Submitter : Mr. William Yates **Date:** 01/18/2007

Organization : The Medicine Shoppe

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I do not understand why this administration has targeted independent pharmacies as a useless business community in which can be done away with. You first asked us to teach seniors about your Medicare Part D plan while at the same time cutting our profits. Now you are going to continue cutting our profits with AMP pricing for Medicaid. My family has been dispensing medicine over 50 years in this small town we live in. I personally went to seniors houses so I could explain Medicare Part D to them. And the thanks we get for our hard work is continued reimbursement cuts. This might be the last cut our pharmacy can take before we have to close the doors. And when that day comes it will be felt through the community.

Submitter : Ms. susan maddox

Date: 01/22/2007

Organization : Sharp HealthCare

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

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

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

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

Submitter : **susan maddox** **Date: 01/22/2007**

Organization : **Sharp HealthCare**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-3-Attach-1.DOC

January 22, 2007

SHARP.

Michael Sullivan
Centers for Medicare and Medicaid Services
75 Hawthorne
San Francisco, CA 94105

SUBJECT: Proposed Requirement to use National Drug Codes (NDC) on Medi-Cal Hospital Outpatient Claims (File Code: CMS-2238-P)

- **Any effort by the state to collect rebates may drive drug manufacturers to completely eliminate 340B pricing in order to avoid duplicate discounts. Should this occur, hospitals stand to lose significant savings achieved through the 340B program. At Sharp HealthCare, this amounts to approximately $3 million.**

- **The proposed rule is based on the Deficit Reduction Act of 2005 which requires state Medicaid programs to begin using NDCs to secure rebates for multiple- and single-source *physician-administered* drugs. Sharp HealthCare is not convinced of the feasibility to comply with the NDC requirement but have estimated the start up costs at $5,500,000. The application has not been tested and would not be workable for compounded intravenous solutions and medications.**

Dear Mr. Sullivan:

Sharp HealthCare, San Diego's largest health care provider, consists of four acute-care hospitals, three specialty hospitals, three affiliated medical groups, and a health plan, along with many other health care facilities, appreciates the opportunity to discuss our concerns regarding the California Medicaid program (Medi-Cal) proposed requirement that all outpatient claims use National Drug Codes (NDCs) for drugs billed.

This proposal is based on the Deficit Reduction Act of 2005 which requires state Medicaid programs to begin using NDCs to secure rebates for multiple- and single-source *physician-administered* drugs. Unlike other state Medicaid programs, California's Department of Health Services (CDHS) has interpreted this provision to apply to all health care provider-administered drugs in the outpatient setting. Sharp urges CMS to provide guidance to CDHS that the language *physician-administered* is not subject to a more expansive interpretation. Imposing this requirement on our hospitals would have serious negative implications as discussed below.

Hospitals participating in the 340B Program are entitled to receive 340B discounts on all covered outpatient drugs. One condition of participation is that a drug purchased under Section 340B shall not be subject to both a 340B discount and a Medicaid rebate. To avoid these duplicate discounts,

340B hospitals are to bill Medi-Cal at acquisition cost (plus dispensing fee) for 340B drugs or "carve out" Medi-Cal patients altogether from the 340B program. Sharp has opted for the latter; that is medications dispensed to Medi-Cal patients are not replaced using 340B pricing. As such, Medi-Cal should be collecting rebates on the outpatient drugs we dispense today. Any effort by the state to collect rebates in addition to 340 B pricing may drive drug manufacturers to completely eliminate 340B pricing in order to avoid duplicate discounts. Should this occur, hospitals stand to lose significant savings achieved through the 340B program. **At Sharp HealthCare, 340 B savings related to non Medi-Cal outpatients amounts to approximately $3 million dollars.**

A far more daunting challenge is the implementation of outpatient claims to use National Drug Codes (NDCs) for drugs billed. Unlike outpatient retail pharmacies, hospitals fill medications dispensed in their outpatient departments using their inpatient dispensing system which is generally not based on NDC. The NDC requirement therefore would necessitate additional labor to track the ongoing data base and the purchase, application, and maintenance of additional software. Additionally, the interface with our information systems and automated drug dispensing would not detect changes in NDC codes. This may be overcome by the implementation of point of service bar coding for unit dose medications. The problems still remain with intravenous medications that are compounded in the pharmacy. The intravenous solution will be associated with two or more NDCs which cannot be scanned at the point of service. We are not convinced of the feasibility to comply with the NDC requirement but have attempted an estimate of the start up costs as listed below:

Pharmacy Technicians to track the NDC codes at each of seven hospitals:	$ 500,000
Interface of Information Technologies	1,000,000
Point of Service bar code application	2,000,000
User training	2,000,000
Estimated Start up Costs:	$ 5,500,000

These costs do not reflect additional hardware or ongoing maintenance and education.

Sharp HealthCare leadership in the Pharmaceutical areas would welcome a site visit to Sharp Hospital(s) to walk through the potentially unfeasible challenge of meeting this requirement. I would be happy to coordinate a visit, perhaps by the CDHS Chief of Pharmacy, Kevin Grospe, at his convenience. I am at (858) 499-4594. Thank you for your consideration of our concerns.

Sincerely

Susan Maddox
Vice President, Legislative and Governmental Affairs

cc: Stan Rosenstein, Deputy Director, Medical Care Services, CDHS
Toby Douglas, Assistant Deputy Director, Medical Care Services, CDHS
Kevin Grospe, Chief, Pharmacy Policy, CDHS
Cindy Garrett, PRO Project Office, EDS

Submitter : **Mr. Brad Houck** **Date: 01/23/2007**

Organization : **Valley Apothecary**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

CMS and Medicaid plans to use AMP vs AWP in determining reimbursement to pharmacies for prescription drugs starting July 1st (pushed back from January 1st 2007)

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

This rule shows a fundamental lack of understanding of the marketplace, it is going to require a substantial amount of education of Congress and the Administration. Pharmacies have already been squeezed to the point where many independent drugstores are having to close due to the poor and slow reimbursements from Medicare Part D plans. The AMP model, atleast as I have read it and tried to understand it, will further cut reimbursements. Maybe the place FDA should be focusing their attention on reducing drug costs is with the manufacturers who operate on much larger margins, as compared to independent drugstore owners such as myself and my wife. Forcing small businesses to shut down across the United States because of ill conceived plans such as this is surely no the intent of our blessed Food and Drug Administration. I will be writing my Congressmen as often as necessary to have the FDA's actions closely looked at. If you want to save money , look to where the money is being made (the drug manufacturers and PBM's) and don't kill out small businesses in an effort to make your agency look like heros. Because when the facts are finally revealed, it will be the FDA with egg on it's face

Submitter : Mr. Tad Gomez **Date:** 01/26/2007

Organization : Medical College of Georgia Health System

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-5-Attach-1.DOC

January 26, 2007

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

To Whom It May Concern:

On behalf of the Medical College of Georgia Health System, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. The Medical College of Georgia is a 632 bed hospital located in Augusta, GA, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. [Insert here a summary of the burdens your hospital would experience and how they would affect the hospital. If possible, please quantify the estimated cost to your hospital if final federal regulations impose the NDC reporting requirement on your outpatient clinic or department. You may wish to supplement this discussion with points or arguments extracted from the attached talking points.]

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Tad A. Gomez, M.S., R.Ph.
Director of Pharmacy
Medical College of Georgia Health System

Submitter : **Mrs. Valerie Rinkle** **Date: 01/29/2007**

Organization : **Asante Health System**

Category : **Hospital**

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Asante Health System includes physician offices and hospital providers.

We are concerned about the NDC billing requirements in this rule.

Physician offices and hospitals do not operate pharmacies like retail pharmacies. We do not track NDC numbers for each drug administered to a patient and we do not have information systems to track the NDC number with a patient account and place the NDC number on the claim.

This applies to physician offices billing on HCFA 1500 claims and to hospitals billing on UB92/UB04 claims.

The administrative burden to physician offices and to hospitals would be immense. Note that initially, HIPAA transaction sets planned to use NDC numbers for drugs, but this idea was eliminated once they noted the operational burden on hospitals and physician offices.

NDC numbers only work for retail pharmacies. Tracking NDC numbers for drugs administered to patients is not possible with technology and physician office and hospital processes at this time.

Response to Comments

Response to Comments

The regulatory impact is understated. Physician offices do not have the systems to track and bill by NDC numbers. The timeframe of January 2007 is impossible.

Submitter : **Mr. Vivek Bhatt** **Date: 01/29/2007**

Organization : **Target**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

How does the government decide to pay less than the cost of the medicine to retail pharmacies???!?? Is the government BLIND to consider there are Manufacturers who sell to Wholesalers who in turn sell to Retailers!! UNDER THIS NEW GUIDELINE, PHARMACISTS WILL LOSE (BELOW COST) 3 TO 4 DOLLARS PER EACH PRESCRIPTION...HAVE YOU EVER GONE TO DUNKIN DOUNUTS AND THE GUY SOLD THE COFFEE AND BAGEL FOR LESS THAN THE MATERIALS IT COSTS HIM TO MAKE, LET ALONE ANY MARKUP????? Is there no value for America's Pharmacists who save lives every day? PLEASE consider a different formula for reimbursement (atleast pay the cost that wholesalers like McKesson sell the product at) AND INCORPORATE A DISPENSING AND EDUCATION FEE, as Pharmacists are liable for mistakes and should be compensated for Drug Utilization Review (DUR, the checking for interactions with medicines and food, and educating the patient)!! PLEASE don't make the mistake that will result in DISASTER for my profession, CMS, and Medicaid beneficiaries. You want to send how much...10 billion dollars to Iraq for reconstruction, another 5 billion to Afghanistan, BUT CUT 8.6 billion dollars to America's Pharmacists in Medicaid (America's Poor)...It's completely UNFAIR, UNJUST, AND SHOULD NOT TAKE PLACE!!!! PLEASE CONSIDER ANOTHER SOLUTION.

Submitter : Dr. Sapna Bhatt **Date:** 01/29/2007

Organization : A&P

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

PLEASE UNDERSTAND THE SHORT AND LONG TERM CONSEQUENCES OF SLASHING PHARMACY REIMBURSEMENTS TO AVERAGE MANUFACTURER'S COST...THE REVIEW DOES NOT CONSIDER THAT RETAIL PHARMACIES DO NOT BUY DIRECTLY FROM MANUFACTURERS IN BULK, AND ARE NOT GIVEN REBATES. SHORT TERM CONSEQUENCE: MEDICAID PATIENTS WILL BE TURNED AWAY FROM PHARMACIES BECAUSE NOBODY WILL WANT TO LOSE MONEY. LESS TIME WILL BE SPENT ON PROVIDING SERVICES TO MEDICAID PATIENTS BY PHARMACISTS. MEDICAID PATIENTS WILL END UP IN HOSPITALS!!!! LONG TERM CONSEQUENCE: CMS WILL GO BROKE FROM PAYING FOR HOSPITAL BILLS AND MORE FREQUENT DOCTOR VISITS BY MEDICAID PATIENTS. TAX PAYERS WILL BE ADVERSELY EFFECTED. SOLUTION: FIX THE DEFINITION OF AVERAGE MANUFACTUER'S COST (AMP) TO INCLUDE MARKUPS BY WHOLESALERS AND RETAILERS TO A FAIR AMOUNT. SECONDLY, INCLUDE A COUNSELING FEE FOR THE PHARMACIST TIME TO TEACH, EXPLAIN, CHECK, AND EDUCATE. LETS PREVENT HOSPITAL VISITS AND STAY HEALTHY...PHARMACISTS ARE KEY HEALTHCARE PROVIDERS AND PARTNERS IN BETTER HEALTH...LETS KEEP IT THAT WAY.

Regulatory Impact Analysis

Regulatory Impact Analysis

SOLUTION: FIX THE DEFINITION OF AMP TO INCLUDE A FAIR WHOLESALE AND RETAIL MARKUP.

Submitter : Mr. Roger Gurnani **Date:** 01/29/2007

Organization : Mr. Roger Gurnani

Category : Individual

Issue Areas/Comments

Background

Background

THE ANSWER IS SIMPLE: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee.

GENERAL

GENERAL

As I see it: WITHOUT PROPER REIMBURSEMENTS TO PHARMACY PROVIDERS, MEDICAID PATIENTS WILL BE LEFT WITHOUT THE BEST AND HONEST ADVICE IN HEALTHCARE...PHARMACISTS. Mail Order pharmacies are a night marc...try using one through all the promts, nobody to speak to, and medicines not coming on time. Please reimburse Retail Pharmacies: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee. IF this does not happen, disaster will. CMS and Healthcare professionals have to come together, because politicians don't know diddly. Save money by cutting the fraud, abuse, and corruption by politicians...not taking fair reimbursements from America's Pharmacists.

Regulatory Impact Analysis

Regulatory Impact Analysis

THE ANSWER IS SIMPLE: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee.

Response to Comments

Response to Comments

THE ANSWER IS SIMPLE: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee.

Submitter : Dr. Wesley Cowell **Date:** 01/30/2007

Organization : South Florida Baptist Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please clarify that hospital outpatient (clinic) administered drugs are excluded from the definition of "physician administered drugs".

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Few facilities have the capability of passing a drug's NDC number from the pharmacy system to the Medicaid claim. The inclusion of the "top 20" multisource drugs complicates this significantly. Most inpatient pharmacy systems utilize unit-dose dispensing and without an electronic point of care documentation system (RFID or barcoding that INCLUDES the NDC# of the unit dose product) would not be able to bill accurately. The reason for this is that FDA approved, generically equivalent drugs are interchanged frequently in this environment based on availability, contracts, cost fluctuations.

Response to Comments

Response to Comments

If the states begin begin to request manufacturer rebates on hospital outpatient clinic administered drugs, this will cause problems for the PHS/340B program due to the statutory protection that the manufacturer has against double discounts because they will no longer be required to offer 340B pricing.

Submitter : Agnes Kolodziej **Date:** 01/30/2007

Organization : Agnes Kolodziej

Category : Other Health Care Professional

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed definition of "retail pharmacy" does not allow for adequate analysis of the costs related to operating such a pharmacy. What normally qualifies as a retail pharmacy are independently owned, grocery, or chain pharmacy locations. Mail-service and hospital outpatient pharmacies do not incur the same costs as the retail pharmacies. These practice sites are able to purchase drugs at a lower cost than retail pharmacies. Any definition of pharmacy that is used in calculating costs must adequately differentiate between various practice settings so that reimbursement can properly cover the true costs associated with each setting.

Submitter : **Jeff Sikes** **Date: 01/30/2007**

Organization : **Georgia Pharmacist**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Community pharmacist (owner) for 28 years

Collection of Information Requirements

Collection of Information Requirements

AMP pricing regarding medicaid reimbursement rates

GENERAL

GENERAL

We have been successfully teaching and training medicaid recipients on how to take their medicines correctly, what side effects to consider important enough to contact either us or the doctor, what to avoid, etc. etc. for 28 years in South Georgia. If the federal government isn't willing to pay us a reasonable profit to take our time to teach and train this special class of recipients, we will not participate in the program period. You pay defense contractors, paving contractors, housing contractors, etc. a reasonable profit for their services, and you should do the same or bettor for the people who look after the health and well being of our medicaid recipients. The government can either pay now for good quality care which has been and would continue to be provided from community pharmacists, or you can pay later when the system has failed and the emergency rooms are filled with simple questions and problems we have been handling for decades.

