and expensive undue hardship on our organization. We have no electronic mechanism to provide this information at the current time and do not foresee any development of one in the future, so this would be a manual process. This manual process would add many more steps to our already massive and complex medication ordering, dispensing, and administrating process. In adding these steps, patient safety would be impacted in a negative way. This would occur because our hospital workflow would be disrupted. Also, we do not have the financial and staffing resources to implement workflow changes that would be required to do this manual process. This would greatly slow down pharmacist order entry and would decrease patient safety.

We do not have separate billing systems for outpatients and inpatients. We have an integrated inpatient and outpatient pharmacy billing system and pharmacy dispensing system. This system relies on the same drug product inventories that may include multiple generic supplies (each with a separate NDC number) of the same medication.

At any one time any of our pharmacies could have several generic and the brand NDC of the same generic entity product on the shelf and/or in our automated dispensing system cabinets (pyxis). Our order entry pharmacists do not know what NDC of the product the specific patient will actually receive from the pharmacy or pyxis. When we order drug products from our wholesaler and a product is out of stock at the wholesaler, they automatically substitute another NDC item for that product. This also creates different NDC numbers in our stock. We do dose by dose dispensing and billing. We do not dispense by prescription in multiple quantities like a retail pharmacy does.

Our current pharmacy information system has no way of sending the NDC number to patient accounting to be placed on the bill. Our current financial system and charge master have no place to enter the NDC number associated with the drug charge on the financial side. We have no room in pyxis or on the pharmacy shelves to divide all products up by NDC number.

We believe trying to implement this process and managing it would cause a great financial cost to our facilities. At rough estimate, we believe it would cost at least $1 per dose dispensed. This would translate to millions of dollars per year for our alliance. Our Johnson City Medical Center facility alone has dispensed about 3.8 million doses during the last year. The financial burden on this one facility would be around 3.8 million dollars per year. The impact on workflow, staffing and financial resources of our hospitals is unrealistic and not justifiable given current fiscal and workforce constraints. We therefore ask you to reconsider this proposal. Thank you for your time and consideration in this matter.

Mountain States Health Alliance is a multiple hospital entity which includes hospitals in Northeast Tennessee and Southwest Virginia. These hospitals are Johnson City Medical Center Hospital, Northside Hospital, Johnson City Specialty Hospital, Johnson County Community Health Center, Indian Path Medical Center, Kingsport Surgery Center, Sycamore Shoals Hospital, Smyth County Community Hospital, Dickenson County Hospital and Norton Community Hospital.

Sincerely,

Martha M. Renfro, DPh
Charge Master Coordinator, Pharmacy Services
Mountain States Health Alliance
400 N. State of Franklin Road
Johnson City, TN 37604
1-423-431-5370
renfromm@msha.com

Submitter : **Larry Wagenknecht** **Date: 02/16/2007**

Organization : **Larry Wagenknecht**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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

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

I am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer s price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. As a pharmacist in Haslett, MI, the proposed regulation, if adopted, would have a significant negative economic impact on the patients in my community. Pharmacists are critical to the care of patients in my community and your consideration of these comments is essential.

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

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

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

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

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

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade. Nursing home pharmacies, PBMs and mail order pharmacies receive discounts, rebates, and price concessions that are not available to the community retail pharmacies, making them a fundamentally different class of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacy for medications. Including these elements is counter to Congressional intent.

3. Removal of Medicaid Data

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

Collection of Information Requirements

Collection of Information Requirements

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

We believe that CMS should use the 11-digit NDC in the calculation of AMP since this is package size most commonly dispensed by retail pharmacies. The prices used to set the FUL should be based on the most common package size dispensed by retail pharmacies, not quantity sizes that would not be purchased routinely by a community pharmacy. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

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

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

Sincerely,

Larry Wagenknecht, Pharmacist
6097 Partridge St.
Haslett, MI 48840
email: amylarryw@comcast.net

Copy: Members of Congress

Submitter : Mr. BILL ALLEN **Date:** 02/16/2007

Organization : AMERIMED PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-2238-P-713-Attach-1.TXT

CMS-2238-P-713-Attach-2.PDF

02/15/2007

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.

I am going to speak to you from the heart. I own an independent pharmacy in a rural town of 1800. I know I can compete every day with chains, mail order and any other delivery system out there if I have a level playing field because my overhead is so much lower than theirs. If you look at the average prescription costs between idependents and the mail orders and chains, you will find we are the lowest because every day we help patients cut costs. We have been the ones promoting generics because we have never had the back in deals that the chains and mail orders and PBM's get paid because of the lack of transparentcy in our system. And we have done this while at the same time paying more for medications than practically anyone in the world. Higher than countries like Canada, Mexico and even Switzerland, higher than chains, higher than mail orders (who are owned or have financial ties to PBM's, chains or drug manufacturers).

And now the goverment wants to add AMP to the unlevel playing field. As a small independent, we will always be on the wrong side of any average formula. This will do more to put us out business than all the decreases that have happened to us in just the last two years, decreased Medicaid reimbursemnets, Medicare Part D, Discount Cards given to everyone. No industry I know has more cost controls on the despensing side. And has this hepled? NO, it hasn't, because the problem is not the despensing side, it is the cost of the product. Even if you negotiate discounts, the manufactures just go up on the costs so in 2 years the prices are right back where they were or higher.

In the past, generics were where a drugstores profit came from. Take that away and you will see less and less generics being used. If a stores average cost of doing business if between $9-10.00 and you are paid less than half that to dispense a "cheap generic" then there is no incentive to dispense that generic. You will see larger costs on the drug side of the equation.

So how do you cut cost? Pay more on the dispensing side so patients will have face to face contact with pharmacists to guide then and consul them on the medications. Look at what PBM's are paid. When CVS which has a book valvue of 27 billion tries to buy a

PBM for 27 billion, then something is wrong. The PBM is making way to much now compared to the 10 to 20 cents a claim when they first started out and make them transparent. Look at the drug manufactures. I have a bottle of 90 generic Zocor for $9.78 then have the same tablet that Merck sells me for $388.52. The same tablet. Pass laws to allow my co-op to negotiate for the same prices that VA, and mail order do. Do away with class of trade laws that have put us on an unlevel playing field. Pass laws to make PBM's transparent. Pass laws that make PBM's pass savings on to the companies that have hired them to look out after their interest. Pass laws that give us the right to negotiate rates with PBM's. Now it is take it or leave it. Come up with a viable reimbursement formula for the despensing of prescriptions tied to the true cost of despensing a prescription not mainly to the cost of the medication. Pass laws that allow the federal goverment to negotiate the price of drugs for the medicare part D patients. We can fill these prescritions and give face to face consultation at a less cost if we have access to the same cost of goods. AMP is not the answer without change the rest of the formulas. One can not come before the other.

Sincerely,

Bill Allen, RPh
AmeriMed Pharmacy
117 West Main St
Hahira, Ga 31632
ballen31632@yahoo.com

Submitter : **Miss. Wendy Marek** **Date: 02/16/2007**

Organization : **Wilkes University Nesbitt School of Pharmacy**

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 Wilkes University Nesbitt School of Pharmacy and I also work at CVS Pharmacy #1325 in Nesquehoning, PA.

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,

Wendy Marek
Student Pharmacist

Submitter : **Mr. John McCorkle** **Date: 02/16/2007**

Organization : **Mr. John McCorkle**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

We are the only pharmacy in a small low income town and closest pharmacy to us is ten miles away. On average 25% of our business comes from Medicaid patients and 40% from Medicare part D patients. Our total volume is a little over 100 prescriptions per day.

Collection of Information Requirements

Collection of Information Requirements

If the following provisions of AMP take place our cash flow will come to an end. We will have to most likely close the doors to our only pharmacy in town.

Response to Comments

Response to Comments

We will have to close the door to our pharmacy!

Submitter : Mr. John Heffernan **Date:** 02/16/2007

Organization : Massachusetts Pharmacists Association

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-716-Attach-1.PDF

MPhA
MASSACHUSETTS PHARMACISTS ASSOCIATION

February 16, 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

The Massachusetts Pharmacists Association (MPhA) is 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.

Summary

MPhA 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. Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510. §447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. §447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed in §447.510 creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself creates an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome. Additionally MPHA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of

500 West Cummings Park, Suite 3475, Woburn, MA 01801 Phone (781) 933-1107 Fax (781) 933-1109

trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006 report entitled: *"Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,"* the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not met by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless states were to mandate mail order pharmacy. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general

public." The following paragraphs will further address the unique contractual arrangements that distinguish mail order and PBM pharmacies from community retail pharmacies.

MPHA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. MPHA is unaware of any state that licenses PBMs, as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

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

As with the nursing home pharmacies, mail order pharmacies that operate as closed door facilities should not be included in the retail class of trade. As such, we believe section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade.

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

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

AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which ultimately reduces the amount that manufacturers receive. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On

balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

Market Manipulation

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

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[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[2] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.
[3] §447.510(d)(2)

As the entities engaged in the profession of pharmacy become more vertically integrated the potential for misuse of this dual reporting mechanism increases. Potentially, a manufacturer with a vertically integrated market position could use the 'rebate period' based reporting to manipulate AMP. Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual time-frame reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP. Furthermore, this ability would exist for a period of three (3) years, the allowable time for revisions. This undue flexibility, afforded to find a market price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

In its simplest form the trigger mechanism could accomplish the following: (i) limit the affects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to-date calculation of AMP. The ability to adjust the posted AMP, between reporting periods, will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag. The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the OIG will act as a damper to market manipulation. The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to fall below the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanism's ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP. Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

Record Keeping

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

Additional Comments

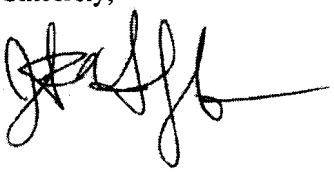
Use of the 11-Digit NDC Rather Than the 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to calculate AMP at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

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

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

Sincerely,



John F. Heffernan
Executive Vice President

cc: Senator Edward M. Kennedy (D-MA)
Senator John F. Kerry (D-MA)
Representative Michael Capuano (D-MA 8th)
Representative William Delahunt (D-MA 10th)
Representative Barney Frank (D-MA 4th)
Representative Stephen F. Lynch (D-MA 9th)
Representative Edward J. Markey (D-MA 7th)
Representative James P. McGovern (D-MA 3rd)
Representative Marty Meehan (D-MA 5th)
Representative Richard E. Neal (D-MA 2nd)
Representative John W. Olver (D-MA 1st)
Representative John F. Tierney (D-MA 6th)

Submitter : **Dr. Joni Cover** **Date: 02/16/2007**

Organization : **Nebraska Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-717-Attach-1.PDF

CMS-2238-P-717-Attach-2.PDF

Nebraska Pharmacists Association

February 16, 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

The Nebraska Pharmacists Association (NPA) is 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.

Summary

NPA 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. Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510. §447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. §447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed in §447.510 creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself creates an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome. Additionally NPA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

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NPA

§447.504 Determination of AMP

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

Defining Retail Pharmacy Class of Trade

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

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

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006 report entitled: *"Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,"* the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not met by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do

not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

NPA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. NPA is unaware of any state that licenses PBMs, as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

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

As with the nursing home pharmacies, mail order pharmacies that operate as a closed door operation should not be included in the retail class of trade. As such, we believe section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade.

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

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

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

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[3] §447.510(d)(2)

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In its simplest form the trigger mechanism could accomplish the following: (i) limit the affects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to-date calculation of AMP. The ability to adjust the posted AMP, between reporting periods, will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag. The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the IG will act as a damper to market manipulation. The long-standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanisms ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP. Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

Record Keeping

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

Additional Comments

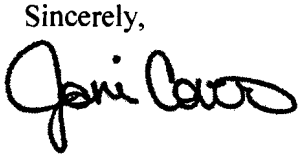
Use of the 11-Digit NDC Rather Than the 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-digit levels for generic drugs in determining FULs.

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

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

Sincerely,



Joni Cover, JD
Executive Vice President

cc. Senator Chuck Hagel
Senator Ben Nelson
Congressman Jeff Fortenberry
Congressman Adrian Smith
Congressman Lee Terry
Governor Dave Heineman

Submitter : **Linda Jones** **Date: 02/16/2007**

Organization : **NYS Department of Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-718-Attach-1.DOC

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany New York 12237

February 16, 2007

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

Electronic Submission: www.cms.hhs.gov/erulemaking

Re: File code CMS-2238-P, Comments on the Deficit Reduction Act (DRA) of 2005, pertaining to prescription dugs under the Medicaid program (42 CFR, Chapter IV, Part 447 – Payments for Services).

To Whom It May Concern:

The New York State Department of Health has reviewed the draft proposed rule to amend 42 CFR, Chapter IV, Part 447 – Payment for Services, under provisions of the DRA 2005.

We would like to provide the following comments to the proposed rule:

I. Background

- CMS should consider including customary prompt pay discounts extended to wholesalers in the Average Manufacturer Price (AMP) calculation since these discounts are required to be reported to the Secretary. Currently, customary prompt pay discounts are included in the calculation of best price (BP); removing them from the AMP calculation would result in inconsistencies in the two variables which are used to determine the unit rebate amount (URA) for single source drugs under the Medicaid Rebate Program. Also, removing customary prompt pay discounts from the AMP calculation may artificially inflate the AMP and new federal upper limit (FUL).

- We strongly support the requirement of manufacturers to include the lowest price available to any entity for a drug sold under a New Drug Application (NDA) approved under section 505c of the FFDCA when determining best price.

- We also strongly support the amendment to section 1927k to require all drugs sold under an NDA (approved under section 505c) and paid for by wholesalers and subsequently distributed to the retail pharmacy class of trade, be included in the AMP calculation.

II. Provisions of the Proposed Regulations

- CMS is encouraged to analyze the relationship between AMP and pharmacy acquisition costs and provide guidance to State Medicaid programs in the development of appropriate reimbursement amount under the estimated acquisition cost (EAC) or other methodology. State Medicaid programs do not have access to actual pharmacy acquisition costs, making it impossible to ensure fair and equitable reimbursement for prescription drugs under the EAC methodology. With CMS guidance in developing an accurate reimbursement methodology that most closely represents the pharmacy's actual acquisition cost, State Medicaid programs would be more willing to adjust pharmacy dispensing fee (based on appropriate criteria) to ensure adequate payment for professional pharmacy services.

- CMS should provide clarification or reasoning for its proposal to revise the definition of AMP to exclude customary prompt pay discounts to wholesalers. We believe excluding customary prompt pay discounts will artificially increase the AMP.

- The availability of AMP is described in the proposed rule to serve two purposes: 1) drug rebate liability and 2) payment. The rule further describes that "while there is no requirement that States use AMPs to set payment amounts, we (CMS) believe the Congress intended that States have drug prices data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices of sale to the retail pharmacy class of trade". AMP, based on a reliable methodology, will provide States with a more accurate estimate of prices available to wholesalers and, to a lesser extent, retail pharmacies. However, the availability of AMP and it's use in new EAC reimbursement methodologies (i.e. non-FUL drugs), will not affect manufacturers from continually pricing drugs at a premium. Manufacturers will continue to set prices without respect to ingredient costs. We believe that the intent to use AMP for payments may significantly disadvantage pharmacies while holding manufacturers relatively harmless.

  We encourage CMS determine reimbursement rates, based in EAC or some other methodology, for all single and multi-source drugs covered by State Medicaid programs. CMS is in a better position than any individual State to substantiate prescription drugs prices and reimbursement methodologies. CMS has already set precedence by setting reimbursement rates for drugs on a national level with the advent of average sales price methodology (106% ASP) for physician administered drugs under the Medicare Part B program.

- We encourage CMS to include mail order prices in the definition of retail class of trade. A majority of commercial third party payers, including those servicing Medicare Part D beneficiaries, encourage the use of mail order pharmacies. Many third party payers provide financial incentives to their beneficiaries in the form of reduced copays when using mail order services rather than the community pharmacy. It is well documented that mail order pharmacies are willing to accept lower reimbursement rates from third parties payers because of their purchasing power and ability to capitalize on economies of scale related to prescription volume. Since mail order pharmacies dispense to the general public, not including these prices would result in artificially inflated AMPs.

- We strongly support the inclusion of Pharmacy Benefit Manager (PBM) rebates, discounts and other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP. In general, there are very few pharmacy transactions/claims that are not processed by or paid through a PBM. Manufacturers provide PBMs with financial incentives associated with drug formulary development and these financial incentives must be included in the AMP calculation. Not including PBM rebates, discounts and other price concessions would significantly increase the AMP resulting in artificially inflated FULs. Also, there are well documented concerns with inadequate transparency regarding financial relationships between manufacturers and PBMs. Not including PBM pricing concessions would continue to compound the transparency issue.

- We are concerned with the financial impact that public access to AMP may or may not have on entities involved in the drug distribution and payment systems. Setting FULs too low will act as a disincentive for pharmacies to dispense generic drugs. If a pharmacy's profit margin is greater for a similar product not subject to a FUL, a pharmacy may be inclined to consult with a patient's prescriber to dispense a more expensive non-generic product. The proposed rule does not affect those drugs that have the greatest budgetary impact on State Medicaid programs. Generally, generic drugs account for a large percentage of pharmacy claims but smaller percentage of expenditures when compared to single source brand name drugs. We encourage CMS to use AMP and other prices available from the manufacturer, including those that are not publicly available, to provide a pricing construct for single source brand name drugs. Currently, each state Medicaid program uses a unique EAC based reimbursement methodology without having access to information submitted to CMS by manufacturers (i.e. BP). This not only limits the ability of states to ensure adequate reimbursement to pharmacies but has no affect on manufacturers setting premium prices for drugs that may not have any significant clinical impact when compared to drugs already in the marketplace.

- We support the proposal to exclude rebates paid to states under the Medicaid Rebate program from AMP calculations. We also support the

inclusion of price concessions associated with sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients in the AMP calculations. Medicaid sales could be a substantial portion of certain drugs classes, including drugs used in the treatment of mental illness and HIV/AIDS. Excluding Medicaid price concessions associated with sales could undermine the actual purpose of the DRA, as Medicaid programs are the predominate users of the FUL. Including rebates paid to States under the Medicaid Rebate program in the AMP calculation may result in AMPs and subsequently FULs that fall below the pharmacy acquisition cost. This would potentially result in accessibility issues for states' Medicaid programs and their beneficiaries.

