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.

==========

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