I find it offensive that the government is going to cut reimbursement to pharmacists for the most cost efficient drugs being used (Generics) while paying the full price for brand name medications which are bankrupting our medicaid system.

Will somebody please do the math and quit rewarding the brand name manufacturers for their unending contributions to our legislators? Of all the errors the government has been accused of making, this is the most egregious and in southern vernacular "Just Plain Stupid" move I have ever witnessed a supposedly educated body make. I'm usually a lot more diplomatic then this, but this only makes sense if the government is using false logic and listening to the wrong people.

I beg our government to consult community pharmacists for cost saving measures. Instead of the $8.5 billion this measure purports to save, we can lend advice which saves this much EACH YEAR, but nobody seems to be listening. We are speaking plain English, the other side is speaking political contributions. Your department has a chance to stop this lunacy before you play a part in destroying the best drug distribution system in the world, not only for our medicaid patients, but others too.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Information gathered from GAO reports

Submitter : Mr. William Dudewicz **Date:** 01/31/2007

Organization : Borden's Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

The Federal Government is proposing a new formula to reimburse Medicaid-Medicare generic prescription drugs, utilizing a formula that is 250% of AMP. This will not provide sufficient reimbursement to pharmacies dispensing prescriptions to their Medicare-Medicaid patients. We (pharmacists) are already fighting to survive under current reimbursement policies. The GAO has already stated that this proposal will not adequately reimburse pharmacies. This is a study that the Federal Government has already done.

Collection of Information Requirements

Collection of Information Requirements

This bill would require pharmacies to lose between 30-40% on the cost of generic drugs dispensed. This is totally unfair, what other business is expeeted to lose money on every transaction that occurs. The impact of this legislation is that pharmacies will have to stop filling these prescriptions, if they are to survive. What does this do to our patients, and their health? We cannot be expected to carry the burden of the federal governments budget wocs. The dispensing fee, averaging $4.00/Rx, is not capable of making up for the differnce. Numerous studies have shown that the dispensing fee should be $10-12/Rx, yet no-one is paying that.

GENERAL

GENERAL

Community pharmacy is already reimbursed at too low a level, reducing this would only foree the closure of many pharmacies, restricting patient access. My business is 97% third party, which means I'm already subject to reimbursement levels set by Insurance companies. I have no control of my mark-up, profit margin, costs, etc. These numbers are already set by Blue Cross, Medicaid, Medicare, etc. Pharmacy profits are already too low, we should be allowed to pay our bills, our employees, our taxes, etc., and still make a profit at the end of the year. I know of no other business that has to deal with this sort of thing. No one can stay in business under the proposed reimbursement formula. Please reconsider, and properly study the impact of this legislation before in is inacted. Thank You, William Dudewicz, RPh.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I'm not sure what this sections means, but obviously the people in charge have not studied what the implications of this bill would be. My pharmacy, an Independant pharmacy in Michigan, is probably 30-40% medicare/medicaid business. This bill would effectively ruin my business, and place 27 people out of work. Reimbursement levels are inadequate now, and many studies by non-pharmacy organizations have proven this time and time again, all one has to do is properly research the issue.

Regulatory Impact Analysis

Regulatory Impact Analysis

All of the comments I have read, is that this legislation will only harm the patients, restricting their access to medications. The profit margins in community pharmacies are already so low, that they can't be reduced any farther without dire consequences.

Response to Comments

Response to Comments

I cannot see anything good coming from this legislation.

Submitter : **Dr. Ken Nelson** **Date: 01/31/2007**

Organization : **Luck Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed CMS-2238-P plan with reimbursement rates that don't even cover cost of most drugs (not to mention costs associated with dispensing) will make it impossible for our rural pharmacy to continue to participate in the medicaid program. The idea of transparent reimbursement for services is welcomed but reimbursement has to be set at a realistic rate which allows us to remain has viable healthcare providers. A recent national survey using data from over 23,000 pharmacies indicated the average cost to a pharmacy to dispense a prescription was roughly $10.50. This current CMS proposal needs to adjust dispensing rates such that thc true cost of providing the service is covered. At that point, an adjustment in actual drug cost could be entertained. Please make adjustments to this plan so that pharmacies can continue to participate in the medicaid program

GENERAL

GENERAL

The proposed CMS-2238-P plan with reimbursement rates that don't even covcr cost of most drugs (not to mention costs associated with dispensing) will make it impossible for our rural pharmacy to continue to participate in the medicaid program. The idea of transparent reimbursement for services is welcomed but reimbursement has to be set at a realistic rate which allows us to remain has viable healthcare providers. A recent national survey using data from over 23,000 pharmacies indicated the average cost to a pharmacy to dispense a prescription was roughly $10.50. This current CMS proposal needs to adjust dispensing rates such that the true cost of providing the service is covered. At that point, an adjustment in actual drug cost could be entertained. Please make adjustments to this plan so that pharmacies can continue to participate in the medicaid program

Submitter : **Harry Lipschultz** **Date: 01/31/2007**

Organization : **Max-Well Pharmacy Services**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Community Pharmacies do NOT receive products (read medications) at cost levels comparable to other organizations; as such they should NOT be included in the same definition of "pharmacy" as mail order, clinics, etc.

Fee schedules for prescriptions dispensed to not come close to our actual cost of dispensing. Those fees need to be adjusted to be more in line with our actual production costs.

Submitter : Dr. Allen Nichol **Date:** 01/31/2007

Organization : Ohio Department of Health/BCMH

Category : State Government

Issue Areas/Comments

Background

Background

I am the Pharmacist in charge of a medication program for about 20,000 children with special needs for the Ohio Department of Health the Burea for Children with Medical Handicaps.
Our Data Base for medications that we pay for is shared with the Ohio Department of Job and Family Services (Medicaid for Ohio).
If this proposed AMP is implemented, Ohio Medicaid will be forced to comply and therefor we will, by virtue of the data base pricing , also be forced into the AMP proposed program. In the past CMS ignored comments surrounding the MTM portion of the Medicare Reform Act, hopefully this will be different. The methodology proposed to further reduce generic drug reimbursement, may have the affect of having pharmacies dispense more branded products, which by nature, are infinitely more expensive. Drugs that are in a therapeutic classification may be more often used, merely to sustain the pharmacy's ability to stay in business. At the same time the patient potentially may end up consuming medications, more expensive and not necessarily the more prudent choice, because of economic restraints put into play, via government interdiction.

Collection of Information Requirements

Collection of Information Requirements

Because the provisions of this proposed regulation will not affect mail order pharmacies, it will by nature, allow the profit structure to stand in place for mail order pharmacies. This will more than likely negatively impact on community pharmacy. Access of local pharmacies may become limited to our fragile (ODH/BCMH) population.
To date Mail order pharmacies have refused to participate as providers to our insured children with special needs population. If this AMP program eliminates community access for these children, and mail order pharmacies continue to refuse to participate in our program, then access is a serious issue. More of these children will be hospitalized because medication compliance will become an issue, and the health care dollars expended will rise disproportionally to the proposed savings on the reimbursement of generic drugs. This movement is ill conceived and should not be moved forward.

GENERAL

GENERAL

CMS again fails to see the forrest from the trees. The only parties that control drug cost are the manufacturers. If CMS, allows Congress to create an opportunity for CMS to directly negotiate with manufacturers, just as the current VA system is afforded, then CMS will be able to negotiate best price. This proposal of AMP will in affect, diminish participation of pharmacy vendors and decrease access for patients. The only net affect will be putting the patients who are frail in some nature, in harms way.
I suggest the entire AMP idea be put on hold until CMS has a realistic approach to this process. Our special needs program will become more at risk, because of mail order's refusal to participate.
Without community pharmacy participation the care of children with special needs , will be at an increased risk.

Regulatory Impact Analysis

Regulatory Impact Analysis

The mail order pharmacies continue to receive significant discounts from manufacturers because of this artificially created trade class distinction. Manufacturers were sued in class action by community pharmacies in 1994 for violations of Robinson Patman/Sherman antitrust violations. All manufacturers as of 2006 have settled the Robinson/Patman portion of the suite. The Sherman antitrust portion is pending Federal District Court Review. CMS needs to look at the pricing disparity and realize that the real issue is with Manufactures establishing class of trade and not for CMS to be punitive to the pharmacy retail class that pays the most dollars to service the vast majority of the patients.
PBM rebates should not be considered in AMP because in most cases that have been litigated, it illuminates the fact that this rebates are held by the PBM and are never shared with the pharmacies that do the community dispensing of medications to the patients. Thus again CMS is being unreasonable by even considering the PBM rebate to establish AMP. This is by your quirey, not operationally feasible.
Your comment that chargebacks or rebates provided to PBMS are passed on to the purchaser, meaning the community pharmacies, is totally inaccurate. No such rebating from PBMS to the community pharmacies (that are not a corporate component of the PBM) exists today.
PBM's do not act as wholesalers-another inaccurate statement.
Mail order in general, should not be considered a factor in determining the AMP, especially in the definition of Retail Pharmacy Class of Trade. Mail order is a restricted vehicle for the delivery of prescription drugs, not available to all patients.
I am also of the opinion that prompt pay discounts, if included in AMP, will have a negative impact back to the wholesale drug distribution system, which needs that cash flow. The incentive for prompt pay will be eliminated, therefore the impact will be negative to the economy of the industry.If wholesale distribution is negatively impacted, it will have direct consequenses for drug availability at the patient level.
The statement of including Medicaid sales in AMP determination is equally inappropriate. Supplemental rebates with the state Medicaid programs are not disclosed, never are shared with pharmacy vendors and may be significant in their negative impact on those vendors participating in the Medicaid program. This statement also is similarly reflective with regard to Medicare D ,MA-PD, being included in AMP caluculation. This should not be included.

CMS-2238-P-17 **Prescription Drugs**

Submitter : **Mrs. Heidi Snyder** **Date & Time:** **01/31/2007**

Organization : **Drug World Pharmacies**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-17-Attach-1.DOC

DRUG Rx WORLD
Pharmacies & Home Care Centers
P.O. Box 1107
New City, New York 10956
(845) 639-4952
(845) 639-4955 FAX

February 21, 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

Drug World Pharmacies is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates 6 pharmacies in New York State. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Heidi Snyder, R.Ph., MBA
President/CEO

Submitter : **Kyle McHugh** **Date: 01/31/2007**

Organization : **H&M Healthcare**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As an independent pharmacy owner in 3 small towns in SC I cannot see how you can ask me to sell drugs to patients for less than I pay for them. The information we have received states that you are going to require reimbursement at or below my cost with no regard for the fact that it costs me $10 to dispense that prescription and I have to pay for the drug before I dispense it and will not get paid until 3 weeks after I dispense it. I will not be able to participate in the medicaid program in my rural towns if this measure is past. It may not seem like much to you but for the patients I care for it means they will have to drive over 20 miles 1 way to get their medicine (if they can find someone who agrees to operate at a loss).
Please reconsider this act that does nothing to address the real problem with high drug prices (the pharmaceutical companies) Every time there has been a cut in Medicaid drugs costs it has come from local small pharmacy owners and never from the drug companies who increase their profits each year but do not release new drugs at the same rate. I would rather see an expanded 340B program than the current suggestion. If you must pass the AMP limits then you must also REQUIRE a $15 dispensing fee to cover my costs of filling the prescription and keeping the medicine on hand. Please think of all the patients and small businesses you will be affecting with this decision.

Sincerely
Kyle F McHugh,RPh
803-247-2133

Submitter : **Mr. Brad Nall** **Date: 01/31/2007**

Organization : **Samford University student**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a P2 pharmacy student at Samford University in Birmingham, AL and will graduate in 2009. I am very involved at my school and stay up to date with anything pharmacy related.

Collection of Information Requirements

Collection of Information Requirements

Way Average Manufacturer's Price is calculated and states being allowed to set dispensing fees.

Response to Comments

Response to Comments

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics. These pharmacies may have access to rebates and price concessions that may not be accessible to community pharmacies. Consequently, I believe that AMP may be set at a rate lower than what community pharmacy can purchase generic drug products.
The proposal does not address dispensing fees and continues to let States determine the "reasonable" dispensing fee they are required to pay pharmacists. I believe that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a $4 dispending fee when studies indicate that the average cost to dispense a medieation is approximately $10.

Submitter : **Mr. Thomas Healy** **Date: 01/31/2007**

Organization : **Healy's Edward Campus Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am concerned that the proposed AMP pricing to be used on Medicaid prescriptions will not fairly reimburse our costs. The GAO's study shows that this cost basis is about 20-40% below the average acquisition cost to pharmacies. Obviously we can not stay in business and sell for under our cost.

A margin of profit OVER our cost is in fact required since dispensing fees alone do not accurately reflect the cost of providing this service. The state of Illinois has a very poor record of adjusting fees (none I am aware of in over a decade).

In my situation only about 5% of my business is Medicaid. I could therefore stop servicing medicaid patients if required. For pharmacies with higher levels of Medicaid populations, they will simply cease to operate.

Submitter : **Mr. Conrad Banks, RPh** **Date: 01/31/2007**

Organization : **Responsive Solutions, Inc**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Our organization is a closed shop home infusion (IV) pharmacy with a small retail component. I am a pharmacist, with retail, hospital \institutional , and home infusion pharmacy practice since 1980 in South Carolina. We service the Pee Dee area of South Carolina and are located in Myrtle Beach, in Horry County.

Collection of Information Requirements

Collection of Information Requirements

This proposed CMS-2238-P poses a great concern for both aspects of our pharmacy and the pharmacy business in general and our ability to sustain or maintain business at the preposed reimbursement levels as indicated in CMS-2238-P in AMP.

The proposed AMP in CMS-2238-P for priscription drugs does not adequately reimburse the pharmacist or pharmacy.

This could potentially change the landscape of pharmacy as the American people know it, controlled by an elite few companies. This proposed change also targets the small home town independent pharmacy which will be gone because they cannot maintain their practice.

GENERAL

GENERAL

AMP is as ambiguous as AWP or ASP. It can be interpreted many ways and does not consider business overhead requirements of drug wholesalers and distributors as applied to AMP for retail practices. If closure and change of access to prescription medication is the intent of CMS then CMS-2238-P will accomplish this end. Only a few large mail order houses and large pharmacy chains will be able to survive this most recent attack on pharmacy reimbursement in the private sector.

I do understand this feedback collection tool and apologize if the format or information is not in proper order. Thank you.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I am not sure this section applies.

With strinking reimbursements and the biased or inaccurate AMP, pharmacy cannot provide service levels that are expected by CMS or the American people.

The continued squeeze on pharmacy reimbursement only adds insult to injury as experienced by all when Medicare Part D was introduced.

Retail pharmacy is not sustainable at AMP reimbursement levels. There is currently a shortage of pharmacist in the US and that will continue with AMP making pharmacy a money losing business model.

Regulatory Impact Analysis

Regulatory Impact Analysis

Is the intent of CMS to eliminate retail pharmacy the purpose of this bill by using AMP reimbursement levels.

Who will define AMP and based on what industry reports indicate most all pharmacist will be dispensing below their acquisition cost. We currently do this a present with certian prescrptions under Medicare Part D.

Response to Comments

Response to Comments

The impact of this is the closure of many pharmacies across the US or the unwillingness of pharmacy to accept AMP based on the losing business model CMS-2238-P proposes.