- We strongly support the inclusion of Medicaid Part D sales, including rebates paid by manufacturers to Prescription Drug Plans (PDP) or Medicare Advantage – Part D Plans (MA-PD), in the AMP calculation to the extent that sales are to the retail pharmacy class of trade. Medicare Part D sales could be a substantial portion of certain drugs classes used by geriatric patients, including drugs used in the treatment of cardiovascular disease and diabetes.

- We request clarification regarding the treatment of sales associated with PBMs and how these differ from payment to PDPs. It is our understanding that PDPs are functioning as PBMs for the purposes of Medicare Part D beneficiaries. We strongly support the inclusion of PDP and PBM rebates, discounts and other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP.

- We strongly encourage CMS to include in the final rule the definition of "State Pharmaceutical Assistance Program (SPAP)", thereby eliminating existing inconsistencies between CMS policy releases and the "Qualified SPAP Checklist" used by SPAPs to attest to CMS.

- We very strongly encourage CMS to include in the final rule provision allowing state Medicaid programs to share with their SPAP the quarterly Unit Rebate Amounts (URA) provided by CMS for manufacturer invoicing purposes. SPAP access could be limited to URA's for which the SPAP has a rebate agreement with the manufacturer, and which specifically authorizes access to such data. Currently, SPAPs are required to calculate their own URA's, which requires collecting and processing manufacturer pricing data for tens of thousands of NDC's. This results in duplicative processing for manufacturers and States, which is unduly burdensome and inefficient considering CMS is already furnishing the state Medicaid programs with the end result. Manufacturers have supported and advocated to CMS for such data sharing arrangements.

- We request that CMS add clarity to the proposed provision exempting SPAP prices from best price. As proposed, "Any prices paid by an SPAP" are excluded from best price. Because SPAPs are generally third-party payers and do not typically purchase drugs directly, we recommend the provision be modified to specifically

exclude from best price "Any prices under an SPAP including rebates paid to an SPAP".

- We strongly encourage CMS to reconsider including rebates to SPAPs in the AMP calculation, which we find inconsistent with excluding rebates paid under the Medicaid program from the same calculation. Like Medicaid, SPAPs are not typically direct purchasers of drugs. Including manufacturer rebates to SPAPs in the AMP calculation could artificially deflate AMPs and subsequently FULs to a point where they are below pharmacies' acquisition cost, which would be problematic for programs utilizing AMP or FUL for pharmacy reimbursement.

- We support the inclusion of sales for specialty drugs through direct distribution arrangements, where the manufacturer retains ownership of the drug and pays an administration or service fee to a third party for storage, delivery and billing, etc. in AMP calculations. With the advent of genetically engineered biologic drugs direct patient sales distribution systems are becoming more common. Traditionally, these drugs are very expensive because of the complex technology required in the manufacturing processes. Not to include direct patient sales in the AMP calculation most likely will increase prices paid to the distributor. Since genetically engineered biologic drugs are very expensive, overestimating the AMP could result in excess overpayments by third party payers, including state Medicaid programs.

- We are concerned that excluding returned goods from the AMP calculation when returned in good faith without evaluating the effect returns may have on the AMP (i.e. significant increase or decrease in the AMP as a result of a returned good) could lead to inaccuracies in FUL and potential future payment methodologies based on AMP to be used by third party programs.

- We have identified an inconsistency associated with BP, AMP and customary and prompt pay discounts. Customary prompt pay discounts are included in the BP calculations but are excluded in the AMP calculation. We request clarification or a reason for this inconsistency.

- We are concerned with the exemption of payments made by a PDP and MA-PD to manufacturers from BP. With the advent of the Medicaid Part D program, there are substantial sales attributable to PDPs and MA-PDs. If included in BP, we believe these sales arrangements would result in more accurate pricing information and would enhance the Medicaid Drug Rebate program.

- We strongly support the proposal to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand name manufacturer's subsidiary in the calculation of AMP and BP.

- We understand that the upper limit payment for multi-source drugs applies in the aggregate. However, we request CMS clarification on how an aggregate

payment system can be implemented prospectively given the uncertainty of utilization for any of the multi-source drugs subject to the FUL.

- We strongly support the requirement that a FUL must be established for each multi-source drug for which the FDA has rated two or more products as therapeutically equivalent. We also agree with CMS applying the FUL to B-rated drugs in order to discourage substitution of B-rated drugs as a way to avoid the FUL in cases where B-rated drugs would be excluded from the FUL.

- We understand CMS' reason for using the reported nine-digit NDC AMP in establishing the FUL. We also agree with CMS comments that AMP reported at the eleven digit level is advantageous to CMS and the states. We strongly urge that CMS require manufacturers to provide CMS with AMP reported at the eleven digit level and that this information be supplied to the states.

- We support the proposal to determine whether a drug product should have a FUL within 7 days after receiving notification that a therapeutically equivalent product is available. Under the current FUL establishment and notification process, there have been many examples where multi-source products met the definition to be eligible for a FUL but the FUL is not released in a timely manner, resulting in excessive prices to pharmacies over extended periods of time.

- We strongly encourage accurate and timely notification of terminated NDCs associated with the establishment FULs. We request CMS clarify or define the meaning of "terminated". Also, we are concerned that if a FUL is removed without notification, NDCs may continue to be billed by pharmacies and reimbursed by state Medicaid programs. This issue may be compounded when state Medicaid programs continue to reimburse for a product that has been terminated and may reimburse at a rate above the price of the previously posted FUL.

- We strongly support the exception to the 30 percent carve-out policy when the FUL group includes only the innovator single source drug and the first new generic in the market or authorized generic.

- We agree with the conditions relating to physician administer drugs and the necessity of State Medicaid programs to bill manufacturers for rebates. However, physicians currently bill any product within the particular Healthcare Common Procedure Coding System (HCPCS) to the Medicaid program regardless of whether or not the manufacturer participates in the Medicaid Drug Rebate program. We request that CMS define how physicians will be notified of the specific drugs excluded from Medicaid payment under these circumstances.

- Physicians will be responsible with delineating differences in billing Medicare by HCPCS compared to Medicaid by NDC. We expect confusion by physicians and other entities as the actual HCPCS and NDC billing units may differ. To optimize Medicaid coordination of benefits with Medicare Part B fiscal intermediaries and increase the accuracy of invoicing and collection of rebates, we encourage CMS to require that Medicare Part B fiscal intermediaries accept NDC billing of Part B drugs. Otherwise, using HCPCS for Medicare then NDC for Medicaid billing could actually become more burdensome for physicians when trying to coordinate billing for patients eligible for both Medicare and Medicaid. The claim would have to be billed first to Medicare (i.e. primary payer) by use of a HCPCS and then secondarily billed to Medicaid by use of a NDC.

- We have some concerns with the inclusiveness of the list of the 20 multi-source physician administered drugs. The list must be inclusive of all NDCs attributable to a particular HCPCS drug code. We are also requesting an explanation of the process associated with updating and revising the list of the 20 multi-source physician administered drugs.

III. Collection of Information Requirements

- No comments

IV. Response to Comments

- No comments

V. Regulatory Impact Analysis

- We are concerned with the accuracy of pricing data in the monthly AMP file provided to states. A preliminary analysis conducted by the DOH reveals some uncharacteristic relationships between AMP and AWP for certain drugs. We noticed several products with an AMP greater than the current AWP. There were also cases in which the AMP was substantially lower than the AWP for single source drugs. We realize that single source drugs will not be affected by the new FUL methodology. However, it seems unrealistic that AMP for a single source drug is significantly lower than the AWP. Pricing comparison issues may be a result of the unit of measure/payment inconsistencies associated with the published AMP. Since the unit of measure/payment is not provided in the CMS file it is impossible to ascertain or adjust for package size or unit of measure/payment discrepancies. We recommend that the unit of measure/payment information be included in the monthly AMP release/posting.

- We request additional information regarding prices associated with the Retail Price Survey. We are concerned that survey prices will not be of any value in developing payment methodologies or equitable reimbursement

calculations. The proposed rule does not provide any clarification on how these prices will be determined. We request Retail Price Survey methodology details including whether the prices incorporate third party involvement, pharmacy discounts, price concessions or invoice costs. Prices based on usual and customary charges will be of no assistance in developing realistic pharmacy reimbursement rates.

Thank you for considering our comments on the proposed rule.

Sincerely,

Linda J. Jones, R.N., Director
Bureau of Pharmacy Policy and Operations
Office of Health Insurance Programs
New York State Department of Health

Submitter : Ms. Nanette Meeker **Date:** 02/16/2007

Organization : Central City Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

This regulation is completely unfair. There is no way that any independant pharmacy can purchase at AMP. Not every town in the US has a large chain pharmacy nor is there any likelihood that there will be. If your intent is to put all independant pharmacies out of business, this is an easy way to do it. Whether CMS likes it or not, businesses do have to make a profit or else they cease to exist.

The first thing you should do is see where the dollars actually go in the pharmacy business. I think you'll find that less than 25% of the money actually goes to the retail side of pharmacy and the 75% that flows to the wholesalers and manufacturers is a much more likely target for reductions.

A cost of dispensing fee based on regional annual independent analysis for cost of dispensing should be included in addition to the FULs for reimbursement determination.

Mail order should not be included in the definition of retail pharmacy as they cannot provide full pharmacy service.

There should be a provision to quickly change the FUL if a provider is requested to provide a product to a patient below cost. (Cost in this case includes the acquisition cost and the cost to dispense.)

Submitter : **Date: 02/16/2007**

Organization : **Kraupner Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-2238-P-720-Attach-1.TXT

CMS-2238-P-720-Attach-2.DOC

Sate of New York (PSSNY) 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 Pharmacist Society of the Sate of New York (PSSNY) regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Gary Goffner, RPH
Ralph Goffner, RPH
Leonard Colluro, RPH
Anthony Valenti, RPH
Armand Baklajian, RPH
Patricia Johnson, RPH
Saul H. Housman, RPH
Joe La Sala, RPH

cc. Congressman Gary Ackerman
Congressman Timothy Bishop
Congressman Joseph Crowley
Congressman Vito Fossela
Congressman John J. Hall
Congressman Maurice Hinchey
Congressman Pete King
Congresswoman Nita Lowey
Congressman John M. McHugh
Congresswoman Carolyn Maloney
Congressman Jerrold Nadler
Congressman Thomas M. Reynolds
Congresswoman Louise Slaughter
Congresswoman Nydia M. Velazquez
Congressman Anthony D. Weiner
Congressman Michael A. Arcuri
Congresswoman Yvette D. Clarke
Congressman Eliot Engel
Congressman Kirsten E. Gillibrand
Congressman Brian Higgins
Congressman Steve Israel
Congressman John R. Kuhl Jr
Congresswoman Carolyn McCarthy
Congressman Michael R. McNulty
Congressman Gregory W. Meeks
Congressman Charles B. Rangel
Congressman Jose E. Serrano
Congressman Edolphus Towns
Congressman Jim Walsh

Submitter : Mrs. Jill Mutz **Date:** 02/16/2007

Organization : Medical Center Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

This proposed regulation would create a definition of average manufacturer s price (AMP), as well as implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Bryan. Texas. Medical Center Pharmacy is a major provider of pharmacy services in this community and your consideration of these comments is essential.

It is critical that AMP data be perceived as a reliable approximation of the prices paid by retail community pharmacies for medications. Yet, the proposed regulation falls short in this goal. For example, in the proposed regulation, pharmaceutical manufacturers can deduct from their AMP calculation the rebates and discounts they provide to health plans and PBMs for brand name drugs. These discounts are paid directly to these entities, not to community pharmacies, and in many cases the actual amount of the price concession is not known due to a lack of transparency. Given that retail pharmacies do not benefit from these rebates and discounts received by the health plans and PBMs, the proposed regulatory definition of AMP would not reflect prices at which retail pharmacies purchase medications and, therefore, would be lower than the acquisition cost paid by retail pharmacies for medications. Only manufacturers sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition.

The DRA directs that the federal Medicaid program significantly reduce payments to the pharmacies for generic medications dispensed, yet does not offset these negative losses with an increase in dispensing fees. Without greater direction by CMS to increase the dispensing fees to pharmacies, incentives to dispense lower cost generics may be reduced. A generic prescription costs about $20, while the average brand name prescription costs $120. Recent studies indicate that it costs a pharmacy approximately $10 to dispense a Medicaid prescription, well below the Texas state dispensing fee. An increase in the state dispensing fees can help assure continued dispensing of lower cost generics.

The DRA requires CMS to publicly release AMP data for each brand name and generic drug reimbursed by Medicaid, in addition to directing that AMP data be used to set FULs for generic drugs. CMS initially delayed the original release of data from July 2006, due to widely documented inconsistencies with how pharmaceutical manufacturers calculate AMP data. CMS has indicated it will release this data this spring, yet has not published a final regulatory definition of AMP. Release of this data at this time would be a disservice to the states, to pharmacies and to the market place in general. According to a recent Government Accountability Office report, using AMPs to set FULs for generics would underpay pharmacies by 36 percent. This could significantly discourage generic dispensing with Medicaid. It would be inappropriate to use flawed AWP data to set new Medicaid generic payment rates this spring, as has been proposed by CMS, until a final definition of AMP is obtained.

In summary, this proposed rule could adversely impact the ability of pharmacists to continue to serve Medicaid beneficiaries. Pharmacies are still recovering from the economic impact of major issues experienced under Medicare Part D. Community pharmacists stepped up to make the Medicare Part D program operational, yet they continue to experience poor reimbursement and delays in payment for the products and services provideIt is inconceivable that pharmacies will be asked again to bear the economic impact of inappropriate planning on the part of CMS. In addition, this proposal could adversely impact our ability to continue to serve Medicaid beneficiaries and provide their needed medications.

Submitter : **Miss. Leslie Browner** **Date: 02/16/2007**

Organization : **UT Pharmacy School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.
I am a student pharmacist at the University of Tennessee College of Pharmacy and am interested in community retail pharmacy practice. I have worked at Walgreens pharmacy, a community retail pharmacy located at 1334 North Highland, Jackson, TN 38301, and I am familiar with the challenges in retail pharmacy practice.

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

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

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

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

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

Collection of Information Requirements

Collection of Information Requirements

Removal of Medicaid Data

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

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

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

GENERAL

GENERAL

Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a

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

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

Submitter : Christina Bass **Date:** 02/16/2007

Organization : University of Tennessee College of Pharmacy

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.
I am a student pharmacist at the University of Tennessee College of Pharmacy and am interested in community retail pharmacy practice. I have worked at Eckerd Pharmacy, a community retail pharmacy located at 1500 W. Main St. Lebanon, TN 37087, and I am familiar with the challenges in retail pharmacy practice.

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

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

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

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

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

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

Collection of Information Requirements

Collection of Information Requirements

3. Removal of Medicaid Data

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

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

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

GENERAL

GENERAL

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

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

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

Submitter : Ms. Lori Lamerand **Date:** 02/16/2007

Organization : Planned Parenthood Mid-Michigan Alliance

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-724-Attach-1.DOC

Lori Lamerand, CEO
Planned Parenthood Mid-Michigan Alliance
3100 Professional Dr., Ann Arbor, MI 48103

Feb. 16, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

As CEO of Planned Parenthood Mid-Michigan Alliance (PPMMA), a non-profit organization that operates health centers in Ann Arbor and East Lansing, I am writing to ask you to designate our organization an important safety net provider in our area.

We provide critical health services to uninsured and underinsured women. Our Ann Arbor and East Lansing health centers serve over 5,000 of patients annually, many of whom could not afford the health services—particularly contraceptives—that we provide.

I am writing on behalf of these thousands of women because they don't have a voice in the critical, life-changing decisions that are made in Washington, D.C.

Furthermore, I am writing because the state of Michigan is currently suffering a severe economic recession which will likely get worse before it gets better. As jobs leave our state and businesses close or go bankrupt, we are seeing more and more people lose their health insurance and their ability to pay for contraception.

For over 70 years in Ann Arbor and over 20 years in Lansing, our health centers have served a segment of the population that cannot normally afford contraception by providing them access to contraception at prices far lower than what is available in the retail market. We have been able to serve this underprivileged community because we could buy contraception from drug manufacturers willing to provide them at nominal prices. Without this ability, we could very soon be out of business in these locations. We dearly need to be able to buy contraception at less than 10% of the average retail price in order to serve poor women who have no other way to get low-cost contraception.

The rule, as put forth by the Centers for Medicare and Medicaid Services ("CMS") on December 22, 2006, gives three kinds of providers ((I) 340B covered entities, (II) intermediate care facilities for the mentally retarded and (III) state owned or operated

nursing homes) the ability to purchase drugs at nominal prices. Some of our health centers are Title X clinics, and therefore are covered as 340B entities. However, Title X funding is being drastically cut, which will have a negative impact on our affiliate and health centers as a whole. . If we also lose the ability to be a safety net provider to our non-Title X health centers, all the poor people we serve throughout our service area could be in jeopardy.

Like other non-340B providers of medical services to the poor, we must rely on section 6001(d) (IV) of the DRA to permit continued access to steeply discounted drugs. The Secretary of the Department of Health and Human Services ("HHS") is authorized to define "other safety net providers" that would be eligible for the nominal pricing exception. We were deeply dismayed when, in the proposed rule, CMS did not define or apply this fourth statutory exception. We very much hope that HHS will exercise the authority granted it by Congress to define "other safety net providers" in the final rule.

The plight of our Ann Arbor and East Lansing health centers, along with other similar non-profit outpatient clinics across the nation, should provide ample evidence to CMS that the other three categories of health services providers are not "sufficiently inclusive" and do not "capture the appropriate safety net providers." Deserving non-profit clinics like our Ann Arbor and East Lansing health centers are not covered by the entities listed in 6001(d), subsections I, II and III. Many of us are slipping through the cracks in this poorly worded clause and taking down our poor clients with us.

On top of that, we have been told by several manufacturers who have historically sold to us at nominal prices that we will have to pay full wholesale prices for all contraception going forward. The belief on the part of CMS that inclusion of non-340B safety net providers in the nominal pricing exception will have an adverse effect on best price is misplaced. Eliminating hundreds of Planned Parenthood health centers from the nominal price exception will not affect best price at all—the only consequence of this policy will be to preclude manufacturers from charitably helping safety net providers like us to serve our patients.