Submitter : **Greg Hines** **Date: 01/31/2007**

Organization : **Hines Pharmacy Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I own and operate an independent retail pharmacy in Bowling Green KY and have very serious concerns about the change to AMP pricing due to take effect on July 1, 2007. The definition and examples of this pricing have not been established yet, but according to everything I hear, the reimbursement for retail pharmacies will be anywhere from 25% to 65% below our cost. These figures are based on what mail-order and non-profit hospital pharmacies can purchase their presctiption drugs, and retail pharmacies can not purchase items at these prices.

Implementation of this rule will put many independent pharmacies out of business or at least cause them to quit accepting Medicaid patients. Pharmacies should not be expected to lose money when filling a prescription. We spend 6-7 years studying to become a pharmacist, which is one of the most trusted professions, but yet

we are expected to work for nothing or at a loss. This is not fair and very short-sighted. Many retail pharmacies in low income rural areas are totally dependent on Medicaid prescriptions for their income. When they close their doors, what will these patients do?

Will they end up in the hospital at a greater cost to our health care system or maybe just die. I understand the need to reduce costs, but the prescription drugs which our country uses are very cost effective, preventing many deaths and unnecessary hospitalizations. Sometimes you have to spend some money to save money.

According to this rule these reimbursement cuts only apply to generic drugs which are already saving the goverment and consumers billions of dollars each year. This rule will encourage pharmacists to dispense more expensive brand name drugs as opposed to the cheaper generic drugs. Does this may any sense? If anything pharmacist should be paid more to dispense generic drugs, because they reduce costs for the entire health care system.

If this change in reimbursement is implemented then the law must also mandate the all pharmacies are allowed to purchase the the lowest possible prices so that a reasonable profit is obtainable. If this is not done then this law effectively put thousand of retail pharmcies out of business. I do not think this was the intent of the law. Can you tell me any other industry which has price mandates like this. If the goverment wants to save money they should mandate prices from the brand name drug industry, because this is where 90% of the dollars are spent in the drug industry. This regulation is a diaster waiting to happen. Remember which profession stepped up and saved the day during the first month of Medicare Part D! The pharmacist. What reimbursement did we get for this service. Nothing. I hope you will reconsider this planned switch in reimbursement based on AMP until you can measure the effects on retail pharmacy. Thank you for your time and attention to this matter.

Submitter : Dr. Kara Carruthers **Date:** 01/31/2007

Organization : Dr. Kara Carruthers

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I oppose the change to AMP for several reasons. A 36% reduction in reimbursement will hurt independent pharmacies, already struggling to meet costs. Our pharmacy has already had to stop dispensing some medicare covered items b/c they reimburse below our cost, adding a formula that takes into account reimbursements and mail order pricing that retail pharmacies are denied access too will only make this list grow. Some of these medieations include nebulizer medications such as Xoponex, Duoneb, Pulmicort, other meds such as MyFortie, Cell-cept, Xeloda, to name a few. The CMS's statement that OTC/front end sales are twice the dispensing sales and that we should be able to mitigate losses in this arena is absurd. An independent pharmacy does not do twice the OTC or front end sales, at least not an independent, and this area is not mitigating losses already felt in the pharmacy as CMS so "expertly" proposes. As Health Professionals who by law are mandated to perform certain services we are already not reimbursed for I have to question why pharmacies have to absorb these costs. Research has shown actual cost associated with dispensing a prescription to be $10 and actual reimbursement dispensing rates are around $4, another place we are already asked to take a loss. This change,in my opinion, will drive medicare patients to more mail order services, this is a population with a high number of medications, medical conditions, physicians, and confusion. In a word, high risk for adverse events, they do not get adequate counseling, education, and monitoring from a mail order pharmacy. These are patients who do not use on-line/phone services well and need one to one interaction for safe drug use. To create a pricing scheme that undercuts retail/independent pharmacies, places retail at a disadvantage, and more importantly places our patients at a disadvantage.

Submitter : **Mr. Allan Davies** **Date: 02/01/2007**

Organization : **Expert-Med, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed AMP pricing for medicaid prescriptions.

GENERAL

GENERAL

Please reconsider your proposed AMP pricing model. It is not fair. Even the GAO agrees.

Response to Comments

Response to Comments

You will drive independent pharmacies out of business. I believe you will impact smaller chains also that do depend on prescriptions for as a revenue stream. Who will take care of the patients who depend on delivery, special needs, consultation. You are creating the end of the superior health care in this country.

Submitter : **Mr. Michael Whitfield** **Date: 02/01/2007**

Organization : **MedWorks Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I recognize the difficulty of establish a cost basis for prescription drugs and that some basis needs to be used. None of the current methods using AWP are accurate in reflecting cost. However, the proposal for using AMP is just as convaluted and inaccurate as AWP. Neither AWP or AMP are a good choice for basing payment.

Also, regardless of what method is used, the payment formula needs to be fair to all providers and to adequately reimburse pharmacies for their true costs of dispensing and a reasonable profit.

Collection of Information Requirements

Collection of Information Requirements

I recommend that no changes be made until a better cost basis and an accurate cost of dispensing can be determined. Pharmacy computers are sophisticated and can track actual cost of goods. I recommend the government programs use a cost of goods basis provided by the pharmacy. The pharmacy could be required to maintain invoices for goods purchased that could show the last cost paid prior to dispensing a particular prescription. These would be subject to audit. The payment mechanism would then reflect a dispensing fee that adequately reflected the cost of dispensing from studies conducted in that area of the nation, and a profit margin consistent with the historical levels for the industry.

GENERAL

GENERAL

Pharmacists are very understanding of the need to control costs in government prescription programs. As evidenced by the significant role pharmacists played in the successful implementation of Medicare part D, often at personal expense, we will work with CMS to develop and implement a fair payment system. Please do not proceed with the AMP cost basis as it is no better than the current methodology and threatens to reduce the number of pharmacies and limit access to those most in need. Let's work harder together to devise a payment mechanism that saves money for CMS but also is fair to pharmacies.

Response to Comments

Response to Comments

It is clear from the GAO's own studies that using AMP will force pharmacies to sell prescriptions below cost or decide not to participate in government programs. Neither of these is acceptable.

CMS-2238-P-27 **Prescription Drugs**

Submitter : **Mr. Richard Robinson** **Date & Time:** **02/01/2007**

Organization : **Harps Food Stores, Inc.**

Category : **Other Health Care Provider**

Issue Areas/Comments
GENERAL

GENERAL

See Attachment

CMS-2238-P-27-Attach-1.DOC

February 1, 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

Harps Food Stores, Inc. is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates 21 pharmacies in two states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

We support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Richard Robinson
Director of Pharmacy
Harps Food Stores, Inc.
P.O. Drawer 48
Springdale, AR 72765-0048

479-751-7601

Submitter : Dr. Suzanne Light **Date:** 02/01/2007

Organization : Northern Montana Pharmacy - Retail

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I do not believe those involved in making the decisions for this proposal really know what kind of impact it will have on community pharmacy in general. Ever since manage care has rolled into pharmacy, pharmacy owners have continually been asked to take less and less reimbursment from the insurance industry. The cost of drugs continue to go up (including generics) and reimbursment continues to go down. Not only do we contend with decrease reimbursement we also have watch managed care organization merge with "mail order" pharmacies again driving community pharmacists out of business. The competition is not even competition because the large corporate managed care-pharmacy organization are not trying to run all aspects of patient care and pharmacy services.

With a continuing behavior of managed care organizations trying to monopolize the pharmacy industry, we do not have a chance to compete nor continue to serve the public.

Maybe it is time for those decision makers to look once again at the problem, which is not at the pharmacy level, but the manufacturing (drug company) level. Is it not enough that managed care organization restrict what doctors can prescribe and pharmacies can dispense....What happen the "what is best for the patient".

Those of you making decision really need to understand how the managed care system works and ever since it's inception it has continually decreased pharmacy reimbursment. We can not serve our patients if we can not pay our bills because you rules and regulations cut our profits. At this point reimbursement is minimal and we are forced to increase our volumes to make up for the terrible reimbursement, which then takes a away from our ability to take care of our patients - AGAIN!!!

This proposal is a bad thing and if you want to see small community phramacies go out a business then go ahead, but I beg of you to reconsider this new pricing structure. Get help from the professionals who know something about pharmacy.

Submitter : Mr. Warren Bryant **Date:** 02/01/2007

Organization : Longs Drug Stores

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-29-Attach-1.DOC

#29

Longs Drugs
Live healthy. Live happy. Live Longs.

General Offices: 141 North Civic Drive, P. O. Box 5222, Walnut Creek, CA 94596

Telephone: (925) 210-6360
Fax: (925) 210-6883

WARREN BRYANT
Chairman, President and CEO

February 1, 2007

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

Via: HTTP://WWW.CMS.HHS.GOV/ERULEMAKING

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

Longs Drug Stores Corporation is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates 509 pharmacies in six states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

LONGS DRUG STORES CALIFORNIA, INC.

Warren F. Bryant
Chairman, President and CEO

Submitter : Mr. Steve Love **Date:** 02/02/2007

Organization : Lillian Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

The AMP based FUL's will not cover my aquisition cost. Even the GAO has said on average AMP will be 36% below my cost. The use of a faulty AMP calculation of the FUL will force me to discontinue service to my Medicaid patients, denying them access to prescription drugs since it is 10 miles to the next pharmacy. For this to work CMS must define AMP to reflct my actual cost, excluding all rebates and price concessions not available to my pharmacy, then allow a dispensing fee that covers my cost to dispense, currently $9.52 per prescription.

Collection of Information Requirements

Collection of Information Requirements

AMP was never intended to serve as a basis for reimbursement.If it is to serve this purpose it must reflect the actual cost paid by retail pharmacy, excluding rebates and prices not available to retail pharmacies. These price concessions and rebates should be included in "best Price" but not in AMP. An accurate definition of AMP will increase state rebates and encourage the use of more affordable generics saving the system money and promoting effective patient care.

GENERAL

GENERAL

Define AMP correctly.
Define dispensing fee Correctly.
Update weekly
Use 11-digit NDC for reporting.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

CMS correctly exludes hospital and nursing pricing. Both are extended pricing that is not available to retail pharmacy and both are not publicly accessible. PBM mail order facilities should be added to this because they meet both criteria. They are extended special pricing and are not publicly accessible. Sales to mail order facilities should not be included in AMP. "Retail class of trade" should include community pharmacies, independent, franchises, chains, mass merchants, and supermarkets. This includes 55,000 pharmacies now open to the public.

AMP must differ from best price if it is to represent the price of drugs for retail class of trade. AMP must reflect our true cost!

Rebates to PBMs are not available to retail pharmacy and should be excluded as should Direct to Patient Sale prices.

PBMs are not regulated at the state or Federal level , therefore ther is no way to audit rebates, discounts, and price concessions. No transparency! To use these figures in the net drug price would be inappropriate. Due to lack of regulation their true information remains hidden and they are allowed to self refer which no other health care entity is allowed to do.

AMP must be reported weekly! We have to pay our suppliers either weekly or bi-weekly and AMP must be current to prevent further loses.

AMP must be reported using the 11-digit NDC to ensure Accuracy. All of our systems and reimbursements are based on this.

Regulatory Impact Analysis

Regulatory Impact Analysis

AMP as defined will not cover our cost!
AMP was never inteded to reflect actual cost to my pharmacy!
For this to work AMP must reflect my actual cost!!
AMP calculation should exclude all rebates and price concessions not available to retail pharmacy including those from PBM mail order facilities.
AMP must be reported using the 11-diget NDC level to ensure accuracy!

Response to Comments

Response to Comments

The GAO findings should be sufficent! Your are asking us to accept a reimbursement that is proven to be below our actual cost. No business can accept this. If and accurate definition of AMP is not used with a dispensing fee that reflects our true cost (currently $9.52 for me), we will be unable to accept Medicaid. This could put many pharmacies out of business.

Submitter : Dr. RICHARD LOGAN **Date:** 02/02/2007

Organization : L & S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The implementation of AMP as currently defined as a reimbursement model will have a devastating effect on my Community Pharmacy Practice. AMP is not now clearly defined and should not be published or used until correctly defined. AMP should reflect the true cost of generics to Community Pharmacy. Pharmacies such as mine do not have access to manufactures rebates, or preferred pricing. The GAO projects a 36 to 65 percent shortfall in cost coverage for the generics I dispense. I cannot continue to serve the 26% of my patients who are medicaid eligible if I am reimbursed below cost. When enacted, AMP should be accompanied by a mandate to State Governments to increase dispensing fees to cover expenses, and encourage generic dispensing. AMP should not be a disincentive for dispensing cost effective generic medications.

Submitter : **Mr. Marshall Davis** **Date: 02/02/2007**

Organization : **Davis Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Reports from the GAO suggest that reimbursement for medications will be approximately 36 percent less than many retail pharmacy acquisition costs. If this report is accurate, I and many of my collegues, as an independent retail pharmacists, will be forced to stop service to this portion of the community. We as a group cannot continually absorb this reduction in reimbursement. I have already lost a significant portion of business due to CMS freezing of insulin reimbursement to 95% of 2003 AWP. Thank-you for your consideration of this matter.

Submitter : **Ms. Gerald Besiner** **Date: 02/02/2007**

Organization : **Wilkinson Pharmacy Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-33-Attach-1.WPD

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

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

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

Submitter : Jeff Scott **Date:** 02/02/2007

Organization : Cheek and Scott Drugs Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to voice a concern regaurding the reimbursement of retail prescriptions. I would like to factually add the cost of dispensing a prescription. In 2006 it cost $9.79 per presciption in operational cost. With your new reimbursment method we will be filling many prescriptions at a loss. I am sure you do not want pharmacies to flop but if this contiues as proposed many will have to close their doors.

Submitter : **Mr. George Warren Jr** **Date: 02/02/2007**

Organization : **Bay and Lake Pharmacies**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I have a hard time understanding how CMS can set the AMP based reimbursement model in place when the GAO reports that community pharmacies would LOOSE money on every Medicaid generic medication dispensed!

My father and I have owned and operated Bay and Lake Pharmacies for 43 years. In this time, we have seen many issues that have threatened our ability to take care of our less fortunate patients.

This issue is like no other. The initial impact will be devasting and force us to stop serving these patients. The longterm care facilities we serve (around 1800 beds) will have to find another provider. Finding a provider that is prepared and willing to accept unprofitable business will be impossible.

After the initial impact, should CMS recognize it's mistake and modify AMP based reimbursement, it may be too late for community pharmacies that have closed.

I also have issues with the classes of trade which are used to determine AMP. Mail order pharmacies are allowed rebates from manufacturers that retail pharmacies are not allowed to collect. This difference, when factored into AMP, skews the values. AMP should be MY aquistion price at the retail class of trade. Do not include mail order pharmacy in the AMP model. If mail order pharmacy is included; eliminate the rebates mail order pharmacies are able to receive.

Level the playing field. We have been asking for this for over 20 years!

Do the right thing and do not proceed till you can be assured the reimbursement model is fair and allows community pharmacies to serve the patients most in need.

Historically, third party payers follow the CMS lead. Don't be a bad leader!