In conclusion, Planned Parenthood Mid-Michigan Alliance is a non-profit outpatient health care facility that serves a critical function in the health and well being of over 5,000 uninsured and underinsured women in Ann Arbor and East Lansing. We are able to provide these services and deeply discounted contraception to these women only because we can purchase contraceptives from drug manufacturers at nominal prices, as we have been doing for over [number] years. Carving safety net providers like Planned Parenthood Mid-Michigan Alliance health centers out of the nominal pricing exception would be devastating to our mission and to our operations—without nominally priced drugs we will likely have to close our doors. Planned Parenthood Mid-Michigan Alliance urges CMS very strongly to reconsider its position and apply the safety net provider exception as provided in the DRA.

Sincerely,

Lori Lamerand
CEO and President
Planned Parenthood Mid-Michigan Alliance

Submitter : **Ms. Stacy James** **Date: 02/16/2007**

Organization : **Planned Parenthood of Montana**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-725-Attach-1.DOC

Planned Parenthood®
of Montana

WWW.PPFA.ORG

Administration
2525 4th Avenue North
Billings, MT 59101
P: 406-248-3636
F: 406-254-9330

Billings Heights Surgical Services
100 West Wicks
Billings, MT 59105
P: 406-245-6075
F: 406-252-1044

Billings Heights Express Clinic
100 West Wicks
Billings, MT 59105
P: 406-248-3636
F: 406-294-8643

Billings West
1844 Broadwater Ave
Billings, MT 59102
P: 406-656-9980
F: 406-656-9928

Great Falls
211 9th St. South
Great Falls, MT 59401
P: 406-454-3431
F: 406-454-3433

Missoula
219 East Main
Missoula, MT 59802
P: 406-728-5490
F: 406-728-5497

Kalispell
795 Sunset Blvd.
Kalispell, MT 59901
P: 406-756-6663
F: 406-756-6713

Helena
1500 Cannon Street
Helena, MT 59601
P: 406-443-7676
F: 406-443-2351

Office of Public Affairs
318 N Last Chance Gulch
Helena, MT 59601-5068
P: 406-457-2469
F: 406-457-2471

February 15, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the CEO of the only Planned Parenthood affiliate in the state of Montana. As such, we cover a vast amount of territory with a small population. Our patient load is largely uninsured and live below the poverty level. Although we receive Title X funding at four of our clinic sites, 10 of our sites receive no federal funding. In most cases we provide the only health services that these women and men access and are able to afford. Most of our patients seek reproductive health care services including oral contraceptives. As they are not insured and live below the poverty level, they cannot afford to purchase contraceptives anywhere else.

Our affiliate started as one clinic in 1969 with a commitment to the people of Montana to provide quality affordable health care and low cost contraceptives. As we saw a great need for low cost contraceptives and compassionate, confidential services in the most rural parts of our state, we developed small clinic sites across the state that allowed greater access to individuals much closer to home. At many of our locations, the closest family planning clinic may be over 100 miles away. The poor cannot afford to drive that far to receive care, nor are they able to afford the cost of oral contraceptives from the pharmacy. They are in an untenable position with few job opportunities and little local health care. Approximately 60% of our patients are below 100% of poverty and only 26% of our patients have any insurance. We do not wish to abandon those patients who are most in need.

For 38 years Planned Parenthood of Montana has been very proud to provide low-cost high-quality reproductive health care and contraceptives. We have been able to do this because we have been able purchase contraceptives from manufacturers who were willing to partner with us by providing nominal pricing for those most in need. Of the 18,000 patients we serve, some 2700 do not have the benefit of 340B priced contraceptives which are provided to the client on a sliding fee scale. Those 2700 patients are just as important to us and have the same critical need for subsidized care as our "Title X" patients. We do not wish to abandon them, but we cannot afford to buy and they cannot afford to purchase oral contraceptives at retail market prices.

Currently the only entities that are eligible for nominal pricing are 340B eligible entities, intermediate care facilities for the mentally retarded and state owned and operated nursing homes. Ten of our sites do not qualify under any of these eligibilities. We are not able to add these clinics to our Title X contracts. Therefore these clinic sites cannot receive nominal pricing and these patients will be unable to access care and contraceptives except with your help.

As a "safety net provider" for these poor and uninsured people, Planned Parenthood of Montana depends on our ability to purchase contraceptives at nominal prices. Should we be unable to do that, there will no longer be a "safety net" for these patients. We are asking you, as the Centers for Medicare and Medicaid Services, to use your authority to name not-for-profit, outpatient clinics such as ours as safety net providers so that we may continue our 38 years of service to greatest number of people possible.

Sincerely,

Stacy C. James, MBA
Chief Executive Officer
Planned Parenthood of Montana
Billings, MT

Submitter : Edwin Rowe **Date:** 02/16/2007

Organization : Rowe's Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-726-Attach-1.DOC

February 15, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Rowe's Pharmacy, a community retail pharmacy, located at 2416 Memorial Boulevard, Kingsport, TN 37664. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy where 99.2% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

C. Edwin Rowe, D.Ph.
434 Center Street
Gray, TN 37615

cc: Senator Lamar Alexander
Senator Bob Corker
Representative David Davis

Submitter : Miss. Lisa Mull **Date:** 02/16/2007

Organization : Expert-Med, Inc.

Category : Individual

Issue Areas/Comments

Background

Background

I am a sales executive at Expert-Med, Inc. and have been selling generic pharmaceuticals over the past 5 1/2 years to Independently-owned pharmacies across the country.

Collection of Information Requirements

Collection of Information Requirements

Please reconsider the reimbursement limits that will be set on independently-owned pharmacies. One of the biggest complaints I have from independent pharmacies,right now, is that they are losing money on medicaid prescriptions. Some times they get reimbursed right above costs of their acquistion cost. And, at times, these reimbursements from Medicaid are close to our cost (the distributor).

I have found over these past 5 years that independent pharmacies all have different acquisition costs. Acquisition cost vary tremendously between independent pharmacies that are small to ones that are in big cities with closed-door, geriatric or hospice contracts. In other words, when it comes to standardizing reimbursement rates they can not be put on the same level. This could drive small pharmacies out of business, and these are the pharmacies that are providing services to customers who are homebound and rely on the pharmacy's delivery service to get their meds. Chain store pharmacies are not providing these services. Independent pharmacies are. Wal-Mart makes money of f of bikes, food, clothing,etc. Their $4 prescriptions draw customers in and while they wait for their medication to be dispensed, they shop around for other things. Stores like these can absorb lower reimburesement rates. However, independently-owned pharmacies make their living off of the medication and service they provide to their customers. And from the feedback I get from my customers on a daily basis medicaid and 3rd party reimburesements hurt already. Please reconsider this strategy. Look at the impact that this could have to indepents. They are an invaluable asset to communities across America. Let's not destroy their efforts.

Suzanne Lamon
Reeves Drug Store, Inc,
125 North First Street
Pulaski, Tennessee 38478

February 16, 2007

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

To Whom It May Concern:

Thank you for the time to review this comment concerning the Deficit Reduction Act of 2005.

I am a pharmacist and the daughter of a mother and father who are both pharmacists. I was raised in our family-owned drugstore which was previously owned by my great-uncle. For YEARS our store has provided not only the service of dispensing drugs to our customers/patients, but also dispensed knowledge and assistance in their health care needs. Pharmacists are considered to be one of the most trusted professions of a community and the most accessible health care provider in a community. Additionally, we also assist our patients in making sure that they can get their medications by offering delivery within city limits and even mailing prescriptions to those who live outside of our little town's city limits for those that cannot get to town for lack of transportation, illness, etc. Therefore, I believe that you should sincerely consider the impact you are about to make in the lives of our patients, our store, and our community when you choose to pick on the retail end of prescription drugs to lower cost without looking at the entire pharmaceutical industry or without looking at how it will affect many pharmacy businesses.

It is my understanding that the implementation of using the AMP calculation would result in a loss for our pharmacies just to fill the prescription. This may not hold true for some mail-order houses of large PBM's that can purchase large quantities and sometimes quantities that are not even available to our buying groups. You must look at the entire picture before you consider the AMP not just how one entity can purchase that drug. The playing field is not equal for all involved in purchasing pharmaceuticals. And you have not even included the manufacturers of the name brand drugs that raise the cost of drugs dramatically. I understand that these companies have to recoup their cost of research that goes into creating a life saving drug. However, you also consider that they are able to produce and pay for an ad on national TV to inform you of that. They also seem to be making enough profit to create and produce ads to inform patients

about their particular drug as to increase the sales of their product. Should this not be the decision of the well-trained and educated physician, not the drug manufacturer to ask the consumer to ask their doctor? While we are discussing large amounts of profit we can also discuss the large PBM's and the salaries and benefits of their CEO's and what they are paying their stockholders. It seems to me that all of this profit is money that is being taken away from the consumers, businesses providing insurance to their employees, and government.

By focusing on the smaller pharmacy businesses in the cost of the deficit for the government and creating an absurd reimbursement for dispensed medications and care for the patient, you will be in effect closing the doors on access to medication and medical information to one of the neediest populations in our country. WE ARE A BUSINESS. We have to make a profit to survive to pay our employees, to pay our light bill, to keep the store up and running. We are not asking to make millions, but to make a fair wage for the cost of the drug and the time that we spend taking care of the Medicaid patients in our state. Ask some Medicaid patients who they go to for help with their medication? Who do they depend on for assistance? How many of those people do and are able to obtain their drugs from mail-order facilities for which you have based some of your prices? I feel confident that you will find that most Medicaid patients depend on their community pharmacist for help and support of the medications in addition to their questions and concerns about other health problems. We, the community pharmacist, are an asset to you. We are the people that are on the front lines caring for this population. All we are asking is that you reimburse us for the services that we provide you and your patients. Do not take away from us and leave the larger entities with the biggest profits untouched.

If you decide that the new AMP calculation is the best course of action for your deficit, then you will most likely be faced with the crisis of where and how Medicaid patients will receive their medications. However, if you choose to give a fair reimbursement to community pharmacies, Medicaid patients will be able to obtain the same service from the group of individuals that they have been receiving it from for years.

Again, I appreciate your time in the is matter.

Sincerely,

Suzanne Lamon, PharmD

Submitter : Mr. Lawrence Sage **Date:** 02/16/2007

Organization : Indiana Pharmacists Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-732-Attach-1.DOC

March 12, 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

The Indiana Pharmacists Alliance is 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.

Summary

NASPA 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. Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510. §447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. §447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed in §447.510 creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself creates an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome. Additionally NASPA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

§447.504 Determination of AMP

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

artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006 report entitled: *"Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,"* the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not meet by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to

this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

NASPA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. NASPA is unaware of any state that licenses PBMs, as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

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

As with the nursing home pharmacies, mail order pharmacies that operate as a closed door operation should not be included in the retail class of trade. As such, we believe section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade.

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

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29." Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to

1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive.

Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the

[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[2] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

As the entities engaged in the profession of pharmacy become more vertically integrated the potential for misuse of this dual reporting mechanism increases. Potentially, a manufacturer with a vertically integrated market position could use the 'rebate period' based reporting to manipulate AMP. Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual time-frame reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP. Furthermore, this ability would exist for a period of three (3) years, the allowable time for revisions. This undue flexibility, afforded to find a market price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

[3] §447.510(d)(2)

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

In its simplest form the trigger mechanism could accomplish the following: (i) limit the affects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to-date calculation of AMP. The ability to adjust the posted AMP, between reporting periods, will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag. The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the IG will act as a damper to market manipulation. The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanisms ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP. Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

Record Keeping

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

Additional Comments

Use of the 11-Digit NDC Rather Than the 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form

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

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

Sincerely,

Lawrence J. Sage
Executive Vice President
Indiana Pharmacists Alliance

Cc Senator Evan Bayh
Richard Lugar
Representative Julia Carson

Submitter : Mrs. Melissa Maeker **Date:** 02/16/2007

Organization : The University of Texas Health Center at Tyler

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-733-Attach-1.DOC

February 5, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

On behalf of The University of Texas Health Center at Tyler, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. The University of Texas Health Center at Tyler is a 115 bed hospital located in Tyler, Texas, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Hospital billing systems are not created to pull this data to a bill. To accommodate, our facility would be required to pay for custom programming from our software vendors. In addition, this would require an additional FTE in the pharmacy department to facilitate continuously updated NDC files in the Pharmacy software. It is not feasible to ask that hospitals attempt to manually add these NDC numbers to a bill. As contracts change quarterly, hundreds of drug NDC #s would need to be modified to ensure integrity in reported data. An estimate of financial ramification to our facility would be over $60,000 per year not including custom programming cost estimated over $30,000. This doesn't even take into consideration a facility having more than one brand of generic being used at the same time in different areas of the facility due to inventory changes.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. It has long been understood in the hospital community that hospital clinic administered drugs are exempt from rebate requirements under the Medicaid stature. Yet the express purpose

of the NDC collection rule for "physician administered drugs" is to facilitate rebate collections by the States. The new rule proposed by CMS to implement Section 6002 of the DRA should take this pre-existing statutory exemption from rebates into account, and similarly except hospital outpatient clinic drugs from the new NDC collection rule. It makes no sense to require the states to collect NDC information so that they can more easily collect rebates on drugs that are exempt from rebates in the first place. Many of these medications are extremely expensive. If all cost savings are passed through to the Medicaid program, it leaves hospitals moving very expensive medications for small fees. This in addition to increased administrative burden and costs bring up a strong debate within our hospital on whether it is worth participating in the 340B program.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. CMS should clarify that the new formula for AMP computation is not applicable in calculating 340B ceiling prices, because the 340B statute expressly provides for continuing to utilize the statutory definition of AMP that existed prior to enactment of the DRA. Driving up 340B costs will have a negative ramification across our facility.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Melissa Maeker R.Ph.
Director of Pharmacy
The University of Texas Health Center at Tyler
Tyler, Texas

Submitter : Mr. Michael Porter **Date:** 02/16/2007

Organization : Medicine mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

This proposed regulation will be absolutely devastating to theRetail pharmacy sector, especially independent pharmacies. Our service and advice to our customers is certainly worth more 1.50 or 2.00. I don't think you are aware of what kind of inventory we have to keep in stock to supply meds to the customers. There is a cost on keeping that inventory on our shelves which may sell quickly or not. If it doesn't sell quickly then we are stuck with it. We are a very trusted profession whcich deserves to be compensated for our services. Right now you are merely paying us to stick a label on the bottle. The costs of running a pharmacy are very high and pharmacist salaries are high as well due to the shortage. We can't stand any more cuts in our reimbursement. We should be paid 10.00 per prescription.We deserve more than what you are trying to pay us. Pharmacists are the ones who save insurance companies millions of dollars per year because of our advice of choosing products that do have generics, and some people ask us if we recommend the generic over the brand. They trust us! Please do not pass this reform. There are other ways to cut costs. Pharmacy has already been cut to the bone. May independents will go out of business and their customers will suffer.

Submitter : Dr. Nancy Horn **Date:** 02/16/2007

Organization : Dr. Nancy Horn

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-735-Attach-1.TXT

March 12, 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, Corner Drug Winchester, is located at 26 E Broadway, Winchester, KY 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 Kentucky 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, Kentucky 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 Kentucky Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Nancy S. Horn, Pharm.D., R.Ph.

cc. Congressman Ben Chandler
Senator Mitch McConnell
Senator Jim Bunning
American Pharmacy Services Corporation

Submitter : **Mr. Lawrence Irene R.Ph** **Date: 02/16/2007**

Organization : **Armada Health Care**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-2238-P-736-Attach-1.DOC

ARMADA
Health Care

February 16, 2007

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

Re: Docket: CMS-2238-P - Prescription Drugs

To Whom It May Concern;

Please accept for consideration this letter pertaining to an announcement by the Centers for Medicare & Medicaid Services (CMS) on December 22, 2006 that requires the imposition of a new methodology to establish reimbursement under CMS program(s) and referred to as "Average Manufacturer Pricing" (AMP). As noted in that announcement, CMS has established a comment period and has invited interested parties to provide their input on the promulgation of specific rules, regulations and specifically on the definition of AMP as it will be utilized in the development of pricing and reimbursement formulae that will set reimbursement rates for prescription drugs.

This comment is provided by Armada Health Care, Inc. on behalf of our pharmacy membership. We serve our members by securing contracts with pharmaceutical manufacturers for a broad array of prescription drugs and we focus specifically on the specialty pharmacy segment and working with specialty pharmacies nationally to provide them access to group discounts. Our manufacturer negotiations specifically target high-cost injectables, infusible, and other select biotech class medications. Our member pharmacies include the majority of independent specialty pharmacies operating in the US. Additionally, our membership also includes the top largest chain pharmacies in the country. In the aggregate, Armada membership now represents more than 7,000 retail pharmacy locations, billions of dollars in specialty pharmacy spend, and millions of patients.

CMS has publicly stated that the proposed rules and introduction of AMP methodology will impact independent retail pharmacies. All of the pharmacies associated with our organization are classified / licensed as retail pharmacies and often dispense traditional drugs in conjunction with specialty medications. Since our membership will be impacted by this action we are offering this comment to provide CMS with information to assist in developing an equitable methodology, one that does not disproportionately impact the sub-class of specialty pharmacy or try to insert it into a 'one size fits all' formula.

Pricing Component Inequities for Specialty Pharmacies –
The cost of an average prescription in a retail pharmacy currently averages ~$100.00 for a brand name drug and ~$40.00 for a generic prescription. By contrast, the average prescription dispensed in a specialty pharmacy easily exceeds $1,500.00 per month. This pricing disparity naturally magnifies the financial impact that any change in reimbursement, such as proposed under AMP methodology, may have on net

reimbursement. While the effect may only be a dollar on a routine brand name prescription and perhaps pennies on a routine generic drug, the magnified effect to reimbursement for a specialty drug may be ten (10) or more times greater in real dollars.

Specialty pharmacies also have significantly greater dispensing costs than a retail pharmacy and routinely serve patients requiring express overnight delivery and special handling. While gross margins may appear larger for a specialty transaction, associated costs are disproportionately large and significantly erode profit even under current reimbursement methods. This disparity should be accounted for in factoring in 'dispensing fees' as they are a stated component of the proposed AMP methodology rule.