Submitter : Dr. Robert Beeman **Date:** 02/02/2007

Organization : Pharmacy service inc

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a pharmacist in a poor area and 95% of my sales are derived from prescription drug sales. (point A) Can not afford to treat poor patients. Example A My gross sales exceeded 12 million in 2005 and our gross profit from these sales was 26%. With the advent of medicare part D our sales were reduced by 2.5 million due to unfair competition created by medicare part D and my gross profit was reduced to 18%. The only senior medicare part D patients left to do business at our store are the extremely loyal and the ignorant. (Point B) Preditory priceing and unfair marketing (Example B) Recently preditory priceing by Sam's Club has further reduced our patient volume because they are charging patients reduced copays on brand drugs $9.00 vs the $30 copay generated by Blue Cross-D. (Point C)Denied and unaffordable care for the people who need it most. Example C Since the 1980's our store has served the mentally ill county and state dependent patients. It is impossible to deal with the part D for authorizations for homeless patients when the insurance companies refuse to provide help based on wrong address information (hence the word homeless), drug formularies, and wrong copays. Point D Unequal access to medication. Example D A patient came to our store with an expensive chemo therapy drug and we received authorization to fill the medication from the insurance company. The $1000 profit generated by billing the account offset the $12,000 cost. However this Bayer drug had restricted sales to specialty pharmacies. Increasingly our access is being denied to profitable drugs by PMB's, Wholesalers, and manufactures. It is my belief they are collaboring behind closed doors to cherry pick more profitable drugs under the gise of specialty pharmacy. What is a specialty pharmacy anyways? It is not on my state application for my pharmacy license.

Collection of Information Requirements

Collection of Information Requirements

Reducing the cost to AMP will cause the extinction of many independent retail pharmacies in poor locations. Our family store has already been forced to reduce staff and due to the aforementioned points and examples. Homeless and mentally ill people due not increase retail sales but they do increase theft. Most chain stores do not cater to these people and are often removed from the property prior to entering the establishment. I would also argue many independents exist in areas were chain stores have closed do to lower retail sales. Many people will have to travel further distances to get there medication.

GENERAL

GENERAL

In general under the gise of reducing cost which I understand the fedral government has allowed legislation to pass which will ultimately cause the extinction of many independent pharmacies. The small special interest groups that have stolen our profits now wish to finish us off and this is what reducing prices to below market prices will eventaully cause. I hope you take the time to evaluate all I have said and not call me a criminal as the president has in the past. I have been audited and not convicted like Medco (large PBM), sponser our local childrens events unlike most cahin stores,
I do not divert drugs from canada like Walmart, Amerisouce Bergen, and Cardinal. I provide health insurance to my employees unlike Wallmart. So why am I called a criminal when the fedral government deals with convicted felons every day. Patient care is a joke when you refuse to help the patients who need it most. However it does reduce cost.

CMS-2238-P-37 Prescription Drugs

Submitter : Mr. Dennis Galluzzo **Date & Time:** 02/02/2007

Organization : Pharmacists' Association of Western New York

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern;
I am a pharmacist in WNY, I own Family Medical Pharmacy.
If Congress allows Medicaid to only reimburse us the proposed amounts tauted by CMS and ignores the comments from the GAO, we as pharmacists will be faced with yet another cut in reimbursement from Third Party sources that will tighten our Gross Margins to levels which will not sustain our business. I know I am a pharmacist but I am learning very quickly what it means to be a businesman in an atmosphere filled with draconian predators seeking to drain off the last remnants of my patient base to Mail Order, Internet and Fast below cost cash providers. And, now CMS is willing to undercut our business and offer us reimbursements that would be 36% below our cost!
Please have mercy!
Sincerely Dennis C. Galluzzo R.PH.

Submitter : Mr. tHOMAS VANHASSEL **Date:** 02/02/2007

Organization : YUMA REGIONAL MEDICAL CENTER

Category : Hospital

Issue Areas/Comments

Background

Background

THE SUBMISSION OF NDC NUMBERS OF INDIVIDUAL PRESCRIPTION TO MMEDICAID WOULD BURDEN THE STYTEM TREMONDOUSLY.IT WOULD BE MUCH BETTER IF THE AGGREGATE DATA WAS GELAMED FOR PURCHASE RECORDS.

Collection of Information Requirements

Collection of Information Requirements

NDC NUMBER SUBMISSION NOT FEASIBLE

GENERAL

GENERAL

i AM THE PRESIDENT OF THE ARIZONA STATE BOARD OF PHARMACY AND FEEL THIS REQUIREMENT WQOULD PLACE UNDO STEEE ON THE PHARMACIES AND RSULT IN HIGHER ERROR AND UNSAFE PRACTICES. THE COST COULD BE HUGE IN BOTH MANPOWER AND REPORTING TIME FROM COMPUTERS ETC. I STRONGLY RECCOMMEND THAT AGGREGATE DAT ABE COLLECTED FROM PURCHAS EHHSITORIES WHICH ARE MUCH EASIER TO GET AND MORE ACCURATE

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

i DIRECT AN EXTREMLEY AUTOMATED PHARMACY AD THIS WOULD BE DIFFICULT EVEN FOR MY HOSPITAL TO COMPLY. MUCH OF THE DATA YOU GET WILL BE HIGHLY INACCURATE FROM MANY HOSPITALS

Response to Comments

Response to Comments

HUGE TIME BURDEN ON AN ALREADY BURDENED SYSTEM

Submitter : Gill Abernathy **Date:** 02/02/2007

Organization : Gill Abernathy

Category : Pharmacist

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Dear CMS,
Currently hospital information systems are not set up to collect NDC information on each drug that we use. A typical 900 bed hospital would administer 10,000 doses per day. Many hospitals are currently focused on trying to meet existing JCAHO Patient Safety Goals which require additional resources as well as USP 797 standards.
These are important for patient safety and yet finding the resources is a challenge. To add on another requirement at this point in time would set us up for failure. In another four years, I believe most hospitals will have bedside bar coding in place; by the end of 2008, I believe the # will go from < 10% to more like 40-50%. This would allow capture of NDC number information. Billing systems would then have to be reconfigured to get that information out of clinical information systems into financial ones, but if the data is captured it should somehow be possible. I have no issue with the valid concept of NDC # capture, we simply need to have time to budget for, acquire, implement and refine the technology needed to do so. A deadline of April 1, 2009 would be more feasible.

Submitter : Mr. Duane Szymanski **Date:** 02/02/2007

Organization : St. Joseph Health System

Category : Pharmacist

Issue Areas/Comments

Background

Background

regarding submission of NDC number with the use of drugs

GENERAL

GENERAL

this proposed regulation would add an undo burden to a bureacracy that continues to put the safe medication management at risk. this proposal would shift already limited professional resources to a function that is likely intended to save the government money but will likely cost the government more money in health care resource needs and injured patients.

Submitter : Dr. David Arrington **Date:** 02/02/2007

Organization : Dr. David Arrington

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I believe this would create an undue hardship since institutions would have to provide this information manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources.

CMS-2238-P-42 Prescription Drugs

Submitter : Mr. STEVEN PERKINS **Date & Time:** 02/02/2007

Organization : COLDWATER PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

2/02/07

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

STEVEN PERKINS R.PH

Submitter : Dr. Joseph Huff **Date:** 02/02/2007

Organization : Columbia Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist in a rural area, Columbia KY. Our customer population is about 60% medicaid recipients. I am confused as to why CMS is cutting the reimbursement on generic medications. It is the high priced brand drugs that are costing the state the money. There are few if any drugs that do not have generic substitutes. I have always tried to switch my patients to the lower cost drug. Now I feel that in order to have enough money to pay our bills, that I may be asking physicians to change back to the brand name drugs. Since we will be reimbursed a significant enough amount to pay for our cost. I am also confused on how politicians can take money from major private insurance companies which continually interrupt the flow of health care in America and they are simply a self-created middle man. They are the only people in the United States benefiting from health care, and they do nothing but manage it. And manage it poorly at that. You can't shut down all the pharmacies by under paying us for drugs that people need, and allow major chains who can "take the hit" to thrive.
If you really want to save CMS and the states some money, make medical billing online also. So that you can see when a drug-seeker is going from ER to ER looking for controlled medication prescriptions. Please do not undercut local pharmacies or pharmacies in general. After all if Wal-Mart continues the way it is I am sure we will soon be the United States of Sam. I also am sure that you will do nothing about that because I am sure they donated plenty to certain political parties. Call me at 270-315-6732

Submitter : JOSEPH GOODMAN **Date:** 02/02/2007

Organization : NDS PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

WE HAVE BEEN IN BUSINESS IN AN INNER CITY AREA OF PROVIDENCE, R.I. FOR 35 YEARS. WE HAVE SURVIVED HURRICANES, BLIZZARDS, COMPETITION OF ALL TYPES. AND REIMBURSEMENT RATES LOWER THAN 25 YEARS AGO.
LAST YEAR MEDICAID PATIENTS WHO WERE AUTOMATICALLY TRANSFERRED TO MEDICARE PART D COST MY SMALL PHARMACY NEARLY $70,000 IN RX REIMBURSEMENT
THE NEWEST PROPOSALS WILL IN ALL PROBABILITY FORCE ME TO CLOSE OUR DOORS.
I SIMPLY CANNOT COMPETE AGAINST THE FEDERAL GOVERNMENT.

Submitter : Mr. Alfred Gagliardi **Date:** 02/03/2007

Organization : Southern Chester County Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am an Independent Pharmacy owner for 33 years.

Collection of Information Requirements

Collection of Information Requirements

CMS and AMP

GENERAL

GENERAL

Frankly, I can not understand why my government has to be involved with free enterprise and an industry that I have served for 33 years. If my government desires to be involved with regulating sales and profits (AMP) in the retail pharmacy business then why not also get involved with every other Industry and regulate how they must sell their product and regulate how much profit they are going to make. I am tired of paying the high fees or prices for autos, life insurance, home owners insurance, professional insurance, health insurance, clothing, food, school taxes, real estate taxes, how about just going to a ball game, etc. The American dream of being an entrepreneur, being your own boss, owning your own business working hard for yourself is being destroyed by our own government. It is just common sense that one can not sell a product for less money then it cost. I love what I do, otherwise I wouldn't have been in retail pharmacy for 33 years, but what CMS is currently trying to do with AMP and its regulations will prove to be the downfall of independent pharmacy if we can not make a reasonable profit.

Submitter : Dr. Larry Clark **Date:** 02/03/2007

Organization : St. Mary's Hospital

Category : Pharmacist

Issue Areas/Comments

Background

Background

This comment is in reference to file code: CMS-2238-P.

On December 22, 2006, The Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the Federal Register to implement certain provisions in the Deficit Reduction Act of 2005 (DRA).

Collection of Information Requirements

Collection of Information Requirements

Under the DRA, hospitals would have to provide NDC information on a billing submission to Statc Medicaid agencies to enable them to bill manufacturers for rebates due to the states under the Medicaid program.

GENERAL

GENERAL

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

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered to the patient.

Regulatory Impact Analysis

Regulatory Impact Analysis

I believe this would create an undue hardship since institutions would have to provide this information manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources.

Response to Comments

Response to Comments

The cost to implement this change for my institution would be approximately $5.00 per medication charged. CMS stated in their proposed rule hospitals would need to provide the NDC manually or implement a one-time systems change in our statements software. They are unable to estimate the cost of this manual activity or system change. Unless a hospital has bar-coding at the point of patient administration in the ambulatory setting, the hospital information system will not yield an 11-digit unique and correct NDC number to submit to the State Medicaid agency. The only alternative would be to manually submit these claims. The care giver would have to record the specific NDC number at the time of their encounter. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication. And we do not currently print NDS numbers on our self-packaged medications.

Submitter : Mr. Roger Cole **Date:** 02/03/2007

Organization : Moundsville Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a community pharmacist and would like to share these comments.

GENERAL

GENERAL

see attachment

CMS-2238-P-47-Attach-1.DOC

#47

To: Acting Administrator
Leslie Norwalk

Subject: **AMP**

My name is Roger Cole and I have been a pharmacist for 30 years and have been a community pharmacist owner for 26 years now. AMP pricing policy is the biggest challenge that I have seen community pharmacy face in my career. The current deficiencies with the AMP pricing scheme will be a financial burden to my pharmacy. Moundsville WV is a small town in WV and we have a high number of Medicaid patients, without a better definition of AMP we will be unable to serve those patients, reducing their access to care and quite possibly cause my pharmacy to become unprofitable and go out of business.

PLEASE REVIEW THESE AREAS OF THE AMP POLICY

Inclusion of mail order pharmacy prices with pharmacy class of trade Page 29

Mail order pharmacies are extended special prices and are not publicly accessible and therefore sales to mail order pharmacies should not be used in AMP calculations. The retail pharmacy should include, independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarkets.

AMP must differ from Best Price

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

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

PBM transparency is necessary to access manufacturers rebates. PBMs are not regulated by state or federal standards and therefore to accurately calculate those rebates without transparency would be improper.

Allowing the use of 12 month rolling average estimate for all lagged discounts for AMP Page 70.

AMP must be reported weekly. My pricing changes daily, monthly reporting will cause too long a delay in updated AMP prices

Use of 11 digit NDC to calculate AMP page 80

Only the 11 digit NDC number can be used for accurate pricing. Inventory control is vital for a pharmacy to control it's costs, larger bottles would cause the pharmacy to over inventory and therefore be at a financial disadvantage.

Assessment of the impact on small pharmacies, particularly those in low income and high volume of Medicaid patients page 110

The GAO findings clearly demonstrate the devastating effects the ruling will have on small independent pharmacies. No pharmacy can stay in business experiencing a 36% loss on such transactions. The deficit cannot be overcome by aggressive purchasing, rebates, generic rebates or even adequate dispensing fees. It is unlikely that states would be willing to adjust their dispensing fees to $10.50 per prescription as determined by a national cost of dispensing study has found.

CMS must employ a complete definition on the cost to dispense.
The definition of "dispensing fee" does not reflect the true costs to pharmacists and pharmacies to dispense medication to Medicaid patients. This definition must include valuable pharmacist time doing all the activities needed to provide prescriptions and counseling such as communicating by phone, fax and email to Medicaid agencies and PBMs regarding the patients needs as well as other real costs to dispense such as rent, utilities and labor costs.

All calculations should be independently verifiable with a substantial level of transparency to assure accuracy. **An AMP-based policy that underpays pharmacies will have dire consequences for patient care and access.**

Medicaid patients in Moundsville WV will lose access to my pharmacy as I cannot keep my doors open with the deficiencies in the current AMP-based policy. Medicaid patients, more than many others need that extra attention to get full benefit from their prescription drugs.

I will leave you with on story about one of my Medicaid patients. This patient has been in and out of the local mental health units several times over the past few years. To say she can be difficult to deal with is an understatement. We fill weekly pill reminder containers to help her manage her medication so she can remain independent. She calls the pharmacy almost daily, sometimes to ask about her diabetes, sometimes to ask about side effects or her blood pressure. We are on call 24 hours and I have been called at home in the middle of the night to answer questions about her low blood sugar or really high readings, "What should I do?" she will ask. We give her the best information and advice we can and she is able to "remain on her own at home". **Pharmacists provide CARE and services far beyond the net net cost of a drug and some small "dispensing fee".**
In the considerations of AMP based policy I ask for your diligent consideration of the points I have tried to make.

Thank-you

Roger Cole RPh
Moundsville Pharmacy
Moundsville WV
304-845-0390

Submitter : Mr. walter toole **Date:** 02/03/2007

Organization : Liberty Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am the owner of a independent community pharmacy in a rural area of South Carolina with a substantial medicaid population. I offer excellent pharmaceutical services to this population and have saved the government funds by being available 24 hours a day and preventing this population from using expensive emergency rooms by calling physicians and helping patients to determine that most of their medical needs are not life threatening.