Pharmacy associations nationally suggest that the average cost to dispense a traditional prescription is as high as $10.00. By contrast, specialty pharmacies incur dispensing expense per prescription well in excess of that figure. These incremental costs typically include taking a thorough patient medical history, comprehensive patient counseling on the drug regimen and disease state, training on administration of injectables, obtaining medical records required for pre-authorizations, and compliance tracking and other cognitive services. We estimate that these costs easily double the average cost to dispense a prescription – or more, based on the complexity of the patient's disease state. Additionally, delivery costs are considered a part of the 'dispensing fee' under AMP. While a traditional prescription might only cost $1-$3.00 to deliver by mail, specialty pharmacy medications, many of which require temperature control, require express shipping with an average delivery cost of $15.00 or more per prescription.

Independent specialty pharmacies are not able to routinely contract directly with manufacturers. As such, National Purchasing Organizations represents the only viable discount opportunity available to them for high-cost specialty pharmacy medications and biologics. However, only within the past year have pharmaceutical manufacturers begun to even consider incentives for specialty products for the independent specialty class of trade and rarely offer our pharmacies direct incentives such as rebates or free goods for specialty medications. This disparity becomes significant when one considers that specialty medications now represent s much as 35% of all pharmacy spend in the US.

However, it is well known that very large customers, such as hospitals and PBM-owned mail service pharmacies, use their leverage to garner significant discounts, preferred terms, rebates, and pricing concessions on specialty pharmacy medications through direct manufacturer contracts. Since these customers represent the majority of total specialty pharmacy expenditures, they move the mean in a direction that creates even greater disparity for small independent specialty pharmacies. Some weighting of this effect in the AMP formula will be critical to mitigate the adverse impact to independent specialty pharmacies.

This issue may be particularly evident when defining "Best Price" for single source or innovator multiple source products. Specialty pharmacy is unique as this category includes many single source and innovator products. A strict definition of "Best Price" would almost inevitably exclude independent specialty pharmacies from providing these products since their acquisition costs will be significantly higher than other trade classes (e.g., hospitals, mail order pharmacies included in the AMP calculation) and would predictably result in a loss on each transaction. These pharmacies would be unable to fill these prescriptions as a result. Since the new methodology will be initially applied to

Medicaid programs, the impact to patients would be severe. These patients commonly obtain their specialty pharmacy medications through local independent specialty pharmacies, not through mail order. If their local pharmacies can no longer viably serve this population, these patients will either go without medication or will be forced to more costly sites of service, such as hospital outpatient departments.

Lastly, we wish to express concern over how establishment of the Federal Upper Limit (FUL) will impact specialty pharmacy. FUL understandably applies to multiple source drugs (e.g., generics with therapeutic equivalents). At this time, the number of therapeutic equivalents in the specialty pharmacy category is very small. However, this issue is currently at the heart of pending legislation in Congress relating to the approval of generics in biologics. We believe that this issue is highly complex as evidenced by the FDA's stance and inability to set scientific standards that clearly differentiate equivalency between/among specialty medications. As such we strongly suggest that all specialty medications be exempt from FUL definition/calculations until this critical issue is resolved in law and in the marketplace.

We would be pleased to provide CMS with specific information or clarifications on the points that we have raised on behalf of the specialty pharmacy industry. You may contact me directly at the address noted herein. Thank you for this opportunity to comment.

Sincerely,

Lawrence S. Irene, RPh
Chief Executive Officer
Armada Health Care

51 JFK Parkway • Short Hills, NJ 07078 • Phone (973)-564-8004 • Fax (973)-564-8010
www.ArmadaHealthcare.com

Submitter : **Mrs. jennifer valentine** **Date: 02/16/2007**

Organization : **medicap pharmacy**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

I would like to send a comment about the Deficit Reduction Act. I do not agree with this proposed act. If the pharmacy is getting reimbursed less for the medications that we fill, then we will not have enough profit to cover payroll or good customer service. The pharamcy will no longer be able to pay the costs for more employees, our raises will be less causing techinicians to eventually find another profession that can pay better.

Submitter : **Miss. Teri Belcher** **Date: 02/16/2007**

Organization : **Medicap Pharmacy**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

If this bill passes, the custom service you expect at a pharmacy, will no longer be available and resulting in not enough money to cover payroll and supplies.

Submitter : **Mr. Jozef Beckley** **Date: 02/16/2007**

Organization : **APhA**

Category : **Academic**

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 Minnich's Colonial Pharmacy in York, PA.

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,

<p><p>Jozef R. Beckley

Submitter : **Dr. Jennifer Askew** **Date: 02/16/2007**

Organization : **NC Association of Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 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 Wilmington, 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,

Jennifer P. Askew, BS, PharmD, CPP

cc. Members of Congress (Senator Elizabeth Dole, Senator Richard Burr, Representative Mike McIntyre)

Submitter : Mr. dale smith **Date:** 02/16/2007

Organization : PBA Health d/b/a TrueCare Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-741-Attach-1.TXT

From: Dale Smith
Sent: Friday, February 16, 2007 1:40 PM
To: Dale Smith
Subject: More than half of all prescriptions dispensed by retail pharmacies are for generic medications, so losing money on every one d

Submitter : Mr. Russ Jensen **Date:** 02/16/2007

Organization : Dean Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-742-Attach-1.DOC

Dean
HEALTH SYSTEM

February 16, 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

Dean Pharmacy is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates eight pharmacies in Southern Wisconsin. We are a major provider of pharmacy services in the communities in which our pharmacies are located.

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

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

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

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

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Russell J Jensen, RPh, MS
Director of Pharmacy

Dean Business Office ◗ Pharmacy Admin ◗ 1808 W. Beltline Highway ◗ Madison, WI 53713 ◗ (608) 258-6550 ◗ Russ_Jensen@ssmhc.com

Submitter : **Date: 02/16/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 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,

Hal Densman

Submitter : Mrs. Suzanne DeMott **Date:** 02/16/2007

Organization : Mrs. Suzanne DeMott

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The formula for AMP based FULs in the proposed rule will not cover our costs and will cause many pharmacies to close. We should get paid what the drugs actually cost us plus a fee to cover overhead costs plus a reasonable profit. The AMP, AWP should be done away with and we should be able to use our AAC (the actual cost).

Submitter : Mr. Neldon McCort, Jr. **Date:** 02/16/2007

Organization : Brookside Discount Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-745-Attach-1.TXT

February 15, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Brookside Discount Pharmacy, a community retail pharmacy located at 1901 Brookside Drive, Kingsport, TN 37660. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Neldon C. McCort, Jr.
1048 Amersham Road
Kingsport, TN 37660

cc: Senator Lamar Alexander
Senator Bob Corker
U.S. Representative David Davis

Submitter : **Date: 02/16/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-746-Attach-1.TXT

Submitter : **Mr. David Machlowitz** **Date: 02/16/2007**

Organization : **Medco Health Solutions, Inc.**

Category : **Health Care Industry**

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.

Submitter : Ms. Teri Miller **Date:** 02/16/2007

Organization : Planned Parenthood of Greater Cleveland

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-748-Attach-1.DOC

February 16, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the Vice President of Health Services and Operations for Planned Parenthood of Greater Cleveland (PPGC), which operates five non-profit outpatient health centers in Northeast Ohio. We provide a broad range of health care services including birth control methods, cancer screenings, pregnancy testing, testing and treatment for sexually transmitted infections, HIV counseling and testing, urinary tract infection diagnosis and treatment, cervical cancer diagnosis and treatment, and HPV vaccinations to uninsured and underinsured women. PPGC serves more than 22,000 unduplicated patients each year, many of whom could not otherwise afford the health services—particularly oral contraceptives—that we provide. We gave served the community for more than 78 years.

Nominal drug pricing is essential to our ability to serve women in the Greater Cleveland community. Consider:

- Ohio currently ranks 48th in the states for access to birth control, and the loss of safety net providers like Planned Parenthood would be devastating to the community.
- The vast majority of our clients are poor women. We make every attempt to accommodate patients who are not covered by insurance by offering a sliding fee scale. This chart illustrates the poverty status of our clients.

As a major provider of family planning services, losing the ability to purchase drugs at a discount will put a severe burden on the agency and our ability to survive, as well as on our clients, and ultimately will result in more unplanned pregnancies and untreated sexually transmitted diseases, thereby increasing medical costs for the state of Ohio and the nation.

Respectfully submitted by,

Teri Miller, M.S.N., C.N.P
Vice President of Health Services and Operations
Planned Parenthood of Greater Cleveland

Submitter : Kent Zellner **Date:** 02/16/2007

Organization : Zellner Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Marvin Cook Jr. **Date:** 02/16/2007

Organization : Scott-Cook Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

[February 16, 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 preseriptions 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,

[Marvin Cook, Jr. RPH]

Submitter : Mrs. LINDA BEARDEN **Date:** 02/16/2007

Organization : MURRAYVILLE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

IF THE GOVERNMENT USES AMP, THEN THE DRUG COMPANIES SHOULD SALE THEIR PRODUCTS TO ALL PHARMACIES AT THE SAME PRICE. AS IT STANDS NOW, WE CANNOT BUY THE MEDICATIONS AT THE SAME DISCOUNTED RATE THAT THE MAIL ORDER PHARMACIES DO.

Submitter : Mr. Joseph Maslak **Date:** 02/16/2007

Organization : Associated Wholesale Grocers / Valu Merchandisers

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-752-Attach-1.DOC

Valu Merchandisers Company

General Merchandise Health & Beauty Specialty Foods

624 WESTPORT RD KANSAS CITY, MISSOURI 64111

February 16, 2007

Via Electronic Mail

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

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

Dear Administrator Norwalk:
Associated Wholesale Grocers appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). We are very concerned about the projected impact of the proposed rule on our supermarket pharmacies.

Associated Wholesale Grocers (AWG) is a retailer owned grocery wholesale cooperative servicing over 1,900 independent grocery stores throughout 21 states. In addition to supplying grocery products, we also distribute health and beauty care, general merchandise and specialty foods through our wholly owned subsidiary, Valu Merchandisers Company. Our retailers own and operate grocery stores throughout a wide diversity of communities, providing needed products and services as well as jobs, tax revenue, and support of local charities. In addition, our retailers operate nearly 300 pharmacies throughout eight states.

AWG is a member of the Food Marketing Institute (FMI), and fully supports the comments filed by FMI and incorporates FMI's comments herein. In addition, we specifically wish to call your attention to the following issues.

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

In this regard, we urge CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Supermarket pharmacy profit margins are in the range of approximately 2 to 3 percent of total revenues. Recent studies suggest that the Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.[1] In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our company will find it increasingly difficult to serve Medicaid

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

patients. This situation is exacerbated by dispensing fee amounts in the states in which we operate that are far below the costs we incur to dispense prescription drugs to Medicaid patients.

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

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

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

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

We appreciate the opportunity to provide you with our concerns and respectfully request that you address them on the record. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to contact me at (816) 360-8350 or by email at jmaslak@awginc.com

Sincerely,

Joseph Maslak
Executive Director, Pharmacy
Valu Merchandisers Company
624 Westport Rd.
Kansas City, MO 64111

Submitter : Vi Do **Date:** 02/16/2007

Organization : NCAP

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-753-Attach-1.DOC

March 12, 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 Durham, 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,

Vi Do

cc. Members of Congress (David Price, Richard Burr, Elizabeth Dole)

Submitter : Jerry Eledge **Date:** 02/16/2007

Organization : LaVergne Drug Store

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am the owner of an independent pharmacy.

Collection of Information Requirements

Collection of Information Requirements

The switch of medicaid pharmacy reimbursement to AMP instead of the current AWP.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Don't know what to put in this field.

Response to Comments

Response to Comments

If pharmacy reimbursement is changed from AWP to AMP it will cause me to stop accepting medicaid prescriptions as I may lose up to 50% of the cost of the prescriptions. This change could cause me to close my business. The changes will permeate throughout my industry closing many small businesses.

CMS-2238-P-754-Attach-1.DOC

February 16, 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,

Jerry P. Eledge
LaVergne Drug Store

Submitter : **Ms. Jennifer Morris** **Date: 02/16/2007**

Organization : **Manning Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

This is regarding the use of AMP pricing for the reimbursement for drugs.

Collection of Information Requirements

Collection of Information Requirements

The provision of the proposed regulations would use manufacturer price as the basis of cost for pricing in community pharmacy practice. Currently we do not have the information we do not have the information regarding what those costs would be. AWP (Average Wholesale Price) is the published price used by all wholesalers, PBMS and pharmacies. Currently a percentage is taken off of the wholesale price when the final retail price of a prescription is figured.

GENERAL

GENERAL

With AMP structure as it is currently proposed, the average pharmacy would be left struggling to find revenue streams to replace the 8-15% margin that would be below the level at which we currently purchase at. In short, we would be reimbursed by Medicare Part D at least 10% below what we can even buy any product for. If AMP is going to be the standard, then substantial increases need to be incorporated into the reimbursement structure to accomodate these shortfalls. This proposed structure also has shortfalls in that constant cost increases by the manufacturer are not addressed in a timely manner.

Regulatory Impact Analysis

Regulatory Impact Analysis

The actual implemention of the AMP Regulation could creat 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 underd the proposed structure. In order to address these concerns, we propose a "trigger mechanism" whereby serve price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

Submitter : **Mrs. Sophia De Monte** **Date: 02/16/2007**

Organization : **APHA**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I urge you to reconsider the new reimbursement criteria for prescriptions under the Medicaid program.

The practice of pharmacy is a service. Providing the product is but 1 step in a process. How does one cure an illness? Is it by trust and faith that the cure will work or is it by the dollar sign?

The bottom line is: You get what you pay for.

How can our nation be a world leader, when our healthcare system is so out of control. Our people need to be educated about prevention, disease management and proper use of medications. What do you call it when you financially strangle the profession that has been the most accessible to the people?
There are better options to rein in healthcare costs.

Thank you,
Sophia De Monte

Submitter : Mr. J. Michael Morton **Date:** 02/16/2007

Organization : Vanceboro Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-757-Attach-1.TXT

February 18, 2007

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

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

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

If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disasterous to my Medicaid patients, which represent approximately 61% of my business.

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,

J. Michael Morton
Vanceboro Pharmacy
421 Farm Life Avenue
P. O. Box 218
Vanceboro, NC 28586

(252) 244-1086

cc. Rep. Walter B. Jones, Jr.
Sen. Elizabeth Dole
Sen. Richard Burr

Submitter : **Dr. Rick Sain** **Date: 02/16/2007**

Organization : **Reeves Sain Drug Store**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I know that The Deficit Reduction Act of 2005has required some changes to Medicaid reimbursemet.

GENERAL

GENERAL

I want to comment on the definition of AMP. As a pharmacy owner, and as President of the Tennessee Pharmacist Association, I am truly concerned that the pharmacy reimbursement for generics under Medicaid will be less than our acquisition costs on a very large numbers of drugs. I know there is need for change, and I do not mind change, but it seems to keep coming on the backs of the pharmacies. We need to really study this to be sure that it is done in a more fair manner. I understand that a GAO study has been done, and I hope this will be taken into consideration. The pharmacists' time and many costs associated with filling a prescription are tied to the mark up on a prescription. If we are not going to be paid for counseling, delivering, etc. then we have to be paid on what it costs to fill a prescription, and this has been shown to average around $ 10.50 per Rx. Again, I hope this will be taken into consideration. I am not for the current definition as it stands on AMP. Thank you.

Submitter : **Dr. Elliott Sogol** **Date: 02/16/2007**

Organization : **Dr. Elliott Sogol**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located in Durham, North 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) 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 and the American Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Elliott M. Sogol, PhD, R.Ph

cc. Members of Congress (Price, Dole)

Submitter : **Mr. John Bahlman** **Date: 02/16/2007**

Organization : **Pharmacy Plus**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 18, 2007

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

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

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

If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disasterous to my Medicaid patients, which represent approximately 42% of my business.

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

Sincerely,

John H. Bahlman, Jr.
Pharmacy Plus, Inc.
2029 Boulevard
Colonial Heights, VA 23834
(804) 520-2400

cc. Sen. John W. Warner
Sen. James Webb
Rep. Randy Forbes

Submitter : **Mr. Richard Savner** **Date: 02/16/2007**

Organization : **Pathmark Stores, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-761-Attach-1.DOC

February 20, 2007

Via Electronic Mail

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

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

Dear Administrator Norwalk:

Pathmark Stores, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). As discussed more fully below, we are very concerned about the impact of the proposed rule on our supermarket pharmacies.

By way of background, Pathmark operates 141 stores in the New York-New Jersey and Philadelphia metropolitan areas and achieve $4 billion dollars in annual revenue, 10% of which is derived from our 129 pharmacies. One of our more noteworthy attributes is our commitment to operating stores in lower income, urban neighborhoods. Not surprising is the fact that many of our customers, and in particular pharmacy patrons, are Medicaid beneficiaries. Quite often, Pathmark is one of the few retail outlets available for these residents to fill their prescription needs. We are proud of our long-standing commitment to serving the needs of people in low-income communities.

Pathmark is also a member of the Food Marketing Institute (FMI), and fully supports the comments filed by FMI and incorporates FMI's comments herein. In addition, we specifically wish to call your attention to the following issues.

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

In this regard, we urge CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Supermarket pharmacy profit margins are in the range of approximately 2 to 3 percent of total revenues. Recent studies suggest that the Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.[1] In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our company will find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts in the states in which we operate that are far below the costs we incur to dispense prescription drugs to Medicaid patients.

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

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

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

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

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

We appreciate the opportunity to provide you with our concerns and respectfully request that you address them on the record. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to contact me at 732-499-3000, X-3105 or email RSAVNER@PATHMARK.COM.

Sincerely,
Richard Savner
Director of Public Affairs
Pathmark Stores, Inc.
200 Milik St.
Carteret, NJ 07008

Submitter : **Date: 02/16/2007**

Organization :

Category : **Critical Access Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-762-Attach-1.DOC

Baystate Medical Center

Submitted Electronically: http://wwww.cms.hhs.gov/eRulemaking.