Collection of Information Requirements

Collection of Information Requirements

The GAC analysis of generic drug costs dated Dec. 22, 2006 which was based on a sample of the most prescribed and highest cost prescriptions used by medicaid recepients estimated AMP-based FULS were on average 36 percent loser than average retail pharmacy acquistion costs. If this regulation goes into effect it will discourage the use of generic drugs and force pharmacies like mine to opt out of the medicaid program. to be an apprpriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy.This should exclude all rebates and price concessions made by manufacturers which are not available to retail pharmacy. Exclude all mail order facilities and PBM pricing from AMP calculations since they are not publicly accessible in the same way that community pharmacies are publicly accessible.

GENERAL

GENERAL

Dear leslie Norwalk, Acting Administrator

I would like for you to reconsider the AMP-based FULS pricing methodology so it will be based on more realistic market pricing. Pharmaceutical manufactures have tier pricing and independent community pharmacies pay the highest tier so this pricing model should be based on wholesale pricing to community pharmacies and not mail order or PBM's or non-profit entities like hospital pharmacies.
If this is allowed to be implemented , within 30 days there will be very few independent pharmacies who will serve the medicaid population because it will be unprofitable.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Response to Comments

Response to Comments

If this regulation is allowed to be implemented, the medicaid population will have fewer pharmacies, fewer generic drugs will be used and hospital and emergency room costs will increase dramatically.

Submitter : **Ms. Craig Tetreau** **Date: 02/04/2007**

Organization : **Scheurer Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

2-4-2007

To Whom it May Concern,

I have been a pharmacist for more than 24 years, in both the retalil and hospital settings. In this time I have seen many changes, and unfortunately the majority of them have inpacted community pharmacy in a negative way. Some of these changes, such as mandatory mail order impeeds my ability to positively have an impact on the patients I care for; because I am not allowed to fill their prescriptions. When pharmacists are taken out of the equation, these patients are left at the mercy of the mercenary pharmacies for profit which is exactly what mail order is. Because of this I have seen many of my former patients go without medication or have to pay a higher price, because of mail order screw ups and the for profit insurance companies don't care and don't police the mail order pharmacies because all they care about is the pocket books.

I am afraid that the AMP Pricing issue is going to be another example of government mismananagement and misplaced trust in private insurers.

The proposal before you is flawed, no body can even identify the amp price. To say that mail order pharmacies and Dispensing hospital inpatient pharmacies prices should be included will skew the price to a lower level that retail outlets will never be able to purchase the medications for. Furthermore, to allow the states such as my state to determine the dispensing fee, will allow the states with financial problems to arbitrarily cut or not pay any dispensing fee just so they can make up budget shortcomings. On the average a retail pharmacy spends roughly 9.00 to dispense a prescription. This amount does not reflect the cost of the medication being dispensed.

The current AMP proposal as it stands will force more retail pharmacies out of business. This will limit access to the poorest of our population. The retail pharmacies that do manage to survive, more than likely will not be accepting medicaid prescriptions, which will have thc same result.

What should you do? Take a look at the profits of the major pharmaceutical Companies. The answer should be self-evident, 1. CAP THE COST OF THE MEDICATIONS FROM THE PHARMACEUTICAL COMPANIES. 2. CHARGE ALL PHARMACIES THE SAME PRICE AND DO NOT ALLOW PREFERENTIAL TREATMENT OR PRICING OF ONE TYPE OF PHARMACY OVER ANOTHER. 3. SET ALL MEDICAID DISPENSING FEES THE SAME BASED ON THE NATIONAL ASSOCIATION OF RETAIL DRUG STORES SURVEYS ON THE COST TO DISPENSE A PRESCRIPTION.

I feel doing this will help us to serve our patients to the fullest because there will be no restricted access. The pharmacist is the last person to see a patient before they get their meds; having a policy that does not take this ability away will assure more positive patient outcomes, and therefore less healtcare cost down the road.

Thank-you for your time.

Craig Tetreau R.Ph.
Scheurer Family Pharmacy
Pigeon, MI 48755
e-mail ctetreau@yahoo.com

GENERAL

GENERAL

See Background field

Submitter : Mr. Michael Rubino **Date:** 02/04/2007

Organization : American Society of Health System Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The requirement to include NDC numbers with the billing information for prescription drugs is an unreasonable mandate. The hospital pharmacy purchases many generic products and may have to vary the brand and or manufacturer based on availability. This results in the purchase of drugs with many different NDC numbers. The hospital will not know which drugs are asssociated with rebates. Attemting to determine which drugs for which patients require NDC and then submitting the information will cause delays in providing patient care and will add to the cost of care for this accounting/clerical procedure. Manufacturer's have the information on purchases of their products and CMS knows the drugs that the covered patient's received. This should allow for rebate data to be obtained without the requirement of NDC's.

Submitter : **Mr. Michael Delpiere** **Date: 02/04/2007**

Organization : **Harbor Drug, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Proposed Medicaid AMP Definition Won't Cover Costs: GAO
Community pharmacies will be paid on average 36% below their acquisition cost for every Medicaid generic drug prescription they fill under a reimbursement formula proposed by the Centers for Medicare & Medicaid Services (CMS), a report by the Government Accountability Office (GAO) has determined. CMS proposed definition is effectively putting community pharmacies out of the Medicaid business, said NCPA Executive Vice President and CEO Bruce Roberts, RPh.
On July 1, CMS plans to begin reimbursing for generics with a Federal Upper Limit (FUL) based on a new definition of Average Manufacturers Price (AMP), which it proposed in a regulation released Dec. 15. As required by the Deficit Reduction Act, the FUL will be a ceiling of 250% of the AMP.

Community pharmacies will lose money on virtually every one of those transactions, the report by GAO, the investigative arm of Congress, confirmed last week. The GAO examined the AMPs of 27 high expenditure generics, 27 frequently used ones, and 23 that overlapped both categories.

For the high expenditure drugs, GAO calculated the new FULs were 65 % lower on average than community pharmacies actual acquisition costs. For the frequently used drugs, acquisition costs were 15% lower. In the overlap category, acquisition costs were 28% lower. For all 77 drugs, the average acquisitions costs were 36% lower.

The complete report (GAO-07-239R) can be found on the GAO Web site.

NCPA supports a fair and transparent system to reimburse pharmacists under Medicaid, but not a system that penalizes pharmacists for participating in the program, said Roberts. No small business can be expected to operate at a loss, and pharmacies are no exception

Submitter : Anthony Czaplicki **Date:** 02/05/2007

Organization : Baptist Medical Center

Category : Pharmacist

Issue Areas/Comments

Background

Background

Pharmacy Director

Collection of Information Requirements

Collection of Information Requirements

Requirement of NDC information on state Medicaid billing submission

GENERAL

GENERAL

This requirement would be a nightmare and increase hospital costs tremendously. The pharmaceutical industry has changed and product availability changes daily. It is very possible that a medicaid patient may receive the same chemical product with different NDC information on a daily basis. Patients receiving Intravenous products will require multiple NDC information. The costs would far outweight any savings

Submitter : Mr. Mitch G. Sobel **Date:** 02/05/2007

Organization : Saint Michael's Medical Center Pharmacy Dept.

Category : Pharmacist

Issue Areas/Comments

Background

Background

Deficit Reduction Act of 2005 (DRA). Under the DRA, hospitals would have to provide NDC information on a billing submission to State Medicaid agencies to enable them to bill manufacturers for rebates due to the states under the Medicaid program. Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered to the patient.

GENERAL

GENERAL

Submission of an NDC number for CMS patients presents a hardship. The operations of a disproportionate share hospital (DSH) or 340B hospital pharmacy is based on acquisition of the cheapest drugs available on formulary from the wholesaler. The wholesaler often changes the generic product supply and prices. Items documented as given to patients should be identified by generic name or American Hospital Formulary Service (AHFS) code. The AHFS code designates drug by class which is more congruent to hospital pharmacy practice. Limiting medications to exact NDC codes will present tedious documentation issues. Most hospital pharmacy computer programs and systems do not track dispensations to patients by NDC number. The programs will track generic name, AHFS codes, strength, dose, quantity, and instructions for use. By limiting the drug dispensation documentation requirements to an NDC number will result in many claims to be submitted inaccurately and fraudulently. We currently use a 340B program that tracks our drug use by NDC number. Because of the aforementioned issues with the NDC number many potential savings have not been realized. These lost savings amount to $100,000 to $200,000 of legitimate 340B dispensations. Once the same generic drug but different NDC number is used, the hospital loses 340B purchasing rights or credits on the previously used NDC number. This is an unfair predicament because the hospital has dispensed a legitimate amount of drug to 340B qualified patients and can not receive credit for the dispensations once the NDC number changes. The NDC number requirement will also cause unfair competition and misrepresentation among drug suppliers and wholesalers. NDC numbers that are not changed because of the inherent system difficulties will cause inaccurate data submissions to CMS. The NDC number requirement is not a realistic expectation of compliance and will create a tremendous hardship to DSH and 340B institutions. This hardship will also create an unnecessary hardship for vulnerable patients. I urge CMS to reconsider the NDC requirement for 340B or DSH medication dispensation documentation.

Submitter : Dr. James Stevenson **Date:** 02/05/2007

Organization : University of Michigan Health System

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Our current charge systems do not include NDC level data so this would need to be created. To obtain this capacity, our hospital will have to make significant changes to our billing systems, at considerable expense in terms of money, staff resources, and disruption of administrative operations. More importantly, this will have to be maintained in order to keep the data accurate. Given the many changes in manufacturer packaging, NDC numbers, and the substantial impact of needing to substitute product sizes due to manufacturer shortages and recalls, this will present a major burden to DSH hospitals trying to comply with this new requirement. My rough estimate is that this would cost the institution over $200,000 annually in maintenance costs alone, on top of the one time effort and costs required to modify our charge systems to accept NDC information.
CMS s proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. In our case, this could amount to over $1 million in savings for Medicaid patients annually.
Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price (AMP), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

GENERAL

GENERAL

I urge that this proposed change be reconsidered and some other, more efficient, mechanism be proposed as an alternative to achieve the desired ends. The proposed rule is a classic example of how administrative rules will drive up the costs of healthcare.

Submitter : Dr. Lori Brown **Date:** 02/05/2007

Organization : Kerr Drug

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposal does not address dispensing fees and continues to let States determine the "reasonable" dispensing fee they are required to pay pharmacists. This lack of guidance could lead to State Medicaid programs underpaying pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a $4 dispending fee when studies indicate that the average cost to dispense a medication is approximately $10.

Submitter : **Dr. Fletcher Johnston** **Date: 02/05/2007**

Organization : **Medical Park Pharmacy West**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Leslie Norwalk

As a community pharmacist which provides services for a large number of Medicaid beneficiaries. The proposed reduction in reimbursement for generic drugs will have a immediate and severe effect on my ability to service this population.

Many Medicaid beneficiaries use a large number of medications and do not have the ability to manage there therapies effectively. Also, a large number of beneficiaries do not have the ability to obtain their medications without the use of our delivery services. Without the management and delivery services that we provide, these patients will be the ones that suffer the most. The proposed reimbursement rates will force the discontinuation of our services to Medicaid beneficiaries.

We simply cannot offer services at a lose. Attached you will find specific comments about CMS 2238-P.

GENERAL

GENERAL

See Attachment

CMS-2238-P-56-Attach-1.PDF

CMS-2238-P-56-Attach-2.DOC

#56

CMS-2238-P: Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005

As promised, NCPA is providing an outline of our position regarding CMS-2238-P, the agency rule which will redefine Average Manufacturers Price (AMP) for use as a Federal Upper Limit (FUL) in the Medicaid program. The move to AMP will result in a significant reduction in Medicaid reimbursement for multiple source generic medications. NCPA will be submitting a comprehensive set of comments on behalf of community pharmacy, however it is our desire for the Centers for Medicare & Medicaid Services (CMS), the agency that runs the Medicaid program, to receive a significant number of comments from the pharmacy community.

This outline is provided so that community pharmacy's comments will have a more unified theme in order to magnify their impact. Please review the rule and these suggested comments and then submit your own comments to CMS from your perspective.

Comments can be submitted electronically, by mail, by express mail and by hand or courier. Full details are outlined on pages 2-4 of the proposed rule. The proposed rule can be found on the CMS website at: http://www.cms.hhs.gov/MedicaidGenInfo/downloads/AMP2238P.pdf.

NCPA suggests you submit your comments electronically by visiting http://www.cms.hhs.gov/eRulemaking. **PLEASE REMEMBER: Your comments must be received by CMS no later than 5 p.m. on February 20, 2007.** Comments should also be addressed to Acting Administrator Leslie Norwalk.

NCPA comments reference the recently released Government Accountability Office (GAO) report on Medicaid Federal Upper Limits (GAO-07-239R) which can be found at http://www.gao.gov/new.items/d07239r.pdf.

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:

> "The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower

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.

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

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

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.—pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP—pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

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

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110

CMS discusses impact on pharmacy:

- On independents: potential "significant impact on small, independent pharmacies."—pg. 101
- On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 ("a small fraction of pharmacy revenues").—pg. 108
- "We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark 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.

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.

Summary of Key Points:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.

2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*

3. Reporting AMP at the 11-digit NDC level to ensure accuracy

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

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

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

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

Treatment of Manufacturer coupons with regard to Best Price—pg. 55
Inclusion of Direct-to-Patient Sales with regard to AMP—pg. 41

AMP Must Differ From Best Price
If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade. CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry. PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.—pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs andreimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP—pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy 5

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

The 11-digit NDC must be used when calculating the FUL.

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110

CMS discusses impact on pharmacy:

On independents: potential "significant impact on small, independent pharmacies."—pg. 101
On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 ("a small fraction of pharmacy revenues").—pg. 108
"We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110
Impact on small pharmacies demonstrated by GAO findings
The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees. The impact on independent pharmacies also cannot be mitigated by an increase in stateset 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.
6 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.

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.

Summary of Key Points:
_ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
_ Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement. To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.

2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Submitter : Mr. Roger Collins **Date:** 02/05/2007

Organization : Harps Food Stores

Category : Other Health Care Provider

Issue Areas/Comments

Background

Background

The CMS proposed regulation on AMP and FUL which will determine reimbursement for generic precription drugs under Medicaid and Medicare do not provide adequate reimbursement as currently proposed. In fact, according to the GAO, reimbursement will average 36% below pharmacy costs. Implementation of this regulation should be delayed until this problem is corrected and a fair reimbursement methodology is developed.

GENERAL

GENERAL

See attachment.

The CMS proposed regulation on AMP and FUL which will determine reimbursement for generic precription drugs under Medicaid and Medicare do not provide adequate reimbursement as currently proposed. In fact, according to the GAO, reimbursement will average 36% below pharmacy costs. Implementation of this regulation should be delayed until this problem is corrected and a fair reimbursement methodology is developed.

CMS-2238-P-57-Attach-1.DOC

CMS-2238-P-57-Attach-2.DOC

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

We support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Roger Collins
President
Harps Food Stores, Inc.
P.O. Drawer 48
Springdale, AR 72765-0048

479-751-7601

Submitter : **Robert Stoneburner** **Date: 02/05/2007**

Organization : **VSHP**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Under the provisions in the Deficit Reduction Act of 2005 (DRA), hospitals would have to provide NDC information on a billing submission to State Medicaid agencies to enable them to bill manufacturers for rebates due to the states under the Medicaid program. Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered to the patient.

GENERAL

GENERAL

VSHP believes this would create an undue hardship since institutions would have to provide this information manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources.