February 16, 2007

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

Re: File Code CMS-2238-P
Deficit Reduction Act/prescription drugs
71 Fed. Reg. 77174, 77188 (Dec. 22, 2006)

To Whom It May Concern:

On behalf of Baystate Medical Center (Baystate), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005, published in the Federal Register on December 22, 2006 (*71 Fed. Reg. 77174, 77188*). Baystate is a six hundred fifty three (653) bed hospital located in Springfield, MA and is a disproportionate share hospital (DSH) under the Medicare program. As a DSH hospital we have utilized the 340B program to assist us in our mission to improve the health of the people in our communities. We fear that if these proposed revisions to the 340B rules are adopted it will hinder our ability to utilize the 340B program in fulfilling our mission.

The most significant issue with the proposed revision is that it appears to violate federal law; hospital clinic administered drugs are exempt from rebate requirements under the Medicaid statute. However, the explicit purpose of the NDC collection rule for "physician administered drugs" is to facilitate rebate collections by the States. CMS needs to review these proposed revisions in light of the pre-existing statutory exemption from rebates and explicitly exempt hospital outpatient clinic drugs from the new NDC collection rule. We are confident that CMS will realize that there no reason for states to collect NDC information on drugs the states are explicitly exempted from collecting rebates on in the first place.

Assuming that these proposed rules are not found to be inconsistent with federal law, additional issues need further examination and clarification by CMS.

In section 447.520 of the proposed rule (*FFP: Conditions relating to Physician Administered Drugs, 71 fed. Reg., 77188*), CMS states that the impact on hospitals will be "small" or "insignificant." This is absolutely not the case for Baystate's billing system as it is not configured to have the capacity to substitute NDC numbers as identifiers for clinic administered drugs (as distinguished from the HCPCS codes known as "J-codes" that are currently used for Medicaid billing purposes). For Baystate to be able to perform this feat it will be necessary to revamp our billing system - - no small task given that this will involve the acquisition or development of an entirely new billing system. This new system will be

expensive, not only in terms of acquiring the system, but also in logistical terms such as employee training and system troubleshooting issues experienced with any new application. CMS suggests that as an alternative to an electronic billing system, covered entities could manually enter these codes in only 15 seconds per claim, a claim that is unsupported and quite at odds with our knowledge of administering outpatient drugs. A sizeable portion of our outpatient drugs are administered to our patients in a tailored method best described as a "cocktail." These cocktails are compounds of multiple drugs, and therefore each drug's NDC number must be identified. There is simply no possible way a person could manually identify the NDC number for each compound in a multi-drug cocktail for each visit in 15 seconds or less.

With respect to calculations of Average Manufacturer Price (AMP), the proposed rule relating to the treatment of prompt pay discounts will likely increase the prices Baystate pays for our outpatient drugs by adversely affecting the formula for calculating 340B prices. It is our experience that the greatest difficulty in AMP assessment is the lack of transparency in the system, something which the General Accounting Office (GAO) reported just several days ago (*PRESCRIPTION DRUGS Oversight of Drug Pricing in Federal Programs*, GAO-07-481T, Feb. 9, 2007). While we agree that AMP calculation should be solidified, we feel a more transparent method should be developed.

Ultimately, we fear that if the 340B program is revised as proposed the burdens will increase while the benefits will be removed, and we will be forced to reassess our participation in the program. Should the Commonwealth of Massachusetts ever wish to impose rebate obligations on these 340B outpatient drugs it would short-change our operating budget by seriously reducing our drug discounts. These revisions would seriously jeopardize a program that has accounted for nearly $5.25 million in annual savings for our hospital.

Thank you for listening to our concerns. We trust that you will review and revise these proposed regulations in light of the issues and concerns we have raised.

Sincerely,

Gary Kerr, M.B.A., Pharm.D.
Director of Pharmacy Services
Baystate Medical Center
759 Chestnut Street
Springfield, MA 01119

Submitter : Mr. C. Stroud Tilley **Date:** 02/16/2007

Organization : Pharmacy Plus of New Bern, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 18, 2007

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

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

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

If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disasterous to my Medicaid patients, which represent approximately 39% of my business.

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

Sincerely,

C. Stroud Tilley, III
Pharmacy Plus of New Bern, Inc.
1204 S. Glenburnie Road
New Bern, NC 28562
(252) 636-3322

cc. Sen. Elizabeth Dole
Sen. Richard Burr
Rep. G.K. Butterfield

Submitter : Mr. David Godbee **Date:** 02/16/2007

Organization : ADDISON DISCOUNT PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-764-Attach-1.WPD

CMS-2238-P-764-Attach-2.WPD

CMS-2238-P-764-Attach-3.WPD

CMS-2238-P-764-Attach-4.PDF

CMS-2238-P-764-Attach-5.PDF

CMS-2238-P-764-Attach-6.PDF

764-6

2/16/07

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,

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,

David Godbee
Addison discount pharmacy

Submitter : **Mr. J. Michael Morton** **Date: 02/16/2007**

Organization : **H&H Drug Company**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 18, 2007

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

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

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

If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disasterous to my Medicaid patients, which represent approximately 69% of my business.

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

Sincerely,

J. Michael Morton
H&H Drug Company
512 Queen Street
PO Box 309
Grifton, NC 28530
(252) 524-4101

cc. Sen. Elizabeth Dole
Sen. Richard Burr
Rep. G.K. Butterfield
Rep. Walter B. Jones, Jr.

Submitter : Mr. RAY ROBERTSON **Date:** 02/16/2007

Organization : PROFESSIONAL PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

WE WILL NOT BE ABLE TO SERVICE MEDICAID RECIPIENTS UNDER THE SCENARIO THAT YOU ESTABLISH AN EXTREMELY LOW (BELOW OUR ACQUISITION COST) AMP WITHOUT ESTABLISHING A MINIMUM DISPENSING FEE.
SEE ATTACHMENT

CMS-2238-P-766-Attach-1.DOC

[date]

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,

[Name]

Submitter : Mr. Ron Fitzwater **Date:** 02/16/2007

Organization : Missouri Pharmacy Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-767-Attach-1.PDF

MPA
Missouri Pharmacy Association
211 E. Capitol Ave. • Jefferson City, MO 65101 • 573-636-7522 • Fax 573-636-7485 • www.morx.com

February 16, 2007

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

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

The Missouri Pharmacy Association (MPA) is 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.

Summary

MPA continues to support federal efforts that are designed to positively affect the affordability of and access to prescription drugs and health care professionals. While we are supportive of these efforts, we are compelled to offer the following comments on CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP, as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. Specifically, we will comment on two sections of the proposed regulation – §447.504 and §447.510.

§447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (1) the proposed definition of the retail pharmacy class of trade; (2) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (3) the treatment of discounts, rebates and price concessions.

§447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record-keeping requirements. The methodology employed in §447.510 creates five areas of concern: (1) there is a potential for market manipulation inherent in the reporting process; (2) the ability or inability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (3) the reporting system itself creates an artificial price lag in the reimbursement basis; (4) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (5) the suggested time for record retention is overly burdensome.

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

§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (1) the proposed definition of the retail pharmacy class of trade; (2) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (3) the treatment of discounts, rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

Mail order pharmacy and PBM sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006, report entitled *"Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,"* the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not met by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption

that mail order pharmacies' and PBMs' discounts, rebates and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs. In Missouri, Medicaid recipients obtain their medications from their community retail pharmacy. Most states bill for and receive rebates or other price concessions directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies, we address the unique contractual arrangements in detail later in these comments.

MPA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public." In order to do so, PBMs would need to be licensed as pharmacies under the applicable state's laws. MPA is unaware of any state that licenses PBMs as pharmacies to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all PBMs.

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

As with the nursing home pharmacies, mail order pharmacies that operate as a closed door operation should not be included in the retail class of trade. As such, we believe section 447.504(e) should be amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade.

Excluding mail order and PBM pharmacies from the definition of the retail trade of pharmacy would offer numerous benefits to pricing data and regulatory oversight, including reduced recordkeeping requirements, reduced risk of price fluctuations and limiting the need for additional regulatory burdens. Since there would be fewer transactions, fewer records would need to be maintained by manufacturers and reported to CMS, thus reducing the reporting requirements of manufacturers. Since mail order pharmacies are most likely to participate in discounts, rebates and other forms of price concessions, the nature of these complex contractual arrangements are more likely to lead to misstatements and errors in accounting and the need for re-statement of pricing information – particularly between quarters – creating pricing volatility and fluctuations in AMP values. Excluding mail order and PBM pharmacies from AMP calculations thus assists in providing greater certainty and reliability in pricing data. Vertical integration between manufacturers and mail order pharmacies creates transactions that are not arms-length and thus afford opportunities for market manipulation. In the future, CMS would

likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

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

Inclusion of Medicaid Sales

It is our belief that 447.504(g)(12) should exclude Medicaid from AMP Data. Unlike Medicare Part D and non-Medicaid SCHIP, which have private party negotiators on formularies and reimbursement rates, Medicaid reimbursement structures vary state-to-state, with some having non-market-based reimbursement rates. Moreover, the inclusions of Medicaid data more likely than not would create a circular loop negating the validity of AMP. Given the above statements it is clear that counting Medicaid would have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs and also be excluded from AMP in the proposed regulation.

Discounts, Rebates and Price Concessions

MPA contends that certain discounts, rebates and price concessions found in §447.504(g)(6) and (9) should not be included in the AMP calculation. Price concessions provided by drug companies to PBM and mail order pharmacies in the form of rebates, charge-backs or other contractual arrangements by their very relationship are not available to out-of-pocket customers or third party private sector parties. The proposed regulation concedes that the benefits of these rebates, price concessions, charge-backs and other contractual arrangements may not be – and MPA asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers and third party payors, and, thus, they are not available to the "general public." Since PBM and mail order pharmacies (1) now often are vertically integrated with manufacturers and others in the supply chain, (2) have contractual arrangements in many states that are not transparent in the health care system and (3) have purchasing power and drug substitution/ distribution control greater than the other entities included in the retail class of trade, they are clearly distinguishable from the community retail pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to reconsider the inclusion of mail order pharmacy rebates, charge-backs and other price concessions.
AMP should reflect the prices paid by retail pharmacies; however, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions manufacturers

should deduct from the calculation of the AMP. While discounts, rebates, charge-backs and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies – but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP.

On balance, we are concerned that including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions.

Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to health care in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers

This section of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record-keeping requirements. The methodology employed to set forth the above tasks creates five areas of concern: (1) there is a potential for market manipulation inherent in the reporting process; (2) the ability or inability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (3) the reporting system itself presents an artificial price lag in the reimbursement basis; (4) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (5) the suggested time for record retention is overly burdensome. The following comments address each of these areas of concern.

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[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[2] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer chooses to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period."[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three years from the quarter in which the data was due.

As the entities engaged in the profession of pharmacy become more vertically integrated, the potential for misuse of this dual reporting mechanism increases. Potentially, a manufacturer with a vertically integrated market position could use the 'rebate period' based reporting to manipulate AMP. Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual timeframe reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP. Furthermore, this ability would exist for a period of three years – the allowable time for revisions. This undue flexibility, afforded to find a market price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

'Claw-back'

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

Pricing Lag

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

[3] §447.510(d)(2)

Severe Price Shifts

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

In its simplest form, the trigger mechanism could accomplish the following: (1) limit the affects of price posting lag; (2) mitigate potential market manipulation; (3) mitigate a possible disincentive to fill generics by the retail pharmacies; (4) limit incorrect public data; and (5) provide CMS with the most up-to-date calculation of AMP.

The ability to adjust the posted AMP between reporting periods will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address and mitigate the issues surrounding pricing lag.

The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the OIG will act as a damper to market manipulation. The longstanding intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate, there is a market disincentive to increase the drug's utilization. The trigger mechanism's ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real-time posting of the generic's AMP. Clearly, the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have the most up-to-date AMP data.

Record Keeping

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

Additional Comments

Use of the 11-Digit NDC Rather Than the 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit NDC should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there also is no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-digit level for generic drugs in determining FULs.

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

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

Sincerely,

Ron L. Fitzwater, CAE
Chief Executive Officer

cc Senator Christopher S. "Kit" Bond
Congressman William "Lacy" Clay, Jr.
Congressman Russ Carnahan
Congressman Emanuel Cleaver
Congressman Roy Blunt
Congressman Kenny Hulshof
Senator Claire McCaskill
Congressman Todd Akin
Congressman Ike Skelton
Congressman Sam Graves
Congresswoman Jo Ann Emerson

Submitter : Mr. Mark Pawlowski **Date:** 02/16/2007

Organization : Planned Parenthood of South Central Michigan

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-768-Attach-1.RTF

Submitter : **Date: 02/16/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a pharmacist by profession. I want to comment on the Formula for AMP.

GENERAL

GENERAL

1).The formula for AMP based Federal Upper Limits (FULS) in the proposed rule will not cover community pharmacy acquisition costs for multiple source generic medications.
2).AMP was never intended to serve as a basis for reimbursement.
3).To be an appropriate benchmark,AMP must be defined to reflect the actual cost paid by retail pharmacy.This will be accomplished by:
a) Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
b) Excluding all mail order facilities and PBM pricing from AMP calculations. Mail order facilities and PBM are extended special prices from manufacturers and are not publicly accessible in the way that brick & mortar pharmacies are publicly accessible.
c). Reporting AMP at 11 digit NDC level to ensure accuracy.

This rule can really impact pharmacist owned community pharmacy. If this rule is implemented the way it is now can force small pharmacy out of buisness and can also effect the service provided by small pharmacies to community on whom people rely on advise for the medications.Closing of pharmacies can also hurt local economy and employment also.
I sincerly hope that this should be counted in decision before implementing and I also hope this rule also dosenot intend to hurt small community pharmacy.

Submitter : Dr. Dusty Pruett **Date:** 02/16/2007

Organization : APCI

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to express my concerns with the proposed rule changes to pharmacist reimbursement. I feel that the proposed changes fail to recognize the impact that pharmacists have on patients. If we are not properly paid for our services we will no longer be able to provide these services to Medicaid customers. Please reconsider the proposed changes and the impact they will have on the community.

Submitter : Mr. Charles Campbell **Date:** 02/16/2007

Organization : LaBrenz Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a regestered pharmacist/pharmacy owner in the state of Michigan. I have been practicing in Michigan for 19 years.

GENERAL

GENERAL

2 points:
1. It is unfair to include mail-order pharmacy in determining AMP. Mail Order Pharmacies pay less for the cost of the drug from the manufacturer than retail pharmacies do. They also receive additional rebates from manufacturers that retail pharmacies do not.
2. In addition to providing a product, retail pharmacies also provide a service. Pharmacies should be appropriately re-imbursed for this service. Michigan is thinking of taxing this service!!

Response to Comments

Response to Comments

If AMP falls below our aquistion cost, we may be forced to stop accepting medicaid. This will deny access to care for our most vulnerable citizens.

Submitter : **Mr. Harold Harmon** **Date: 02/16/2007**

Organization : **H & M Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 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,

John Harold Harmon

Submitter : **Dr. Christy Bolt** **Date: 02/16/2007**

Organization : **H & M Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 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

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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.

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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,

Christy Bolt

Submitter : **Dr. Ashley Johnson** **Date: 02/16/2007**

Organization : **H & M Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 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

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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,

Ashley Johnson

Submitter : **Mr. sharad gandhi** **Date: 02/16/2007**

Organization : **auburn pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Propose regulation cms-2238-p for rx drugs should not be supported.
this change will force small independent pharmacies like mine to colse down.I am located in predominanty medicaid patient area and I will not even be able to buy medications at the rate cms is proposing to reimburse back to me.this will force me to close this pharmacy and this will deprive poor people of badly needed medications.I have been serving these poor people since 20 years.They depend on me to take care of their family rx needs.Please vote against this proposition and help poor people of your constituency.
Thank you,
Sharad Gandhi Rph

Submitter : **Mr. Robert Roppel** **Date: 02/16/2007**

Organization : **Prescription Shoppe**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs, I am pharmacy owner located in Crookston,MN. We are a major supplier of pharmacy services in our rural community. The CMS's proposal to reduce reimbursement rates to AMP will have a devastating effect on our business (and our patients). The AMP as used by CMS has to ignore sales to PBMs and Mail Order. Manufactures sell drugs to them at a rate no retail pharmacy can buy them for. The AMP has to ignore rebates and concessions that drug companies give to PBMs and Mail Order pharmacies----I don't get them!!! When CMS sets the AMP they can't use Medicaid data since those sales are regulated by the government and the inclusion of Medicaid data would create a circular loop negating the validity of AMP. The AMP should also be updated weekly because manufactures raise prices consistantly and pharmacies could get caught in the lag time.

Sincerely,

Robert. D Roppel R.Ph.
211 N Main
Crookston, MN
56716

Submitter : **Mr. David O'Brien** **Date: 02/16/2007**

Organization : **Cordova Drug Co., Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Cordova Drug Co., Inc.
Box 220
516 First Street
Cordova, Alaska 99574
(907) 424-3246 Fax (907) 424-3245
email cordovadrug@ctcak.net
February 16, 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 Cordova, Alaska. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

Sincerely, David A. O Brien RPh, Owner

Submitter : **Mr. Richard Dreiling** **Date: 02/16/2007**

Organization : **Duane Reade**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-778-Attach-1.DOC

Submitter : Mr. chris decker **Date:** 02/16/2007

Organization : pharmacy society of wisconsin

Category : Pharmacist

Issue Areas/Comments

Background

Background

comment on calculation of AMP for use in determining the federal upper limit of prescription drugs in the Medicaid program.

Collection of Information Requirements

Collection of Information Requirements

447.504 and 447.510

GENERAL

GENERAL

see attached

CMS-2238-P-779-Attach-1.PDF

Submitter : Dr. curtis rising **Date:** 02/16/2007

Organization : the medicine shoppe

Category : Drug Industry

Issue Areas/Comments

Background

Background

I am a pharmacist and come from a small town of 1000 people. I have been practicing in rapid city sd a town of 50000 people.

Collection of Information Requirements

Collection of Information Requirements

i am concerned and outraged about the future amp pricing upon drugs. I do not know where the offices that are doing the pricing of these drugs. The OAC's study showed that the price would be 36 percent below the cost of medications to my pharmacy. What is not understood is that if this goes through and is encacted then there will be very few pharmacies that will accept medicaid. My home town pharmacy closed down because of medicare part d and the cut backs that they imposed. That will be nothing compared to the fall out of the amp pricing. Not only will there be no pharmacies that will not take medicaid payments but there will be no pharmacies in any town under 10000 population. And worst of all there will be no pharmacy coverage for those who need it most ie. the medicaid population. As a pharmacist i am out raged that no one sees pharmacist as professional citizens that provide an invaluable service. I save lives every day. People ask me questions about their health all day long and i don't get paid for that now. If you expect pharmacy to cure the high cost of medications by cutting our services then you are not seeing the big picture. Why have there been no cuts to the manfacturers that charge such a high price on the medication that cost them pennies to produce. Example, zocor was 120 dollar per 30 tabs 6 months agor and now they are being produced at 60 dollars per thousand. Congress and CMS needs to attack the high cost of prescriptions at the root, the manufactures. It is not right to put the whole cost on pharmacy. If things aren't done right what will happen is that there will be no pharmacy that will take medication insurance of anykind and then where the nation be.

curtis rising

Response to Comments

Response to Comments

Pharmacies have been the target of many regulations and cutbacks in the drug industry.

Submitter : Mrs. Catina Griffith **Date:** 02/16/2007

Organization : Professional Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

If cms cannot set an AMP cost basis that covers actual drug costs or legistates a fee that results in a profit, then it becomes impossible for an independent pharmacy to fill these prescriptions.

CMS-2238-P-781-Attach-1.DOC

Submitter : Mr. Les Gwyn-Williams **Date:** 02/16/2007

Organization : Terry's Family Pharmacy,inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-782-Attach-1.DOC

Submitter : **Mr. Mel Rauton** **Date: 02/16/2007**

Organization : **Prescription Center, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 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 and owner of Prescription Center, Inc. in Charleston, Sc. 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 the South Carolina Pharmacy 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 and would result in FULs that are lower than a retail pharmacy s acquisition cost.

3. Removal of Medicaid Data

Including these data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. The inclusion of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

4. Manufacturer Data Reporting for Price Determination Address Market Lag

The risk of price fluctuations due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns, the South Carolina Pharmacy Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the Association comments on the lack of clarity on claw back from manufacturer reporting error.

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. 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 submitted 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,

Mel Rauton, Jr., R.Ph.
Owner
Prescription Center, Inc.

107 Rutledge Avenue
Charleston, SC 29401

Submitter : **Ms. Walter Hughes** **Date: 02/16/2007**

Organization : **Sadler-Hughes Apothecary**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This is absurd. It is obvious the field is skewed against independent pharmacy.If you are to proceed with AMP, you need to have different AMPs for different classes of trade.

Submitter : **Ms. Honor Montgomery** **Date: 02/16/2007**

Organization : **VPhA/CVS Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. (My pharmacy is CVS located in Richmond, VA. 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 Virginia Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Ms. Honor Montgomery

cc. Members of Congress (individualize)

Submitter : Mr. Larry Rodick **Date:** 02/16/2007

Organization : Planned Parenthood of Alabama, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-786-Attach-1.DOC

Submitter : **Ms. Tammy Hartsell** **Date: 02/16/2007**

Organization : **Remedy Shoppe Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As a small independent pharmacy, I serve a very diverse community. I serve those with insurance, those without insurance, medicare and medicaid patients==all the same. I already serve patients with medications that cost me more to buy than I get reimbursed. That is before paying for staff, or overhead. I do this because I am my brothers keeper and responsible to do my part for the greater good. I cannot however serve my patients for the percentage that are medicaid and survive. Nothing is less expensive today, employees, taxes, vials, phone power, rent are all more expensive today than last year. We small businesses serve in areas where access is not always readily accessable. As with all healthcare access is paramount for prevention, intervention, monitoring and counseling. It is only fair that pharmacies are reimbursed fairly so that access is not compromised. Independent pharmacies need to be able to continue to serve our patients, be part our commmunities, and provide access to the lifesaving medications that everyone deserves.

Submitter : **Dr. Richard Bowie** **Date: 02/16/2007**

Organization : **Bowie's Discount Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I own and operate a small rural pharmacy in Alabama. I have been in business for 30 years and had planned to sell the store in a few years and retire. If AMP goes into effect, I will stop taking medicaid (25% of my business) and most likely close within a year.

Collection of Information Requirements

Collection of Information Requirements

Associated Pharmacies, inc. sent to you a very good detailed item by item adressing of each of the proposed regulations and I agree with each of their points. Since you will not tell us what the price is that we will be paid which is of itself proof that something is very wrong, and I must aasume that the GAO's report that I will loose 36% on each prescription is correct.

The AMP regulation is legally wrong becuase in Alabam (and most other state) I can not legally sell a presciption [or anything else] below cost. It is morally wrong because it will hurt so many innocent people. I have a customer (call her E.C.), she is a real customer and would make a good testimony before congress. She is 88 years old and live by herself. She has no one to help her except a niece that checks in on her several times a week. She depends heavily on me for advice and help with her medicine. When she brought in all of her Medicare Part D 'stuff', she was nearly in tears and did not know what to do. I help her understand her medicine and watch to see that see is taking it right.

If I stop taking medicaid, she will have to pay someone to take her more than 10 miles to a chain drug store and I fear to think what will happen to her without me to help her. She is only one of many that I serve that will pay dearly for this government mistake.

Please do not implement AMP. Pharmacy as you and I know it will not survive.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Richard Bowie
Bowie's Discount Pharmacy
5100 Curry Highway, suite 150
Jasper, Alabama 35503
205-221-4090
fax- 205-295-1521

Submitter : Dr. BRIAN HANEY **Date:** 02/16/2007

Organization : FAMILY PHARMACY SOUTHEAST TEXAS

Category : Pharmacist

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-789-Attach-1.DOC

Submitter : **Date: 02/16/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

This is in regards to the proposed cuts in Medicaid Reimbursement. As the latest findings show, the average cost to dispense any prescription is approximately $10.00. This is in addition to the actual cost of the medication. Obviously, for a pharmacy to stay in business, the pharmacy must receive payment to cover the cost of the medication, the $10 dispensing fee PLUS a profit. This is how any business is run. You cannot sell products at less than you pay for them. The AMP will result in pharmacists being paid about 36% less than it costs to aquire the drug, not counting the dispensing fee or an actual profit. You will cause pharmacies to go out of business if they choose to accept AMP. You will also cause many patients to lose out on their first line of health care (their pharmacist) if these pharmacies close, or simply choose not to do business with medicaid/medicare to remain open for their other patients. Health care costs are astronomical. This, however, is NOT the way to cut costs.

Submitter : **Mr. Gary Hamm** **Date: 02/16/2007**

Organization : **ApotheCARE Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Reimbursement to retail pharmacies based on AMP is totally unfair and undermines the present pricing system established by the government and insurance companies. This is the system ALL retail pharmacies used when evaulating and accepting contracts. Changing one component (AWP or MAC TO AMP) without considering the Fee component (left up to the states to decide and no guarantee it will be adjusted) will decrease pharmacy reimbursements with no recourse. It amounts to changing rules midstream. Unless the federal government can guarantee a fee increase there is no way retail pharmacies can cover their expenses, many of them such as HIPPA are non-funded mandates, and be able to stay in business. Futhermore it is my understanding that the present formula to calculate AMP will actually reflect prices up to 50% below what retail pharmacies actually pay for generic drugs. Also it will take away the incentive for pharmacist's to spend the extra time it takes to do formulary management to change medications to therapeutically equivalent generics, which may lead to less total savings to the government. In conclusion, I support the more extensive comments that are being filed by Kentucky Pharmacist Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Gary Hamm RPh.
270-739-0303

cc. Members of Congress

Submitter : Mr. Anthony Apa **Date:** 02/16/2007

Organization : University of Tennessee

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-792-Attach-1.DOC

Submitter : **Mr. kam shah** **Date: 02/16/2007**

Organization : **sapstein pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Implementation of "AMP" in pharmacy is a sure way to erase independent pharmacy as we knew it.

AMP would be valid for determining transactions between a manufacturer & his next step down the trade chain(e.g.a drug wholesaler) but using it to compute what a community pharmacist is dispensing to his patients!

This sort of "community experiment" with health of American citizens is totally uncalled for since it will be irreversibly wipe-out a delicate network of "little apothecaries" throughout this beautiful nation of ours; just because some handful of minds had a bright idea of filling nations economic gap with an "apperent what seems like a layer of creamy profit on medicines" !!

Medicines are not a merchandise ! yes a package of a prescription contains 80% of net cost of drug from manufacturer; but what about all other costs to run that train of healthcare trolly & jobbers & wholesalers & delivery cycles & stocking costs & investment related costs & residual pills left in the bottle & safeguarding american health with checks & balances & more cross-checks with MD's & other communications?

I wonder how many healthcare professionals were involved in this monumental decision to erase pharmacies?

Submitter : Dr. Douglas Garrett **Date:** 02/16/2007

Organization : Garretts Drugcenter

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

CMS is proposing an overly broad inclusive definition of "retail class of trade" for use in determining the AMP (Average Manufactruers price) used in calculating the FULs (federal upper limit) of the generic drug program. The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies can purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBMs and mail order pharmacies from the AMP determination recongnizes that these are not community pharmacies, where the vast majority of Medicaid clients have prescriptions dispensed. Mail order pharmacies do not meet the "open to the public" distinction, as they require unique contractual relationships for service to be provided to patients. PBMs do not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Both these types of organizations do not dispense to the "general public" and, therefore, should be excluded from the information used in the calculation of the AMP to be used for determining an FUL.

Retail pharmacies like mine do not have the rebates and concessions paid by manufacturers to them like mail order and PBMs. These rebates and concessions must be excluded from the calculation of the AMP used to determine the FULs.

AMP data is not currently publicly available so that retail pharmacies can actually determine what the relationship will be between the proposed AMP-based FULs and the prices retail pharmacies pay to acquire the drugs but the GAO conducted an analysis of this relationship using the highest expenditure and the highest use drugs for Medicaid in the analysis. They reported that retail pharmacies will be reimbursed, on the average, of 36% less than their costs to purchase the drugs. If this is true, I will drop Tenncare immediately in both my stores that serve two different rural areas.

Medicaid data should not be used to caculate AMP it is already regulated by federal and state governments.

Use the 11 digit NDC versus the 9 digit NDC. Retail drugstores, including chains do not buy in 40,000, 25,000, 10,000, or even 5,000 package sizes like the PBMs and Mail Order do, because we do not force doctors to use the drugs we want and make the most money on. Those sizes are not practical nor affordable unless one is doing that.

Thanks for your attention,
Doug Garrett

Submitter : **Dr. Deborah Bowers** **Date: 02/16/2007**

Organization : **Yorkville Pharmacy**

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. I am a pharmacy owner located in York, South Carolina. 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 the South Carolina Pharmacy 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 and would result in FULs that are lower than a retail pharmacy s acquisition cost.

3. Removal of Medicaid Data

Including these data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. The inclusion of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

4. Manufacturer Data Reporting for Price Determination Address Market Lag

The risk of price fluctuations due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns, the South Carolina Pharmacy Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the Association comments on the lack of clarity on claw back from manufacturer reporting error.

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. 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 submitted 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,

Deborah D. Bowers, PharmD, RPh
Yorkville Pharmacy
822-B E. Liberty St.
York, SC 29745
803-628-7934
yorkphar@bellsouth.net

Submitter : **Mr. Brad Houck** **Date: 02/16/2007**

Organization : **Valley Apothecary**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 16, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located Virginia. 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 Virginia Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Brad Houck, RPh
Valley Apothecary Inc
1802 Braeburn Drive
Salem, VA 24153

cc. Senator John Warner
Senator Jim Webb
Representative Bob Goodlatte

Submitter : Dr. KENNETH JOHNSON **Date:** 02/16/2007

Organization : JOHNSON DRUG COMPANY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Here you go again, squeezing juice from a dried up old cactus when there are ponds full of fresh water all around. Why not, Pharmacies are easy targets, we've done just about anything and everything for everybody for some time now for next to nothing. We haven't had to try to put a value on our professional skills for so long now that everyone takes us for granted. We aren't supposed to get paid for anything but the medication. We are like the "Scrubbing Bubbles" of the health care system. "We work hard so you don't have to" and we do it for free! We have let ourselves be devalued while becoming the most trusted profession. Every body trusts us and our advice but nobody wants to pay for it without so much red tape its not worth the effort to get paid. We're feeling the squeeze from all sides, prescribers, insurance companies, drug companies, government, and our patients, all of which keep piling on more responsibilities, expecting more than human of us, and wanting to pay less and less for it every day. Well as much as we care for our patients, like it our not, we are like any other business. We must be able to make a profit to afford to stay in business. I hate that retail pharmacists and pharmacies have to keep trying to re-invent themselves, their services, and their inventories, selling anything they can to try to make enough to stay in business. The sad thing about it is that we used to be able to afford to do things for our customers for free, go out of our way to show we cared, to go the extra mile, not because we thought we had to or that it was expected of us, but because we wanted to, it was our way of making a difference. It made us feel good being more than someone that was just there to make money off their illness, condition, or injury by filling their prescriptions. I guess we were making enough money then to take home a good paycheck and keep the store out of the red so maybe that's why many elder pharmacy statesmen talk about "the good old days" with a gleem in their eye. They loved their jobs. They had the time to spend with their customers. Quality still mattered more than quanity because the profit margin was there to put you at ease. Today volume and variety is the key. You have to fill so many scripts a day now and offer so many oddball, hairball services to make enough profit to stay in business, that the extras have become headaches. You resent the extras because now they are expected of you. This is where pride comes in. If you value your cognitive services and your professionalism and have pride in yourself its hard to keep a positive attitude when to everyone else keeps telling you what you do isn't worth what it was yesturday. You can only swallow your pride for so long before you start to choke on it and pass out. It's way past time for retail pharmacies to stop feeling gilty for valuing our own services and trying to make a profit. I don't really expect it to do much good but it's time to speak up or fade away quietly. You can only squeeze a cactus so long without getting pricked and its time we started pricking some of these squeezers when and if possible. If we don't stand up for ourselves well be squeezed dry without a fight and will be sad for us and the millions of customers and patients we serve.

Submitter : Mr. Scott Mace **Date:** 02/16/2007

Organization : Rock Hill Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

After being a community pharmacist for 14 years, I finally was able to realize my dream and open my own pharmacy. My wife and I have worked very hard to make it successful. We help people. We serve, we inform, we get people better. We are squeezed tight by low reimbursements and only lose customers to mandatory mail order. We cannot continue to do this and dispense prescriptions for less than it costs us. I don't know how anybody can be asked to do that. Independent pharmacists are a dying breed and we are trying so hard to survive. Please let us continue to serve those that need it most. I don't want to get rich, I only want to be paid a fair price for the services I provide. Thank you.

Submitter : **Mrs. Pamela Guy** **Date: 02/16/2007**

Organization : **Guy's Family Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Pamela C. Guy, R.Ph.
Guy s Family Pharmacy, Inc.
817 Randolph Street
Thomasville, NC 27360
336-476-5632
The6guys@northstate.net

February 18, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy(s) is Guy s Family Pharmacy, Inc. and is located at 817 Randolph Street, Thomasville, NC 27360. 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,

Pamela C. Guy, R.Ph.

cc. Members of Congress: Howard Coble

Submitter : **Dr. Carolyn Conlee Luckett** **Date: 02/17/2007**

Organization : **Dr. Carolyn Conlee Luckett**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attached:

February 18, 2007

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

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

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

Carolyn Conlee Luckett, Pharm.D.

Submitter : Daniel Schreiner **Date:** 02/17/2007

Organization : Deer Creek Drug

Category : Pharmacist

Issue Areas/Comments

Background

Background

CMS-2238P: Implementing the Medicaid Drug Rebate Program provisions of the Deficet REduction Act of 2005
This agency rule will redefine Average Manufactures Price (AMP) and result in a significant reduction on the Medicaid reimbursement for multiple source generic medications.

GENERAL

GENERAL

Implimentation of this rule will be devistating to thousands of independent pharmacies and may result in their discontinuation of Medicaid services. The key factors in this problem are:

The formula for AMP-based Federal Upper Limits (FULS) in the proposed rule will not cover pharmacy acquisition costs for multiple-source gneerics. (estimated to be 36% below actual cost).

Average Manufature Price (AMP) was never intended to serve as a basis for reimbursement.

To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retil pharmacy. This can be accomplished by :

1. Excluding all rebates and price concessions made by manufactures which are NOT available to retail pharmacy
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are exteneded special prices from manufacutrers and they are not publicly accessible.
3. Reporting AMP at the 11 digit NDC level to ensure accuracy.

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS's cost savings estimates ignore inceascd costs. AMP-based FULs will not cover pharmacy acquisition costs for multiple soureced generic medicaitons. The GAO found that the AMP-Ful costs were 36% lower than average retail pharmacy acquisition costs for the first quarter of 2006.

This finding validates the contention of community pharmacy that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition costs.

Response to Comments

Response to Comments

Page 101 mentions there is a potential "significant impact on small, independent pharmacies". This is demonstrated by GAO findings that there would be an average 36% loss on each transaction. No business can stay in operation while experiencing such a loss. This deficit cannot be overcome by aggresive purchasing practices, rebates, generic rebates, or even adequate dispensing fees.

Recent data from 23,000 community pharmacies and 832 million prescriptions show the average cost to dispense a medication at $10.50. If these dispensing costs, in addition to drug acquisition costs are ot covered pharmacies simply cannot afford to continue participation in the Medicaid program. The proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

The Definition of "Dispensing Fee" does not reflect the true costs to the pharmcies to dispense Medicaid drugs. This definition must inclde valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling (required by law,) and other real costs such as rent, utilities and mortgage payments.

All calculations of AMP and Best Pree must be in dependently verifiable with a substantial level of transparency to ensure accurate calculatons. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for paitient care and access.

Submitter : Mr. Galen SchultZ **Date:** 02/17/2007

Organization : Mr. Galen SchultZ

Category : Pharmacist

Issue Areas/Comments

Background

Background

Pharmacist that owns Pharmacy and has seen Pharmacy policies for 30 years.

Collection of Information Requirements

Collection of Information Requirements

Such a dramactic change in Pharmacy reimburstments would cost the jobs of thousands of people across America. No business (Corporate or private) can operate with a negative gross margin.

GENERAL

GENERAL

Pharmacics need help not a kick in the belly.