Submitter : **Mr. Mark Jacobs** **Date: 02/05/2007**

Organization : **Shopko Stores Operating Co., LLC**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

I am writing to provide my views on CMS December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation Shopko Stores LLC operates 134 pharmacies in 13 states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

" Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy s acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

" Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy s cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being files by the National Association of Chain Drug Stores (NACDS). I appreciate your consideration of my comments.

Sincerely,

Mark R. Jacobs RPh
Pharmacy Mgr.

Submitter : **Mr. Dennis Dawiedczyk** **Date: 02/05/2007**

Organization : **Shopko Stores Operating co.,LLC**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

I am writing to provide my views on CMS December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation Shopko Stores LLC operates 134 pharmacies in 13 states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

" Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy s acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

" Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy s cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being files by the National Association of Chain Drug Stores (NACDS). I appreciate your consideration of my comments.

Sincerely,
Dennis Dawiedczyk RPh
Pharmacist

Submitter : Mr. Greg Moorer **Date:** 02/06/2007

Organization : Oak Ridge Pharmacy

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The pharmacy industry provides valuable prescription services for Medicaid recipients. I am deeply concerned with the proposed reimbursement model based on AMP. According to the GAO's report, community pharmacies such as mine will lose an average of 36% on each generic prescription filled for Medicaid recipients. My pharmacy will not be able to fill Medicaid prescriptions under such an environment. This will dramatically decrease access of prescription drugs for the medicaid recipient. Without local pharmacies providing and monitoring prescriptions for this population, the cost of Medicaid will far and above exceed any savings that might be realized through AMP pricing for generic prescriptions.

Submitter : Lynda Staggs **Date:** 02/06/2007

Organization : Medical Arts Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Before any pharmacy realizes a profit from filling a prescription, the cost for filling that prescription must be recouped. Recent studies fix that cost at approximately $10.00 per prescription. Reimbursement rates must allow parmacies to cover their cost plus make a profit. It is difficult to ascertain the true cost of a drug with so many tiers in the pricing schedules. There needs to be one fee schedule for retail and one fee schedule for institutions and both need to be based on quantity purchased. If pharmacies close because of unfair reimbursement rates, how will millions of patients in rural areas receive prescriptions? For the nation's elderly, receiving a presciption in the mail is not enough. They need and deserve a face-to-face relationship with a pharmacist. Without the thousands of interventions by pharmacists on a daily basis, a health care crisis is a real possibility.

Submitter : **Date: 02/06/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

am concerned over several issues - cost based on AMP will not reflect our acquisition cost at all so will break even at best on all outpatient meds; under 1102(b): who determines what is a physician administered medication v. a nurse administerd one in the hospital outpatient setting? Have multiple incidents weekly where the physician will order the medication but not be physically preent when it is given; the inclusion of a dispensing fee will not come close to covering the additional overhead present in a hospital outpatient setting - This is partially justified by statistics showing steady growth in prescription volume. I do not believe this. Actual cost cannot be recouped from only increasing volume without sacrificing quality; Reprogramming the software system to transmit the NDC codes on claims will not be an easy or cheap task

Submitter : **Ms. James Burr** **Date: 02/06/2007**

Organization : **Meadow River Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

This pharmacy opened in Dec. 2003. When have had a steady customer growth due to great customer service. We are always there for the customer. Although all our customers are not medicaid eligable we do serve a great many who are. We are against this, and if passed our pharmacy and our customers would suffer greatly.

Submitter : Mr. JAMES REED **Date:** 02/06/2007

Organization : EXPRESS RX DISCOUNT PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

DEAR SIR OR MADAME,

WITH THE IMPLEMENTATION OF MEDICARE PART D IN 2006, I HAVE HAD TO GO INTO DEBT IN EXCESS OF $200,000.00 JUST TO STAY IN BUSINESS. REIMBURSEMENT RATES ARE WAY TOO LOW AS THEY STAND TODAY. I COSTS US AT LEAST $10.00 PER PRESCRIPTION TO FILL NOW. HOW CAN WE STAY IN BUSINESS AND REMAIN AN ASSET TO THE COMMUNITY IF WE ARE FORCED OUT OF BUSINESS OR EVEN WORSE, BANKRUPT! THIS IS A REALITY OUT HERE IN THE PHARMACY COMMUNITY. PLEASE DO NOT CUT REIMBURSEMENTS TO US AND PLEASE INFORCE A TIMELY PAYMENT FROM THE THIRD PARTY ADMINISTRATORS AS THEY ARE THE MAIN COST TO THE MEDICARE PART D PROGRAM.
RETAIL PHARMACY GETS THE LEAST MONEY OF ANY PART OF THE PROGRAM BUT CONSULTS WITH THE PATIENT EVERY TIME THERE IS A PROBLEM WITH THE TPA WITH OUR CUSTOMERS PRESCRIPTIONS.
BELIEVE ME PLEASE! PHARMACY CANNOT SURVIVE ANY FORM OF LESSER REIMBURSEMENT.
SINCERELY,
JAMES REED (OWNER)
EXPRESS RX DISCOUNT PHARMACY
7032 EAST BRAINERD ROAD
CHATTANOOGA, TENNESSEE 37421
(E-MAIL: EXPRESSRXTN@AOL.COM)
PHONE 423-899-3278

Submitter : Mr. James Cary **Date:** 02/06/2007

Organization : ClearSpring Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

It is my understanding that CMS is considering reimbursing Pharmacy care providers for dispensed drugs at the Average Manufacturer Price or AMP . This will not work for the following reasons, different drug outlets, i.e. hospital versus retail, chain pharmacy versus independent pharmacy, low income versus everything, closed-door/mail-order versus retail. All of these different venues purchase drugs at different prices and to add more confusion there are back-end rebates.

My suggestion is to use actual NET ACQUISITION PRICE then add a reasonable profit and fill fee. This will simplfy the process and allow community pharmacy to continue to serve Medicare patients.

Thank-you
James S. Cary
ClearSpring Pharmacy, Ltd.
Wheat Ridge, CO 80033
303-940-1689 x14

Submitter : **Dr. Dean Flanagan** **Date: 02/06/2007**

Organization : **Americare Pharmacy Inc**

Category : **Pharmacist**

Issue Areas/Comments

Response to Comments

Response to Comments

AMERICARE PHARMACY INC
515 WEST CALIFORNIA
GAINESVILLE, TX 76240
940-668-6868
apinc94@suddenlinkmail.com

Leslie Norwalk
CMS

My name is Dean Flanagan Pharm D, MBA, CDE, I own and operate Americare Pharmacy Inc in Gainesville, Texas. I am confident that implementation of the AMP-based FULs will have devastating effects on my pharmacy and the patients that I serve.

As reported, I can not absorb a thirty six percent loss on Medicaid or Medicare prescriptions. The profit margins in a community pharmacy are razor thin now. I have been holding out in the hopes that reimbursement will improve with legislation to allow negotiations between pharmacy providers and drug benefit managers. Community Pharmacy has been forced to provide services at the drug benefit manager s desired compensation rate or opt out of the profession.

For the past ten plus years, I have seen profit margins shrink. I am the only pharmacist in the pharmacy, I work fifty five hours, six days of each week. The profitability of my profession does not allow me to hire a second Pharmacist or a part-time Pharmacist. The AMP-based FULs will no doubt be a death blow to community pharmacy.

I have a few questions for you. Why are generic drugs the target of this legislation, when brand drugs represent the greatest share of drug cost in the health care budget? Why is the pharmacy provider expected to provide the majority of the budget reduction when the drug cost represents the bulk of the cost of a prescription?
Why would you ask me to take a thirty six percent loss on the cost of the drug ingredient rather than make the request from the manufacture? Why would you favor legislation to shift market share from generic drugs to brand drugs? If you truly desire a budget reduction, why would you multiply the cost of a health care program, by forcing providers to utilize brand drugs when generic drugs represent a small fraction of the cost of a brand? Why would you favor legislation that will, without doubt increase the cost of the health care program? Was this agenda planned to reduce the budget or supply a win-fall for the brand manufacture? What PAC influenced the legislation to exempt brand drugs and target generic drugs? Could this be the same group that developed a clause to prohibit drug price negotiation by CMS on economies of scale for the Medicare prescription drug program? Who benefits form legislation that shuns the most cost effective and budget friendly class of drugs in favor of the far more costly brand drugs. It is blatantly apparent to me who the winner is in this legislative agenda, are you one of the winners?

Let me give some suggestions on how to solve the health care issues and provide a meaningful health care program for the United States. Shift a few billion dollars from the war industry grants and energy industry grants into providing health care to middle class Americans who have worked and sacrificed their entire life for this country.

Thank you

Dean Flanagan Pharm D, MBA, CDE

Submitter : Mr. David Seaver **Date:** 02/06/2007

Organization : MA Soc of Health-System Pharmacists

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

A hospital will have to maintain barcoding at the point of patient medication administration. Many, if not most, hosptials do not have an outpatient bar code medication administration system. Hospitals bill out by medication, be it a brand or generic medication.

The usual hospital information system will not yield a 11-digit unique NDC number to submit to the State Medicaid agency. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

The impact on workflow, staffing and financial resources of the hospital is unrealistic and not justifiable given current fiscal and workforce constraints. This is an incredible burden given the current cost-cutting fiscal constraints with which hospitals are currently faced.

The claim "[W]e believe the cost of adding the NDC to each claim would be minimal", ignores the necessary Information System costs for implementing such a change. More expensive still would be a paper system.

This is a burdensome requirement whose benefits are far outweighed by the costs to implement.

Submitter : Harlan Smith **Date:** 02/06/2007

Organization : The Medicine Shoppe.

Category : Pharmacist

Issue Areas/Comments

Background

Background

Providing cost effective precriptions requires the use of generic drugs. If incentives favor more expensive Brand Drugs the cost of the program will go up. Not only do we need to wisely utilize generic subsitution but also make sure that reimbursement is based on readily available sources to the class of trade that dispenses the medication

Collection of Information Requirements

Collection of Information Requirements

To ensure accuracy AMP should be at the 11 digit level.

GENERAL

GENERAL

Pricing must be fair to community pharmacy. AMP and FULs must reflect realistic acquisition cost for this class of trade. It is impossible for pharmacy to sell prescriptions for less than they pay for them.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Mail Order pharmacies need to be transparent on there true cost. There figures should not be included in community pharmacist standards without community pharmacy being able to purchase at True FULs and AMP.

Regulatory Impact Analysis

Regulatory Impact Analysis

the very existance of a delivery system depends on fair and equitable reimbursement. Last year my income was about 30% of the standard due to keeping my store open and my employees with jobs in order to provide high quality pharmacy services to our patient base.

Response to Comments

Response to Comments

Timely updates of prices must be made Good pharmacy services keep patients from more expensive emergency room visits and hospitalizations Optimizing the pharmacy approach to the health and quality of life of patients is a very cost effective way to lessen total health care expenditures. The trust patients place with their community pharmacy indicate the importance of one on one care. I would not want to have my personal Dr visit over the phone or self diagnostics from reading a pamphlet Patients need pharmacist to explain the proper use of their medications

Submitter : Mr. John Eklund **Date:** 02/06/2007

Organization : Preston's Care Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The formula for AMP-based federal upper limits in the proposed rule will underpay pharmacies based on our actual acquistion cost for multiple source generic drugs by up to 40%. Yes BELOW OUR COST. I do not understand how the GAO can conclude that the proposed AMP ruling will cause each independent pharmacy to LOSE MONEY FILLING PRESCRIPTIONS, yet, the AMP RULE, seems to chug along. Pharmacies are already underpaid for their services by large PBM's who dictate pharmacy reimbursement, while enjoying huges profits themselves. We are often paid less than our costs yet continue to serve the public. The average cost to fill a prescription has been calculated to be $10.50, while fees paid to us are less than four dollars, often $1.25 per prescription. Anyone from any government agency is welcome to come to my pharmacy to see my invoices and the amounts that I am paid for prescriptions and see that Pharmacists are not the reason for high prescription drug costs. Possibly the government should look into the practices of the PBM's, seek transparency in thier transactions and look into their profitablity. Then the government would know who is getting rich and who is doing the WORK!

Prices paid to manufacturers are NOT THE PRICES I PAY. Rebates and price concessions made by manufacturers are NOT GIVEN TO ME!

Antitrust laws established to prohibit price fixing, combined with the manufacturers policies of different 'classes of Trade' have allowed PBM's to hand pharmacies non-negotiable contracts, establish mail order outlets (which receive prices I can only dream of), giving them the ability to become the force that they have become.

AMP was never intended to serve as a basis for pharmacy reimbursement.

To be an appropriate benchmark, AMP must be defined to reflect the ACTUAL COST PAID BY RETAIL PHARMACY. This will be accommplished by excluding all rebates and concessions made by manufacturers which ARE NOT AVAILABLE TO RETAIL PHARMACY (Class of trade!) and by excluding ALL MAIL ORDER 'PHARMACIES' AND PBM PRICING from AMP calculations. As I said these prices never were and continue to be NOT OFFERED TO COMMUNITY PHARMACY.

Again, it seems that the large,profitable, institutions are influencing government decisions while the little guy's voice goes unheard.

Respectfully,

John Eklund, RPh.

Submitter : Mr. JOHN OCONNELL **Date:** 02/06/2007

Organization : Mr. JOHN OCONNELL

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The change from AWP to AMP is going to be just fine....assuming that AMP is an accurate reflection of our actual acquisition cost (AAC). the GAO study finding that AMP will be 36%, on average, below our AAC is disturbing. Just because you feds run a deficit doesnt mean that small business can. Without adequate reimbursement, we will not provide services. Without adequate reimbursement, i will make sure to give my customers your phone number and you can figure out what they should do.

Submitter : **Dr. Brian Vu** **Date: 02/06/2007**

Organization : **Carepoint Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed AMP calculation for generic drugs will be detrimental to independent pharmacies, which have 90% of their business dependent on medi-cal prescription revenue.

Our pharmacy, in particular, serve an important segment of the low-income patient population--minorities who cannot speak English. Most of our patients are Hmong, Vietnamese, Cambodian, Thai, Laotian, and Hispanic amd we have translators to give the correct drug information. If these non-English speaking patients were to get their medications at the retail chain pharmacies (because all of the independents would be out of business, the pharmacies would not have translators. Thus, the non-English speaking patients would not receive the appropriate drug information and find themselves in the emergency rooms at hospital all across the state due to incorrect usage of medications. Thus, this would cost more money to the taxpayers.

GENERAL

GENERAL

Bottom line is that independent pharmacies cannot stay in business with the new AMP calculation. The new calculation does not cover the cost of product that independents must pay and does not cover the overhead cost to dispense the medication. If independent pharmacies all go out of business, this will be a severe barrier to quality, personal, access to pharmacies for the patients, especially non-English speaking patients.

The AMP calculation needs to cover the cost of drugs, overhead cost to dispense the drug (employees, PGE, vials, labels, phone, etc...), and a decent profit in order to keep the independent pharmacies in business. Many independent pharmacy owners are making less money than they would working for retail chain pharmacies, especially after the medicare part D hit their bottom lines. Now, with the threat of AMP, independent do not stand a chance. The real segments that will be devestated are the patients, because poor pharmacy care from chains, and the taxpayers, because they will share in the cost of patients entering emergency rooms due to incorrect drug usage.