Submitter : Mr. Warren Moy **Date:** 02/17/2007

Organization : Sanford Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-803-Attach-1.DOC

Submitter : Melissa McCall **Date:** 02/17/2007

Organization : Melissa McCall

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-804-Attach-1.DOC

Submitter : **Mr. Pete Crouch, R.Ph., CPP** **Date: 02/17/2007**

Organization : **Eden Drug, Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 18, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy(s) is located at 103 W. Stadium Dr. in Eden, 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,

Pete Crouch, R.Ph., CPP

cc. Members of Congress (Nelson Cole)

Submitter : Mrs. Gail Warner **Date:** 02/17/2007

Organization : Mrs. Gail Warner

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-806-Attach-1.DOC

Submitter : **Mr. David Ray** **Date: 02/17/2007**

Organization : **Brooks Eckerd Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Retail comunity pharmacist working for Brooks Eckerd Pharmacy in low income urban Kingston,ny. I'd estimate more than 50% of Rx business is Medicaid/Medicare. I'm the supervising pharmacist for this store. Our coustomer base is mainly low income people. The profitability and survival of this store is dependent on State and federal reimbursments.

Collection of Information Requirements

Collection of Information Requirements

I have no idea what the net net cost of Rx drugs is to Brooks Eckerd pharmacy. Does anyone know the net net cost of Rx drugs is to ANY outlet? I worked for an HMO several years ago, after working and owning a retail pharmacy. I was absolutely shocked at the prices the HMO paid and what I paid as an independent! Now the HMO would sign a yearly contract with a manufacture and the net price they got was at least 10 times lower than I as an independent and I assume outher retail pharmacies paid. Now that we have giant PBMs, which New York State attorney general Elliot Spitzer investigated and found widespread abuse in prices paid and the cost saving supposed to go to employers. The PBMs were pocketing the money and seemed to be the only ones benefiting. We must simlify the Rx pricing structure! Let ALL pharmacies compete on a level playing field. PBMs insist on mail order for maintance drugs, WHY? Are they afraid to let others in on there pricing structure? I can only hope that CMS really looks at what the pharmacy pays for the drugs. Lets take the curtin down and see whats really going on. I suspect many rebates(kickbacks) going on. Remember that all is negotiable. So please lets not peanalize retail pharmacy to the very real extent of extinction, which will lead to fewer choices and inevitably higher prices for the taxpayers. Thank you for considering my thoughts. Sincerly David P. Ray Supervising pharmacist Brooks Eckerd Pharmacy 485 Broadway Kingston,NY 12401 845-338-4155 fax=845-338-3365

Submitter : **Mr. Shaun Moizuk** **Date: 02/17/2007**

Organization : **Phi Delta Chi**

Category : **Academic**

Issue Areas/Comments

Background

Background

I am currently a Pharmacy student at Ohio Northern University, and also a brother in and president of the Alpha Upsilion chapter of Phi Delta Chi, a national pharmacy fraternity. Beyond this i am also a pharmacy technician and have worked in a pharmacy for over two years.

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to retail pharmacies in general. It is estimated that the reimbursement will be far below what it actually costs retail pharmacies to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what pharmacies 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 the pharmacy i am employed at. 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. Michael Flynn **Date:** 02/17/2007

Organization : Mr. Michael Flynn

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to pharmacies. It is estimated that the reimbursement will be far below what it actually costs for a pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what is actually paid 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 : **Miss. Jennifer Houp** **Date: 02/17/2007**

Organization : **PPA - Student Pharmacist**

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 Creighton University and I also work in the pharmaceutical industry.

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 Houp
Student Pharmacist

Submitter : **Mr. Kyle Melin** **Date: 02/17/2007**

Organization : **Mr. Kyle Melin**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As an Pharmacy Student and Intern, the proposed AMP definition under CMS-2238-P Prescription Drugs is of great concern to me. It 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 pharmacies 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. Curtis Clarambeau **Date:** 02/17/2007

Organization : New Richland Drug PC & Brothers Pharmacies

Category : Pharmacist

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I am a pharmacist & own 4 pharmacies in SD & MN. Two of the pharmacies are the only pharmacies in the small towns they serve. One of the pharmacies is located in a clinic that was built specifically to serve Medicaid patients in a 3 county area. Transportation is provied to the clinic so the patients that cannot drive can see their medical provider & get their prescription in one place. If this bill passes as is this store will probably close & additional money will be needed for them to then be transported to the next town to get their prescription.
New Richland Drug is also the only pharmacy in town with the next closest town about 15 miles away. New Richland Clinic, New Richland Care Center (a 62 bed nursing home), Royal Villa (a 40 appartment complex for low income elderly), Country Neighbors (a 15 bed assisted living facility), the remaining buisinesses, as well as the general population of this small town depend on us for their precription & otc medication. I wonder what the additional costs will be if our closure results in the closure of the local clinic. With the lack of accesable health care will emergency room visits increase? With the lack of health care here will state or federal funded transportation cost rise? Small town pharmacies are already closing at an alarming rate. This will, in no uncertain terms, increase the rate of closures in stores like mine.

Submitter : Mr. Timothy Kilmer **Date:** 02/17/2007

Organization : Ohio Northern University

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

I am a third year pharmacy student that can see great harm for the profession of pharmacy under the proposed CMS-2238-P Prescription Drugs. This would not allow reimbursement of the pharmacy for some medications being dispensed. The pharmacy will actually be losing money. This could force the pharmacists to deny patients their medication if the pharmacists are not reimbursed. The AMP definition needs to be changed so that the costs of the pharmacy can be reimbursed so that all patients can get the medication they need now and in the future.

Submitter : **Dr. Leighann Lucas** **Date: 02/17/2007**

Organization : **Dr. Leighann Lucas**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 17, 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 Chester, South Carolina. 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 the South Carolina Pharmacy 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 and would result in FULs that are lower than a retail pharmacy s acquisition cost.

3. Removal of Medicaid Data

Including these data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. The inclusion of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

4. Manufacturer Data Reporting for Price Determination Address Market Lag

The risk of price fluctuations due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns, the South Carolina Pharmacy Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the Association comments on the lack of clarity on claw back from manufacturer reporting error.

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. 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 submitted 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,
Leighann Lucas, Pharm D

cc. Members of Congress, John Spratt

Submitter : Mr. Jay Brown **Date:** 02/17/2007

Organization : Mr. Jay Brown

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-815-Attach-1.DOC

Submitter : Mr. kamlesh shah **Date:** 02/17/2007

Organization : chatham pharmacy inc

Category : Pharmacist

Issue Areas/Comments

Background

Background

business of dispensing medicines to community is not just the cost of manufacuring a tablet or other dosage form. It's much much more....

Collection of Information Requirements

Collection of Information Requirements

term AMP is totally out of sync with normal supply channel of medicines . The amount of time & efforts spent in changing all these pricing definitions is only going to cause business closings & patients hardships !!

GENERAL

GENERAL

WE hope all these legislature can prepare themselves to face their respective constituents regarding what this "Prescription Price " bill is going to do to their areas neighborhood retailers & prescription services & its irreversible effects.

Submitter : Dr. Presley Johnston **Date:** 02/17/2007

Organization : Med-Equip Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I have been a pharmacist for 34 years and recognize the importance of having pharmacist-provided medications available to people where they live. For 9 of those years I worked as a pharmacist in Illinois. Medicaid reimbursement was so poor in Illinois that pharmacies refused to accept medicaid prescriptions (chains and independents alike). The suggested changes by CMS to medicaid reimbursements would pay the pharmacist 36% less than the medications can be acquired for from the pharmacy wholesaler. What the pharmacist can purchase the medication for is dependent on the price set by the manufacturer and the percentage charged by the wholesale house. This is different than what the VA and other government contract healthcare facilities pay.

Collection of Information Requirements

Collection of Information Requirements

The proposed legislation will put pharmacies to the point of refusing to accept medicaid prescriptions. In Illinois, this resulted in a governmental clinic pharmacy taking all the medicaid prescriptions and having people in metropolitan Rockford, Illinois stand in long lines to get medications. Rural patients had to drive for hours to get their medications filled. Another provision that has been proposed in the legislation is to have mail-order pharmacies approved by CMS provide medicaid prescriptions. What the authors don't realize is that if all these chronic medications are filled by mail-order pharmacies and only short-term prescriptions like antibiotics are filled by local pharmacies, the local pharmacies will disappear because the chronic prescriptions that keep their doors open have been taken away.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Every time a legislative act adjusts or dictates prescription pricing the pharmacist is the one who takes the cut. Pharmacies are making less than 15% margin over what they can buy the medications for. Major cuts have not put a ceiling on the pharmaceutical manufacturer as to pricing, wholesale houses as to their percent margin, major insurance companies as to the premiums or copays they can require in their prescription plan. The pharmacists sees the same medications with equal or higher cost to them and a cut in the margin that they realize at the bottom line. Pharmacist provide valuable services to the patients they serve and know, helping the physicians (most people are seeing more than one) recognize how their patients are taking the medications and the outcome that is different from what the medical practitioner predicted. In the long run pharmacists prevent and decrease higher cost of healthcare by preventing adverse effects or increases in hospitalization and physician office visits.

Submitter : **Mr. Ryan Mercer** **Date: 02/17/2007**

Organization : **Mr. Ryan Mercer**

Category : **Academic**

Issue Areas/Comments

Background

Background

I am a second year pharmacy student at Ohio Northern University's College of Pharmacy

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to community pharmacies as a whole, but more specifically, independents. It is estimated that the reimbursement will be far below what it actually costs community pharmacies to buy the drugs. I request that CMS redefine AMP so that it reflects the actual cost pharmacies 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 brand name drugs 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.

Submitter : Dr. Michael Haithcoat **Date:** 02/17/2007

Organization : City Drug Xpress

Category : Pharmacist

Issue Areas/Comments

Background

Background

I have practiced pharmacy for 31 years in a retail community setting in Tennessee. I have worked with the Medicaid program and the patients that depend on those services on a daily basis during my years of pharmacy practice. I feel that my experience as a pharmacist and business owner give me the ability to comment on the proposed regulation regards determination of the new Medicaid Federal Upper Limit(FUL) using a regulatory definition of AMP. I thank you for this opportunity to submit my comments.

Collection of Information Requirements

Collection of Information Requirements

The calculation of AMP should be determined based on prices paid by retail pharmacies. These are the true prices of the pharmacies that the Medicaid population utilize in their communities. Rebates and other price concessions that are available to mail order pharmacies and PBMs are not given by manufacturers to community retail pharmacies. Therefore they should not be included in the calculation of AMP.

CMS claims that all stores sell products other than prescription drugs and somehow think that overall sales are approximately two times that of prescription drug sales. In the case of the pharmacy where I practice, prescription drug sales are 98 to 99% of total sales. The improper determination of FUL would be a disaster to my practice site.This notion of "other sales" should not be a factor in any decision regards FUL determination.

CMS is using an improper definition of "retail class of trade" for use in determining the AMP to be used in calculating FUL. The AMP definition should only use manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies. Mail order pharmacies are not "open to the public" as they require specific contracts to provide their services to patients. PBMs do not purchase prescription drugs from manufacturers or wholesalers and do not dispense drugs.Both of these entities should be excluded from the information used to determine AMP that will beused for FUL.

GENERAL

GENERAL

I would again thank you for the opportunity to make these comments. I also would state that I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regards this proposed regulation.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

A mechanism must be developed to address manufacturer reporting of data used in price determination. Both price changes and market manipulation due to the timing of manufacturer reporting could have detrimental effects under the proposed regulations.

I feel that CMS should use the 11 digit NDC to calculate FUL for a particular drug dosage form and strength. This would insure that the most frequently dispensed package size by retail pharmacies would be used in cost calculations.

Submitter : Mr. ED CHIN **Date:** 02/17/2007

Organization : Mr. ED CHIN

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Preseription 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 eover 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. Robert Wylie **Date:** 02/17/2007

Organization : Mr. Robert Wylie

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-821-Attach-1.DOC

Submitter : **Mr. Jeremy Sakel** **Date: 02/17/2007**

Organization : **Phi Delta Chi**

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. If the re-imbursement is not at least what I pay to buy the drug from my distributor, I will be forced to no longer honor these prescriptions. If AMP were defined so that it covered 100% of drug 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. This is ridiculous. I cannot afford to fill the prescription if only half of the initial drug cost is covered. This would not even include any shipping charges from my distributor. Also, each manufacturer defines AMP differently.

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 more.
Thank you,
Jeremy Sakel
Doctor of Pharmacy Candidate
Registered Ohio Pharmacy Intern

Submitter : Dr. Franz Neubrecht **Date:** 02/17/2007

Organization : Michigan Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

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

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

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

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

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

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

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade. Nursing home pharmacies, PBMs and mail order pharmacies receive discounts, rebates, and price concessions that are not available to the community retail pharmacies, making them a fundamentally different class of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacy for medications. Including these elements is counter to Congressional intent.

3. Removal of Medicaid Data

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

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

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

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

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

Submitter : **Mr. Blayne Young** **Date: 02/17/2007**

Organization : **Ohio Northern University Raabe 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 future in pharmacy. It is estimated that the reimbursement will be far below what it actually costs pharmacies to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what pharmacies 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.

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Thanks... Blayne Young

Submitter : Dr. David Moll **Date:** 02/17/2007

Organization : Gresham Professional Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

This law was put into place to lower costs to the government for prescription drugs for Medicaid patients.

Collection of Information Requirements

Collection of Information Requirements

The provisions of these regulations propose to lower pharmacy reimbursements significantly so that ultimately, pharmacies may CLOSE as a result of these cuts. Thus, many Medicaid patients would be denied access to their medications and end up in hospital emergency rooms, costing the government considerably more than they save in denying adequate reimbursement to pharmacies.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Thc GAO has estimated that pharmacies will lose 36% on the average prescription reimbursement with the current formula and method of calculating it. How can they expect to SAVE money when they are not allowing pharmacies to service our patients? We are not making the money like the PBMs are; the government decided to use the PBMs to administer the Medicare program and our reimbursements plummeted then!
Instead, these big conglomerates are pocketing our tax dollars! I wont mention other policies of the Bush administration taking money away from our country...

Regulatory Impact Analysis

Regulatory Impact Analysis

I highly suggest that Congress REPEAL this act, as it is NOT the way to save money. STOP SUPPORTING THE ACTIVITIES IN IRAQ! Then you will save money!!! And keep thc funds in this country to help our citizens!

Response to Comments

Response to Comments

None

Submitter : **Dr. Brandon Cooper** **Date: 02/17/2007**

Organization : **Soo's Drug & Compounding Center**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those adjustments to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.
PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.
Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP. pg. 70
AMP Must Be Reported Weekly
There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Collection of Information Requirements

Collection of Information Requirements

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of Dispensing Fee does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.
Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients medical needs and can weigh them against their patients personal preferences when working to ensure that a doctor s prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included
The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.
All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

AMP Must Differ From Best Price

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.
CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.
The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of

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

GENERAL

GENERAL

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.
The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.
Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.
If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

Response to Comments

Response to Comments

CMS s Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:
The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006. -GAO-07-239R p.4
This finding validates community pharmacy s contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.
The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.
None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

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

AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report Medicaid Drug Rebate Program Inadequate Oversight Raises Concerns about Rebates Paid to States (GAO-05-102).
However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in Best Price but should not be included in AMP.
An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

Submitter : Mr. GEORGE COSTA **Date:** 02/17/2007

Organization : BALDWIN PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

RE: AMP FORMULA PRICING/ TO USE AMP AS A FORMULA FOR CALCULATING REIMBURSEMENT FOR MEDICAID PRESCRIPTIONS WOULD FORCE RETAIL PHARMACY TO ACCEPT PAYMENT FAR LESS THAN OUR COST. THIS WOULD BE DEVASTATING TO OUR BUSINESS. IT ALSO GIVES AN UNFAIR ADVANTAGE TO MAIL ORDER & PBMS WHO ENJOY SPECIAL PRICING NOT AVAILABLE TO RETAIL PHARMACIES. PLEASE RECONSIDER REIMBURSEMENT FORMULA

Submitter : Dr. Gary Maly **Date:** 02/17/2007

Organization : Iowa Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-828-Attach-1.TXT

Submitter : Mr. Don Ray **Date:** 02/17/2007

Organization : MACH - SCPhA

Category : Pharmacist

Issue Areas/Comments

Background

Background

31 years at a pharmacist in South Carolina
I have worked as a chain pharmacist for almost 8 years, an independent pharmacist for about 13 years, state government for over 7 years, federal government for almost 2 years, and with a free medical clinic pharmacy for over 1 year (while volunteering monthly for the same organization for the past 10 years). I am currently involved with the South Carolina Pharmacy Association as an active member that is concerned about the future of pharmacy. I believe we need to protect the public and the best way to do that is to keep pharmacists on the front lines of communications and give pharmacists the help and reimbursements that they need in order to feel good about the job that they are doing in taking care of the nations people. I have given away thousands of hours of health care in over 30 years of active service as a pharmacist. The pharmacist is the most accessible health care professional and should be conpensated reasonably when it comes to third party reimbursements that are out of his control.

Regulatory Impact Analysis

Regulatory Impact Analysis

February 17, 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: Preseription 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 concerned pharmacist employed in at Moncrief Army Community Hospital in 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 think you are going to create an uneven playing field if these changes are not made. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,
Don A. Ray RPh

Submitter : Mr. Ryan Reeves **Date:** 02/17/2007

Organization : Phi Delta Chi

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 much less than what it actually costs my pharmacy to buy the drugs. I request that CMS redefine AMP so that it reflects what the pharmacy actually pays for the product. If reimbursements do not cover costs, many independent pharmacies may have to turn their Medicaid patients away.

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.

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.

Ryan R. Reeves,
Doctor Of Pharmacy Candidate, Ohio Northern University,
Registered Ohio Pharmacy Intern

Submitter : **Pam Kohrman** **Date: 02/17/2007**

Organization : **Benet's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 17, 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 s 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.

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 Kentucky 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, Kentucky 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 Kentucky Pharmacist Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,
Pamela Kohrman, R.Ph

cc. Members of Congress

Submitter : Mr. Justin Saunders **Date:** 02/17/2007

Organization : Phi Delta Chi

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Under CMS-2238-P the AMP definition needs to be redefined. Reimbursement rates will not be sufficient to cover the actual cost for my pharmacy to buy drugs. I would like to respectfully request that CMS redefine AMP so that it reflects what I acutally pay for the product. If this does not occur many independents will be forced to stop serving medicaid patients.

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, Medicaidreimbursement will not cover pharmacy acquisition costs.

From what I understand the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing the definition for AMP. If AMP were defined so that 100% of pharmacist's ingredient costs were covered then adequate reimbursement could be attained. Properly defining AMP will provide a step in the right direction toward fixing this problem.

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 costsan incentive will be created to dispense more brands that could end upcosting Medicaid much, much more.

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

Thanks,
Justin

Submitter : **Dr. Amanda Baker** **Date: 02/17/2007**

Organization : **Medical Arts Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-834-Attach-1.TXT

Submitter : **Mr. Kenneth Kremer** **Date: 02/17/2007**

Organization : **Keaveny Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I have been a Pharmacist since 1970 and was the owner of a rural, Independent retail pharmacy for 28 years. We served a community of about 2000 people with a surrounding rural area of maybe 1500 people.
If these people were to lose pharmacy services they would be forced to drive at ablout 20 miles 1 way to the nearest pharmacy.

GENERAL

GENERAL

See Attachment

CMS-2238-P-835-Attach-1.DOC

Submitter : Mr. Kelly Pratt **Date:** 02/17/2007

Organization : Prescription Shop

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

First of all I would like to say I believe in America and the freedom we have here. I believe this country was based on freedom for everyone concerned from the poorest to the richest. Over the many years so many changes have occurred that I do not believe our forefathers would recognize they were in America if they were to see it today. I am a local independent community pharmacy owner/pharmacist. I have been a registered pharmacist for almost 25 years, owning my own store for a little over 9 years. I remember when I first graduated I was so excited about the contribution to society I could make thru the many opportunities pharmacy would afford me. Thru the years, I have enjoyed the opportunity to dispense medications and counsel my patients, and, for lack of better terminology, just make these hometown partners 'feel better'. But, as the years have gone by many obstacles have come along to try and destroy that great hometown environment. There has been reduced reimbursements, slow reimbursements, mail order, and so many other practices by giant PBM's that threaten the exsistence of local pharmacies like mine. But, I am going to be like our forefathers and fight for the freedom I believe in. This brings me to the discussion I would like to submit concerning AMP-based Federal Upper Limits in this proposed rule. There are various prices extended to different pharmacy classes, of which retail pharmacy experiences the least affordable. I believe we all need to do our part in making healthcare affordable, but we also need to be fair about it. Why can retail pharmacy not have the same opportunities for rebates and special pricing that other types of pharmacies are extended? It costs my pharmacy $10.14 to fill a prescription-I wonder what the price would be with lowered acquisition costs or rebates? Public access defines retail pharmacy class of trade, therefore, I recommend that 'retail pharmacy class of trade' include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies-a definition that currently encompasses some 55,000 retail pharmacy locations. These medicaid patients so often need immediate attention to obtain and understand their medications. I would like to propose the following summary of key points about AMP:

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

If the current proposed rule is allowed to proceed I believe there will be many LOCAL pharmacies in jeopardy of going out of business (I refer you to the GAO study of AMP-based Federal Upper Limits). These medicaid patients need more than dispensed medications-they need local contacts and friends. Once again, I believe in the old America way where things were fair for everyone-no business monopolizing. I ask that you keep these comments in mind as you consider the fate of CMS-2238-P.

God Bless America,

Kelly Pratt, R.Ph., community pharmacy owner

Submitter : **Date: 02/17/2007**

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

We urge CMS to revise its interpretation of Section 6002 of the DRA and not require the reporting of physician-administered drugs to hospital outpatient or clinic settings.

Submitter : **Dr. Clarence Lloyd** **Date: 02/17/2007**

Organization : **Dr. Clarence Lloyd**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 17, 2007

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

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

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

Definition of Retail Pharmacy 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 the California Pharmacists Association (CPhA) address athis issue more competely. I join with CPhA in opposing the inclusion of PBMs and mail order pharmacies in the definition of the retail pharmacy class of trade found in ?447.504(e).

Calculation of AMP Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies
AMP should reflect prices paid by retail pharmacies. Including any discounts, rebates or any other concessions that are not available to retail community pharmacies is counter to Congressional intent.

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 the California Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Clarence L. Lloyd, Pharm.D.
4433 Dogwood avenue
Seal Beach, California 90740-3039
562/598-6434
Email aomlloyd@yahoo.com

Submitter : **Mr. Michael Durbin** **Date: 02/17/2007**

Organization : **Campbell's Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

2/17/2007

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,

Campbells Drug
Michael Durbin RPH
PO Box 305
McKee, Ky 40447

Submitter : **Mr. Timothy Markson** **Date: 02/17/2007**

Organization : **Dahl Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 17, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacy owner located at Dahl Pharmacy 1200 Nicollet Minneapolis MN 55403. We are a major provider of pharmacy services in the community especially focused in serving the Medicaid and Medicare patients in our area, providing unique services not provided by large chain pharmacies, 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 the Minnesota 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 and would result in FULs that are lower than a retail pharmacy s acquisition cost.

3. Removal of Medicaid Data

Including these data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. The inclusion of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

4. Manufacturer Data Reporting for Price Determination Address Market Lag

The risk of price fluctuations due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns, the Minnesota Pharmacists Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the Association comments on the lack of clarity on claw back from manufacturer reporting error.

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. 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.

Despite the increases on cost of goods due to manufacturer s price increases on drugs, pharmacy remains the most cost effective part of the health care delivery system. In the thirty years I have been practicing Pharmacy I have not seen a single increase in my reimbursement rates. They have only decreased, and we have had to continue to find ways to become more efficient, which we have done.

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

Sincerely,

Timothy B. Markson R.Ph.
cc. Members of Congress

Submitter : Mr. Troy Gahm **Date:** 02/17/2007

Organization : Mr. Troy Gahm

Category : Pharmacist

Issue Areas/Comments

Background

Background

Retail pharmacist for 15 years, Ohio Board of Pharmacy rules committee 2 years, Ohio Pharmacy Association past president, Independent pharmacy owner 10 years

Collection of Information Requirements

Collection of Information Requirements

Amp is a unfair was of pricing prescription drugs. This will cause the closing of rural pharmacies like mine that serviec many poor and elderly population.

Submitter : **Ms. Laurel LeBlanc** **Date: 02/17/2007**

Organization : **Lake Elmo Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 17, 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

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 Lake Elmo Minnesota. We are one of two providers of pharmacy services in our 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. These organizations do not dispense to the general public, nor do most Medicaid clients have access to them for their prescriptions. Including these entities does not represent the actual providers of Medicaid pharmacy services.

More extensive comments submitted by the Minnesota 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 the actual providers of Medicaid pharmacy services. Including PBM's and mail order pharmacies is counter to Congressional intent and would result in FULs that are lower than a retail pharmacy s acquisition cost.

3. Removal of Medicaid Data

Including these data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. The inclusion of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

4. Manufacturer Data Reporting for Price Determination Address Market Lag

The risk of price fluctuations due to timing of manufacturer reporting and the extended ability to revise reported data are amplified under the proposed structure. In order to address these concerns, the Minnesota Pharmacists Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the Association comments on the lack of clarity on claw back from manufacturer reporting error.

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. 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 submitted by the Minnesota Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Laurel G LeBlanc, RPh

Lake Elmo Pharmacy
11240 Stillwater Blvd N
Lake Elmo, MN 55042

(651) 773-0889

cc. Senator Norm Coleman (R) MN
Senator Amy Klobuchar (D) MN
Representative Michelle Bachmann (R) MN

Submitter : Mr. KERRY GRIFFIN **Date:** 02/17/2007

Organization : FRANKLIN PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I own an independent Pharmacy in a rural area of Georgia and have served this area for 21 years. I am concerned that proposed cuts in Medicaid will adversely affect my business and my ability to remain as a provider for Medicaid recipients in my area. The current proposed basis for determining my cost for generic drugs , average manufacturer's price, would result in a reimbursement far below my acquisition cost and therefore a negative profit on each generic prescription I fill.

I currently own the only Pharmacy in our County and the loss of our providership would severely limit Pharmacy access to Medicaid recipients in our area of Georgia . I ask that this method of evaluating my generic drug cost be redefined in a manner that more closely reflects my true cost of goods. My wholesaler is greatly concerned about the future of retail pharmacy in general, independent and chain pharmacies, if this AMP valuation is used. They know my true cost.

Thank You

Submitter : Mr. John Grossano **Date:** 02/17/2007

Organization : Mr. John Grossano

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-844-Attach-1.DOC

Submitter : Mr. Noah Sharp **Date:** 02/17/2007

Organization : Phi Delta Chi

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-845-Attach-1.DOC

Submitter : Mr. Jeff Bartone **Date:** 02/17/2007

Organization : Phi Delta Chi

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-846-Attach-1.DOC

Submitter : Mr. Jonathan Hoover **Date:** 02/17/2007

Organization : Self

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Leslie Norwalk,

With the current reimbursement policy of utilizing AWP for processing Medicare and Medicaid prescriptions, the typical pharmacy currently is losing money with each prescription from these agencies. In fact pharmacies are currently receiving an average of 94-95 cents on the dollar for processing and filling these prescriptions for patients receiving these services respectively. Pharmacies are not refusing these prescriptions at the present time because we believe greater good results by managing the health of this population. However, this might not actually be a feasible reality starting July 1, 2007 if a pricing schedule using AMP is adopted. It is not in the philosophy of any sector of healthcare in this nation to refuse patients healthcare based on an ability to pay, however if the result of accepting prescriptions from patients with a primary insurance of Medicaid or Medicare with an AMP-based reimbursement schedule is drastic earning losses, pharmacies will have no choice but to start cutting back on the amount they can help these patients in order to stay in business.
In the grand scheme of total healthcare profit earnings, pharmacies earn an average 3% profit, while drug manufactures, on the other hand, earn on average in the 20% range. Therefore, it would be impractical to build a price based system on the sector of healthcare that continually earns the highest profit margin, which at this time are the drug manufacturers themselves. It is without doubt that the cost of healthcare is rapidly approaching an unaffordable service for government agencies to provide as is a serious problem which needs to be examined in a thorough and rapid manner. A quick fix by altering a payment schedule which is AMP-based is not a viable option at this, or possibly, any time.
As a pharmacy student graduating in 2008, I hold this matter extremely important and am deeply concerned by the effect this legislation will have on the profession of pharmacy if passed and actually takes effect. So taking this into light, I urge you to please reconsider implementing CMS-2238-P and avoid the grave consequences this act will duly cause. Thank you for your time and consideration on this matter.

Sincerely,

Jonathan Hoover
Ohio Northern University
Pharmacy Candidate 2008

Submitter : Mrs. Karen Walters **Date:** 02/17/2007

Organization : Ritzman Pharmacies Inc.

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-848-Attach-1.DOC

Submitter : **Mr. Daniel Wills** **Date: 02/17/2007**

Organization : **Grandpa's Compounding Pharmacy**

Category : **Other Technician**

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

February 17, 2007

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

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

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

Definition of Retail Pharmacy 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 the California Pharmacists Association (CPhA) address this issue more completely. I join with CPhA in opposing the inclusion of PBMs and mail order pharmacies in the definition of the retail pharmacy class of trade found in ?447.504(e).

Calculation of AMP Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies
AMP should reflect prices paid by retail pharmacies. Including any discounts, rebates or any other concessions that are not available to retail community pharmacies is counter to Congressional intent.

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 the California Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Dan Wills

Submitter : Mr. Ambalal H Patel **Date:** 02/18/2007

Organization : Aoociation Of Indian Pharmacist President, walgree

Category : Pharmacist

Issue Areas/Comments

Background

Background

Government rebate from manufacture & Amp for prescription drugs for retail pharmacy., Government should go endorse fair practice , clean parctice of any bussiness , no rebate programme for rx drugs or any thing doing bussincss with government , because if gov. takes rebate from drug manufacturers supposc 10/ 20/ 30 or 40 % whatever , that can increase wholesale price of drug to 200 to 300 % or some time more, ultimatelcy it is like accepting kickback in official way by making law & give them right to increase prices without control on them on mathematical calculation base. since this PBM & insurance comp. came in the market medicines are going higher & higher , there is a reap off from PBM & insurance comp. on the name of rebate & co-payment from consumerside, each medicine have 50 Some time 60 or 100 $ co-payments wchich people can not afford.

Collection of Information Requirements

Collection of Information Requirements

provision for this law gov. sholud be out of rebate programme , controll PBM & insurance comp. they can not increase co-payment every week or every month, because people do not get there pay raise every week or every month. Drug Manufactures can not increase price every week or every month , or should have law provision for drug price control.if you make AMP provision for prescription drug then all the retailes shold get there medicine at the cost of AMP_ minus 10% , & they should be reembursed highe dispensing fee atleast 12$ per rx. Another provisio in law should be PBM & insurance company should pay at least what medicare part D decides. they should not play with our dispensing fee & not controll our profession of pharmacist . Another issue of by law you should have provision no insurance comp or PBM or medicare part D can enforce not to have coverage under preffered drug least , basicaly they should not have controll on our profession decision or requrements of the patient. If they want to stay in the bussiness they have to cover everything under the law because they are taking money from the people under insurance premium. if they can not afford to stay in bussiness theu should be out & give other chance. On the name of insurance premium & there management fees, drug rebate from the company , insurance comp& PBM pocketing money as a profit & make big money under some other provision as stock option, prifit sharing which is not right by denying coverage to the paying people or medicare people

So Government should have protecting laws for every profession, & every bussiness company doing bussiness with profession & professionals. In short we should have laws nobody should involve in rebating programmes in any bussiness that jack-up whole sale price of anything. it should be direct prices to commomn public or bussines from the manufacturers. kick-back on the name of rebate should be out from the law books. no body except few institution should be exemped or nobody.

GENERAL

GENERAL

generaly government should make laws like in medicine & drug bussincss by law it should be direct price to people from manufacture, no kick-back under the name of rebate programme should be alloweed to pbm or insurance comp. or even government should not involve in rebate. there should not be preffered list of coverage programme of medicine or health coverage. insurance & pbm are taking advantage of this thing by denying coverage to the people.,

Response to Comments

Response to Comments

government should have price control laws ON manufactures, no rebates in medicine practic & pbm & insurance should not controll professional descison by making coverage formulary. gov. should have proper controll on pbm & insurance.

Submitter : **Date: 02/18/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

"See Attachment"

CMS-2238-P-851-Attach-1.DOC

Submitter : **Dr. Terry Davis** **Date: 02/18/2007**

Organization : **Savage Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Community pharmacies can not purchase drugs for the same prices as Chain drug stores, mail order pharmacies, and other large organizations. These proposed regulations will not give independent drug stores adequatc compensation for filling prescriptions.

GENERAL

GENERAL

We can not fill prescriptions at the level of reimbursement you are setting. You will cause pharmacies to either shut down or to refuse to fill prescriptions for these types of plans.

Submitter : **Dr. Diane Eicher** **Date: 02/18/2007**

Organization : **Wohlner's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-853-Attach-1.TXT

CMS-2238-P-853-Attach-2.PDF

Submitter : Dr. Alan Corley **Date:** 02/18/2007

Organization : Corley's Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-854-Attach-1.DOC

Submitter : **Mr. manu patel** **Date: 02/18/2007**

Organization : **amar pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

the goverment accountability office has fount that ann"AMP bases FULs were, on average, 36 percent lower than average retail pharcy acquisiton costs" (GAO-07-239R) this finding validates that AMP is not appropriate as basclinc for rcibusscmcnt and must bc dafines to rcflct pharmacy acquisition cost.

the application of a faulty AMP defination in calculating of the FUL will force may independent pharmacies to drop sevice to their madicaid patients and some indcpcndents pharmacy will go out of business.this lack of access to timely and safe prescription drug care will lead to additional costs of frequent doctors visit, emegency room care, hospital stays and above that severe effect on patient health. those pharmacies that remain in the medicaid program will face to perverse incentive to dispense, higher cost brand medicines thus driving madicaid costs higher

so please act appropriateley on this AMP price wich is fair to all
retail indepndent pharmacies. as you knows that independent pharmaies providing services like delivery of medicines and may other sevices.

Submitter : **Mr. Brenden OHara** **Date: 02/18/2007**

Organization : **Walgreens**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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 The North Carolina Association of Pharmacists 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, the North Carolina Association of Pharmacists 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 North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Brenden P. O Hara

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Jonas Daugherty** **Date: 02/18/2007**

Organization : **Glaxo SmithKline**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
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In conclusion, I support the more extensive comments that are being filed by North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Jonas B. Daugherty, RPh, MS

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Mr. P.David Smith** **Date: 02/18/2007**

Organization : **Medicap Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

Sincerely,

P David Smith RPh

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : WILLIAM MIXON **Date:** 02/18/2007

Organization : WILLIAM MIXON

Category : Pharmacist

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. (My pharmacy(s) is located Hickory, N.C. 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 The North Carolina Association of Pharmacists have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

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

Sincerely,

William Mixon
Measured Dose Pharmacy
Hickory, NC 28602
Wmixon@charter.net

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Bill Burch** **Date: 02/18/2007**

Organization : **Central Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

Sincerely,

Bill Burch, RPh

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : KAYREN BRANTLEY **Date:** 02/18/2007

Organization : WHITE STAR PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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Sincerely,

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : JAMES BRANTLEY **Date:** 02/18/2007

Organization : KERR DRUG

Category : Pharmacist

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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

Sincerely,

JAMES BRANTLEY
cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Richard Cardin** **Date: 02/18/2007**

Organization : **K-Mart**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation
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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 Rocky Mount, NC. 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 The North Carolina Association of Pharmacists 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, the North Carolina Association of Pharmacists 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 North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Richard Cardin

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Margaret Ervin** **Date: 02/18/2007**

Organization : **Carmel Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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Margaret f. Ervin

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Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Stefanie Ferreri** **Date: 02/18/2007**

Organization : **UNC School of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

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Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation
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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 teach at the University of North Carolina School of Pharmacy and I teach future pharmacy students who will be community owners and be involved in the profession. These students will be 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 The North Carolina Association of Pharmacists have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

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Sincerely,

Stefanie Ferreri, PharmD

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