Sincerely,

Brian Vu, Pharm.D.
Carepoint Pharmacy

Submitter : MARY GLAVAN **Date:** 02/06/2007

Organization : PURE SERVICE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Robert McGivern **Date:** 02/06/2007

Organization : Ohio Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The definition under CMS2238P will cause more Independent Pharmacies to go out of business. The reimbersement will be far below actual costs to the pharmacy that I work in. CMS should redefine AMP so that it reflects what we actually pay for product. The way they define it now it only covers 1/2 the cost on average. HELP SMALL PHARMACIES

Submitter : Dr. Carrie Fish **Date:** 02/06/2007

Organization : MedCenter Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. David McPeek **Date:** 02/06/2007

Organization : Seifried Pharmacy, Orrville, OH

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Prescription reimbursement will be based on acquisition prices no retail pharmacy has access to.

Regulatory Impact Analysis

Regulatory Impact Analysis

I don't understand how this can even be considered! Basic business principles are based on selling for more than you buy for; this will not be the case if this is put into effect.

Response to Comments

Response to Comments

Could put me and many other pharmacies who serve Medicaid patients out of business. Only alternative under these conditions is to turn Medicaid patients away, which I really don't want to do.

Submitter : Mr. George Bartell **Date:** 02/06/2007

Organization : The Bartell Drug Company

Category : Health Care Industry

Issue Areas/Comments

Background

Background

My name is George D. Bartell, Chairman and CEO of the oldest drugstore chain in the country, headquartered in Seattle, Washington and operating 54 stores in major population centers in Western Washington.

Collection of Information Requirements

Collection of Information Requirements

See Attachment A

GENERAL

GENERAL

See Attachment A

CMS-2238-P-91-Attach-1.RTF

#91

ATTACHMENT A

MODEL COMMENTS TO CMS
SUBMIT COMMENTS TO:
HTTP://WWW.CMS.HHS.GOV/ERULEMAKING.
COMMENTS DUE FEBRUARY 20th

==========

February 6, 2007

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

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

The Bartell Drug Company is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Company operates 54 pharmacies in Washington State. We are a leading provider of pharmacy services in the communities in which our stores are located.

This proposed regulation, if adopted, would have a significant negative economic impact on my pharmacies. It could jeopardize our ability to provide pharmacy services to Medicaid beneficiaries and the general public, and even our ability to remain in business. This regulation should not move forward unless substantial revisions are made. Incentives need to be retained for pharmacies to dispense low-cost generic medications.

I request that CMS please take the following actions:

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

- **Define AMP to Reflect Retail Pharmacy Purchasing Costs**: CMS' proposed regulatory definition of AMP is problematic because it would result in AMP values

that do not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires. Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Retail pharmacies like mine do not have access to the special prices offered to these classes of trade.

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. While this may appear to be reasonable, perhaps generous, for the reasons stated in this letter it would force retail pharmacies like mine to sell most generic prescriptions at less than our cost of goods, even before the cost of filling the prescription is considered. The cuts will be devastating to retail pharmacies. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system. The findings of the GAO study confirm our own opinions and our own analysis.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs. Current dispensing fees have been acceptable to retail pharmacies because retail pharmacies made a profit on the sale of the prescription. With the profit removed, the dispensing fee in my state covers half, at best, of our actual cost of dispensing.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

George D. Bartell
Chairman and CEO, Bartell Drugs

Submitter : **Ms. carol sparks** **Date: 02/06/2007**

Organization : **Ms. carol sparks**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Submitter : Mr. donald hare **Date:** 02/06/2007

Organization : Mr. donald hare

Category : Pharmacist

Issue Areas/Comments

Response to Comments

Response to Comments

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mrs. Danielle Forsythe **Date:** 02/06/2007

Organization : Pure Service Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Jo Prang **Date:** 02/06/2007

Organization : BHP, Inc. dba Medicap Pharmacies of the Black Hill

Category : Pharmacist

Issue Areas/Comments

Background

Background

Prescription Drugs; AMP RegulationCMS 2238-P RIN 0938-AO20 The BHP, Inc. Corporation is writing to provide our views on CMS December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. Our Corporation operates 4 pharmacies in our area. We are a dependable, personal-service oriented provider of pharmacy services in the communities in which our stores are located.

Collection of Information Requirements

Collection of Information Requirements

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

GENERAL

GENERAL

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I ask that CMS please do the following: #1. Delay Public Release of AMP Data: The Centers for Medicare and Medicaid Services (CMS) should not make Average Manufacturers Price (AMP) data public until a final regulatory definition of AMP is released. This definition should reflect the prices at which traditional retail pharmacies purchase medications. CMS indicates that it will start putting these data on a public website this spring. However, release of flawed AMP data could adversely affect community retail pharmacies if used for reimbursement purposes. CMS has already delayed release of these data, and we urge that release of these data be delayed again.
#2. CMS needs to define AMP to Reflect Retail Pharmacy Purchasing Costs: CMS proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires. Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade. In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.
#3. Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy s acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.
#4. Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy s cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs. I support the more extensive comments that are being filed

Regulatory Impact Analysis

Regulatory Impact Analysis

the cost of doing a prescription in my pharmacy is the estimated national average of $10.17. Any insurance that does not include at the very least an $8 fee and offer at least an 18% profit margin are going to be refused at our pharmacies from now on. And yet, this will result in a loss of 10% of my business. Add this to the over 25% loss of Medicare Part D if this mis-guided AMP goes through, and I will have lost over a third of my business. I doubt anyone can stay in business six months after such a loss. Either that, or I can continue to take the poor-paying insurances that attach only the product to the price, and not the pharmacist time and expertise, and keep Medicare Part D with AMP and go out of business in 6 weeks. No private business can survive what you are expecting us to "hand-out", which is essentially paying the Medicare Part D customer to get their prescriptions from us.

Response to Comments

Response to Comments

I urge you to reconsider this whole issue of AMP. The burden has been and will continue to be on the backs of pharmacists and pharmacies to make Medicare Part

D successful. However, the impact of fewer pharmacies providing services will be profound. The poor and house-bound will be underserved and therefore the death-rate will rise.

Submitter : **Mrs. Maria Fowler** **Date: 02/06/2007**

Organization : **Hoffman's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

My name is Maria Fowler, and I am the owner of Hoffman's Pharmacy, an independent,community pharmacy that has been serving Ashtabula County's health care needs since 1941. In addition to filling prescriptions and providing our patients with health care information, we provide special services such as free prescription delivery, prescription compounding, and eharge accounts, and we also are the only pharmacy in our county which services Hospice of the Western Reserve. We serve an impoverished area, where the average home price is $42,000 and a majority of our patients are Ohio Medicaid receipients.

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mrs. Barbara Wamsley **Date:** 02/06/2007

Organization : Mrs. Barbara Wamsley

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Response to Comments

Response to Comments

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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. JOSEPH WUIS **Date:** 02/06/2007

Organization : SELF EMPLOYED, NCPA, MPA, APHA

Category : Pharmacist

Issue Areas/Comments

Background

Background

I AM A 64 YEAR OLD PHARMACY OWNER WHO HAS OWNED OVER 12 DIFFERENT PHARMACIES IN MY LIFE. I HAVE SEEN MANY CHANGES IN THE 40 YEARS BUT NONE AS POORLY THOUGHT OUT AS THE CURRENT AMP. THIS WILL COST THE TAXPAYER BILLIONS AND RESULT IN A LOWER LEVEL OF TREATMENT AND PATIENT SERVICE.

GENERAL

GENERAL

THE ATTEMPT TO REDUCE COSTS IN MEDICAID SPENDING IS TOTALLY GOING TO MISS THE OBJECTIVE AND RESULT IN ELEVATED COSTS. THIS WILL ABSOLUTELY OCCUR IF A BELOW COST (AMP) METHOD TO DETERMINE PHARMACY COST BASE IS USED IN DETERMINING REIMBURSMENT. I AND ANY OTHER INDEPENDENT OR CORPORATE OWNER WILL BE CERTAIN TO ATTEMPT TO SWITCH THE PATIENT TO A MORE COSTLY (BUT PROFITABLE) BRAND NAME MEDICATION INSTEAD OF THE COST EFFECTIVE (BUT UNPROFITABLE) GENERIC. WHO IS THE PERSON WHO THOUGHT OF THIS IDIOT PLAN BECAUSE THEY HAVE OBVIOUSLY TAKEN A HEFTY BRIBE FROM THE BIG PHARMACEUTICAL INDUSTRY WHO WILL REAP BILLIONS FROM THIS PLAN. PLEASE NOTE THE PHARMACY WILL ONLY CONTINUE TO MAKE THE NORMAL MARGINS AND NOT A WIND-FALL LIKE THE BRAND NAME COMPANIES. AMP IS NOT CURRENTLY A WORKABLE ANSWER AND MUST BE REJECTED.

Submitter : Mrs. Jill Raicevich **Date:** 02/06/2007

Organization : OPA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The way pricing is going. There is no way to provide a QUALITY pharmacy experience to people who really need counseling. The incentive is not there even if the most well intentioned RPh. is there to help. They will be driven out of business. My husband and I have thought of starting an independent pharmacy but are scared into staying with the big chains who clearly don't practice what they preach. Does anyone remember the phrase "A friend for Life". they were bought out by companies who care more about drive-thrus & selling lotto tickets, and keeping their RPh's on duty in their 24hour stores. How nice it would be to find a company that would treat their RPh's like professional, family men& women. That won't happen if they have to continue to make up for lost money by selling out to the government & insurance reimbursements.

Submitter : Mr. Steven Fettman **Date:** 02/06/2007

Organization : Davies Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

We offer free delivery service to many Medicaid patients. With the proposed cuts, it will restrict access to their meds since so many are home-bound or don't have transportation.

We are still battling the lower reimbursement from Medicare D and have had to cut our store hours as a result. We are an independent pharmacy that has been part of Canton, Ohio for almost 45 years. With these cuts we will have to cut our services as well as access to medications.

Please redefine AMP and be sympathetic to the small business owners that truly care about their patients.

Submitter : Dr. Candace Haugtvedt **Date:** 02/06/2007

Organization : Ohio State University

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to pharmacies. 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.

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

Organization : Mrs. Beth Butcher

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : ohio pharmacists association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : Mr. Tony Jones

Category : Pharmacist

Issue Areas/Comments

Background

Background

Proposed rules regarding reimbursement rates to retail pharmacies.

GENERAL

GENERAL

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

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

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

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

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

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

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

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

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

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

Organization : BVHS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

CMS-2238-P-106 Prescription Drugs

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

Organization : Medicine Shoppe#1065

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

CMS-2238-P-107 Prescription Drugs

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

Organization : BVHS

Category : Health Care Professional or Association

Issue Areas/Comments
GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Mr. Keith Rumpler

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : **Medicine and More Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator Leslie Norwalk,

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

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

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

Organization : **APHA**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Holzer LTC Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. This would be a great tragedy for residents of nursing homes and foster children of which many still have traditional Medicaid in my state of Ohio. In addition, prescribers may be forced to prescribe brand name drugs which would inevitably cost the state more tax dollars to fund very needed programs and services.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Our pharmacy serves a rural population of which about 75% are Medicaid recipients. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

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

Submitter : John Schlitt **Date:** 02/06/2007

Organization : CVS Pharmacy and Ohio Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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 : Amy DeMarsh **Date:** 02/06/2007

Organization : BVHS

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : **Ver Helst Snyder Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

r.e. proposed AMP drug cost basis

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

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

Organization : **Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : **Walgreens**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Antwerp Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Organization : Rite Aid

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

GENERAL

GENERAL

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

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

Organization : Dr. KRISTIE FIELD

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : **Smith's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attatchment

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

#121

Subject: Medicaid Program: Prescription Drugs; AMP Regulation

CMS 2238-P RIN 0938-AO20

Smith's Pharmacy is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates one pharmacy in Virginia. We are the only provider of pharmacy services in the community in which our store is located.

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

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

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

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

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

- Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

- Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Chris Buchanan

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

Organization : Dan Horn Pharmacy and Health Services

Category : Pharmacist

Issue Areas/Comments

Response to Comments

Response to Comments

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

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

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.
Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

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

Organization : kdhhs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Organization : Blacker's Pharmacy Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : **The Kroger Company**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

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

Organization : Ohio Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do 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. William Bidwell **Date:** 02/07/2007

Organization : Giant Eagle

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Dr. James Lindon **Date:** 02/07/2007

Organization : Lindon & Lindon, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I agree with the changes

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

Organization : **sutcliffe pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Response to Comments

Response to Comments

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

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

Organization : CLINIC PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacy owner of an inner city pharmacy that has taken care of poor and aged(Medicaid and Medicare) patients for over 25 years. The proposed definition under CMS-2238-P Prescription Drugs will cause great harm to my Pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. As over 60% of my business is Medicaid the impact of the proposed regulation will certainly put me out of business, leaving thousands of Medicaid patients without service. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the products. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away or as in my case,put me out of business!

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

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

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

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

Organization : **Dr. Robert Maley**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Pohlman Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : The Kroger Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Organization : promise pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

Collection of Information Requirements

Collection of Information Requirements

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

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

Organization : **Mr. nilkesh patel**

Category : **Individual**

Issue Areas/Comments

Background

Background

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

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

Organization : personal comment

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

Organization : **Ohio Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

Response to Comments

Response to Comments

I am writing to express my great concern about CMS-2238-P. The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect. Failing to issue a clear definition will certainly result in many pharmacies going out of business and compromised patient care. Your attention to this matter is greatly appreciated!

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

Organization : myrtle ave. pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

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

4

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

Organization : **Miss. Mary Sparks**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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

Collection of Information Requirements

Collection of Information Requirements

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

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

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

GENERAL

GENERAL

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

Organization : Ohio Northern Univsersity

Category : Other Health Care Provider

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Dr. David Uddin

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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

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

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

Organization : Mr. William Branning

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : OPA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Fitzgerald's Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Regulatory Impact Analysis

Regulatory Impact Analysis

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

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

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

Organization : Webb's Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

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

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

#147

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Organization : Dr. Javier Vazquez

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

CMS-2238-P-149 Prescription Drugs

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

Organization : Jessica Everhart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : MEDICINE SHOPPE

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : ST ELIZABETH'S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : University of Cincinnati College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

GENERAL

GENERAL

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.

Response to Comments

Response to Comments

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.

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

Organization : **Moose Professional Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

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

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

Organization : Mr. Michael Crotty

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Chapman Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Response to Comments

Response to Comments

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Hawkey's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : Pharmacy Student, Samford University

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

Organization : **Chapman Pharmacy**

Category : **Other Technician**

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Response to Comments

Response to Comments

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : University of Cincinnati

Category : Academic

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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

Collection of Information Requirements

Collection of Information Requirements

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.

GENERAL

GENERAL

see

Response to Comments

Response to Comments

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

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

Organization : HealthCare Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : ASP

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Mr. Joseph Jeffries

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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

GENERAL

GENERAL

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

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

Organization : **Ohio Northern University**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Leslie,
Hello, I am Lauren Palowitz. I am currently a 6th year Pharmacy student at Ohio Northern University. I hope to someday open my own pharmacy and I am concerned about how this will affect my pharmacy. I realize that as I student I haven't fully grasped this concept, but I don't understand why the pharmacy is the organization that will be shorted, when the drug companies are who make the greatest profits. I hope to see in the future a way that drug companies have some regulation of what CMS will pay and therefor how much they can charge the pharmacy, but at this point in time, I do not feel that it is fair to pentalize the pharmacy and pay them less than they are paying for a medication.
The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Thanks,
Lauren Palowitz
Pharm D Candidate
Expected Graduation May 07

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

Organization : ShopKo Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Sincerely,

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

Submitter : Dr. Stephanie Hollander **Date:** 02/07/2007

Organization : The Kroger Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Dwight Dobbins **Date:** 02/07/2007

Organization : Harding Road Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Amber Wilkins **Date:** 02/07/2007

Organization : Ohio Northern University

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Reimbursing pharmacies based on AMP is not the best solution to a growing problem which pharmacies are already taking the hit for. As I'm sure you are well aware, pharmacies currently make about 3 cents on the dollar for every prescription that comes through a pharmacy. Cutting into this 3 cents even more is going to result in a decrease in patient care delivered to patients because cuts elsewhere are going to be made to make sure the pharmacy can stay in business.

I would propose further looking into the drug manufacturers who are currently getting about 22 cents on every dollar and who are currently increasing health care costs faster than any other facet in the profession. It is hard to understand why drugs such as Ambien CR get approval from the FDA with little changes in therapeutic effect versus Ambien alone. It is obvious the sole reason for developement is to extend the patton for the brand name drug and to congtinue getting outrageous profits per prescripton. Most manufacturers are enjoying a profit almost double that of most S&P 500 businesses.

Medicaid and Medicare alike are already hurting pharmacies in many states who are currently losing money per prescription based on poor reimbursent rates from the government. Please research this issue furhter and a deeper understanding would allow better alternatives.

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

Organization : Casey Jackson

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. henry hudsor **Date:** 02/07/2007

Organization : Dr. henry hudsor

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

This proposal will drive pharmacies out of business. It is terrible for the profession of pharmacy. Retail drug stores cannot purchase their drugs at the same price as mail order facilities. They should be considered as separate entites.

Submitter : Miss. Stephanie Denham **Date:** 02/07/2007

Organization : Ohio Northern University Raabe College of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. RICHARD CARANO **Date:** 02/07/2007

Organization : VILLAGE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Erie Drug , 4502 Lewis Ave, Toledo, OH 43612

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am an independent pharmacy that has been loocated in Toledo Ohio since 1930. We are a family organization employing 19 people.

Collection of Information Requirements

Collection of Information Requirements

The level at which you set AMP is critical to the survival of my business.

GENERAL

GENERAL

CMS must define AMP as 100% of the cost of the medication to the Pharmacy, if not I feel must providers will withdraw from the Medicare D Program.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

A realistic definition of AMP has to be 100% the cost of the medication to the provider or pharmacy.

Regulatory Impact Analysis

Regulatory Impact Analysis

As I currently understand AMP, it will only cover about 50% of the cost I must pay for medication

Response to Comments

Response to Comments

If AMP is set less then my cost, then we will not participate in the medicare D program, and the recipients will be unable to get medication.

Submitter : Dr. Ned Looney **Date:** 02/07/2007

Organization : Integrative Healt Solutions

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Currently I practice as a Naturopathic Physician but for over 20 years I practiced as a retail pharmacist. The pricing methodology proposed (AMP)is grossly unfair to the retail pharmacy. Only if complete access to all discounts offered at every level, mail order, government, HMO and PPO's are offered to any willing buyer will this system be fair. A level playing feel in the purchase of prescription products is essential for this program to truly bring about the cost savings the bill writes imagined.

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Ohio Northern University/Spectrum Health

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will
cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition,
Medicaid reimbursement will not cover pharmacy acquisition costs.
Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Submitter : **Miss. Kara Kreisher** **Date: 02/07/2007**

Organization : **Miss. Kara Kreisher**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independent may have to turn their Medicaid patients away. My independent store provides low cash prices for those who can't afford their meds along with a lot of other specialized attention that people would not normally receive. We are already struggling to make ends meet, so imagine what will happen if AMP reimbursements take effect, we will not be able to pay our bills and will go out of business.

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

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

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

Submitter : Ms. Joseph M. Lahovich **Date:** 02/07/2007

Organization : The Fred W. Albrecht Grocery Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. Steven Martin **Date:** 02/07/2007

Organization : The University of Toledo College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually eosts my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mrs. Laura Morris **Date:** 02/07/2007

Organization : OPA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

2155 Riverside Drive
Columbus, Ohio 43221-4052

Submitter : Mr. Barry Klein **Date:** 02/07/2007

Organization : Klein's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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.

We serve many mentally ill patients in our pharmacy and this patient population needs their medication inorder to better manage their healthcare and reduce overall health care expenditures that would result in inpatient admission.

Submitter : Mr. John Jackson **Date:** 02/07/2007

Organization : Mr. John Jackson

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Richard Lee **Date:** 02/07/2007

Organization : Northeast Washington Medical Group Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a pharmacist working in a rural setting in Colville Washington. If CMS-2238-P is passed as is, I am afraid that we will have to do one of two things. Either stop filling Medicaid Prescriptions or just plain close our doors. A recently released GAO report found that the reimbursement formula in a proposed CMS regulation, based on new definition of Average Manufacturer's Price (AMP), will result in pharmacists being paid 36 % less on average than their acquision cost on every Medicaid generic drug presciption they fill. According to a national study conducted and released Feb1, by the Coalition of Community Pharmacy Action (CCPA), comprised of NCPA and NACDS, the average cost to dispense a prescription in the United States is $10.500, not including the cost of the medication itself. Taking this into consideration and also the fact that the Bush Administration has proposed $8.4 billion in Medicaid cuts over the next five years, leaves me in a very sad situation. I can not fill prescriptions below my cost and stay in business. No pharmacy can, but this is what the proposed legislation will do to us. And who will be affected the most, it will be the poorest of the poor of our nation because they will no longer have quick access to good pharmaceutical care. Another thing should be noted. I manage a professional pharmacy in a medical clinic, thus we carry very little OTC merchandise. 99% of our sales are prescriptions, thus there is no way to make up the shortfall selling merchandise other than prescriptions.

GENERAL

GENERAL

AMP- based FULS will not cover pharmacy acquisition costs for multiple-source generic medications. The GAO report specifically finds:
"The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquision costs from the same period for 59 of the 77 drugs in our sample. We found that these estimated AMP-based FULs were on, on average, 36 percent lower than average retail pharmacy acquision costs for the first quarter of 2006.-GAO-07-239R p 4.

This report just validates our contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmcy acquisition cost. Using a faulty AMP definition in calculating the FUL will force myself and many other independent pharmacies to close their doors. AMP was never intended to serve as a baseline for reimbursement. If AMP is to accurately work, CMS must define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions not availabel to retail pharmacy.

INCLUSION OF ALL MAIL ORDER PHARMACY PRICES IN RETAIL PHARMACY CLASS OF TRADE. -PG. 29

Hospital and nursing home pharmacies are extended prices not available to retail pharmacy and are not deemed to be "publicaly accessible." Mail order facilities are operated almost exclusively by PBMs, are extended special prices and they are not publicly asccessible in the way brick and mortar pharmacies are publicly accessible. Thus, sales to mail order facilities should not be in cluded in AMP.

INCLUSION OF DIRECT-TO-PATIENT SALES WITH REGARD TO AMP PG. 41

The rebates paid to state Medicaid programs, to the Dept of Defense and to the Dept. of Veterans Affairs are rightly excluded form AMP calculations. At the same time, CMS should also exclude rebates paid to PBMs as these rebates are not available to retail pharmacies. if you do include these rebates paid to PBMs, the AMP would be driven below available market price and thus prescriptions would be filled below cost at retail pharmacies.

HOW PBM PRICE CONCESSIONS SHOULD BE REPORTED TO CMS, - PG 33

There is no regulatory oversight for PBMs, either at the state or federal levels, thus to include rebates discounts, or other price concessions would be improper. There is no transparency in the PBM industry.

ALLOWING THE USE OF 12 MONTH ROLLING AVERAGE ESTIMATES OF ALL LAGGED DISCOUNTS FOR AMP - PG.70

AMP must be reported weekly. If you proceed as decreed by this legislation, the published pricing data will be at least 60 days gehind thee market place pricing. Invoice pricing to community pharmacy continues to change daily thus pharmacies would end up paying more and being reimbursed less. AMP must be reported weekly.

USE OF THE 11 DIGIT NDC TO CALCULATE AMP- PG 80

Based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-digit NDC would not adequately cover phamracy acquision cost.
The 11- digit NDC must be used when calculating the FUL.

ASSESSMENT OF IMPACT ON SMALL PHARMACIES, PARTICULARLY IN LOW INCOME AREAS WITH HIGH VOLUME OF MEDICAID PATIENTS. - PG 110

There is no way I can stay in business and sell prescriptions at 36 % below my cost. I already look for every discount available just to stay afloat. I am a professional pharmacy and 99 % of my business is prescriptions. I don't have an OTC section that you suggest could be used to make us profitable. According to a recent survey of over 23,000 community pharmacies accross this nation, the average cost of filling a prescription is $10.50. That was based on studying the data of over 832 million prescriptions,and that does not include the cost of the medication. If these costs are not covered, in no way can I continue to fill

Medicaid Prescriptions or stay in business

Both GAO and the HHS office of Inspector General have issued reports citing historical variances in reporting the calculation of AMP. If AMP is not properly calculated, disaster awaits us

Submitter : **Ms. Michael Cox** **Date: 02/07/2007**

Organization : **Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist, it is our duty to take care of the patient's needs on a daily basis. We are on the front lines of the health care needs of millions of patients and I find it unfortunate that these pricing guidelines are being considered. Many pharmacies will not be able to operate at a loss and will be forced to close as a result of this change. This will leave many elderly and sick without a local pharmacy and pharmacist to go for medications and questions concernig their healthcare needs. I ask that these pricing guidelines be reconsider so that pharmacies can continue to serve the public's needs in a fair and equitable business environment. Thank you for your time.

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

Organization : Ohio Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do 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.

If you have any questions, please contact OPA.

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

Organization : Ohio Pharmacists Association

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : hesston pharmacy inc

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

I am appalled at the poor design of the Deficit Reduction Act of 2005 and how this will negatively affect retail pharmacy. The recent GAO stuffy estimates that the AMP-based FULS may be on average 36% below our acquisition cost. We can not afford to sell anything below our acquisition costs, let alone 36%. If we don t make a profit, we can t pay our employees, we don t pay the rent, and we are out of business. I have been a small pharmacy owner for 15 years. In that time, we have not has on dispensing fee increase from KS Medicaid. We have has 2 decreases in dispensing fee. Yet all of our expenses have increased. I can t believe our government expects us to provide services below our acquisition cost.

You will have retail pharmacies leaving Medicaid. Medicaid beneficiaries will find themselves without a pharmacy in underserved rural areas.

We are already in a buying group that negotiates for the lowest price. We have been counseling patients to use generics for 15 years to save money. If dispensing a generic costs me money, I will ask the physician to use a different product (a brand name) so that we will receive a dispensing fee. Other pharmacies will be forced to do this also and you will see a shift back to brand names, costing the Medicaid program lots more money in every state.

We have always provided all of our customers Medicaid, Insurance or private pay professional counseling services so they can use their medications accurately and safely. Medications used correctly prevent allergies, drug interactions, hospitalizations, emergency room visits and further drug treatment, saving Medicaid thousands of dollars.

Please don t put your community pharmacists out of business. We spent 6 years in college and we learn continually to keep up with new drugs side effects, drug interactions, and how to correctly use medical devices. We are accessible to the low income and elderly in our communities and they need us. We deserve fair reimbursement.

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

Organization : Ohio Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do 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.

If you have any questions, please contact OPA.

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

Organization : Alert Pharmacy Services, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacy owner how can we dispense medications when we get paid less than what we pay our wholesaler for the medication. No business can survive when you are selling things below the cost. The AMP formula needs to be changed.

Submitter : Miss. LN Nguyen **Date:** 02/07/2007

Organization : Ohio Pharmacists Asociation

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Miss. Victoria Tkacz** **Date: 02/07/2007**

Organization : **Ohio Pharmacists Association**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Cheri Welling **Date:** 02/07/2007

Organization : ONU

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a 6th year pharmacy student at Ohio Northern University. I will graduate in May 2007.

GENERAL

GENERAL

I really think it would be a big mistake to define AMP this way. Aren't we trying to move toward making healthcare more available to everyone?! If AMP is defined this way, some pharmaccies may have to result to turning away medicaid patients to even stay in business. The definition of AMP needs to include the community pharmacy's acquisition costs also.

Submitter : Mr. NICHOLAS RAGAJI **Date:** 02/07/2007

Organization : WESTSIDE PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : R. Bryan Hutcheson **Date:** 02/07/2007

Organization : Bryan's Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Miss. Jen Quellhorst** **Date: 02/07/2007**

Organization : **Ohio Northern University**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Submitter : Miss. Jenna Gorsky **Date:** 02/07/2007

Organization : Ohio Northern University

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Mr. Joseph Ferguson

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Average Manufacturers Price cannot be easily defined as the industry really dose not have a true standard definition. The AMP that each pharmacy varies widely by as low as 2% and can go as high as 80% for non-Medicaid pharmacies. Manufacturer's charge a higher AMP to Medicaid dispensing stores because of the mandated rebate requirement that they must pay to each state for the purchase of these products. In order for pharmacies to continue to provide care for the Medicaid population, they must be given a fair and just reimbursement for their services, otherwise Medicaid recipients will find it harder and harder to find pharmacies willing to contract with Medicaid to provide pharmacy services.

AMP is defined differently by each source of prescription medications. There is no standard. The easiest explanation is that the more that you buy the lower your cost of purchasing. To obtain lower cost requires very very high purchase in quantities similar to the purchases of the Veteran's Administration. This size purchase is beyond the financial ability of anyone except a government if purchasing for an entire nation. It is not achieved by purhasing for a community.

In order for AMP to work, you must provide a mandated requirement that all manufacturer's sale their product at the same price set by you to all purchasers (pharmacies) regardless of the size of the order. In short you at CMS must become price controllers and setters for the nation for the entire pharmacuetical industry. This will insure that you will have a true AMP and that you will be covering pharmacuetical products at 100% of the true cost to pharmacies.

Please rethink your definition of Average Manufacturers Price. It is imparative that you redefine this to cover true community pharmacies acquistion costs. The definition should be issued as soon as possible before AMP takes effect.

Submitter : Ms. Rachel Westendorf **Date:** 02/07/2007

Organization : Ms. Rachel Westendorf

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Peter Ratycz, R.Ph. **Date:** 02/07/2007

Organization : DISCOUNT DRUG MART

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Scott Amstutz **Date:** 02/07/2007

Organization : Ohio Northern University

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : SSHP

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defincd 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 Waters **Date:** 02/07/2007

Organization : Donohoo Pharmacy Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Kristina Reinstatler **Date:** 02/07/2007

Organization : Ms. Kristina Reinstatler

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am currently a pharmacy intern and will be finishing my PharmD in 2009. The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Ms. Desiree Winkle** **Date: 02/07/2007**

Organization : **Ms. Desiree Winkle**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Robert Waters **Date:** 02/07/2007

Organization : Waters Pharmacy Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. KEVIN ARNOLD **Date:** 02/07/2007

Organization : VILLAGE DISCOUNT DRUGS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

IF AMP IS PASSED INTO LAW AS CURRENTLY CALCULATED, OUR PHARMACY WILL COMPLETELY DROP OUR MEDICAID PROGRAM. WE SERVICE 30-40 MEDICAID PATIENTS DAILY WHO WILL BE FORCED TO LEAVE THEIR LONGSTANDING INDEPENDENT PHARMACY RELATIONSHIP AND SEARCH TO FIND A PHARMACY (PROBABLY A LARGE CHAIN WHO WILL NEVER KNOW THEM BY NAME) WHO ACCEPTS MEDICAID. IS THIS REALLY WHAT THE GOVERNMENT WANTS?

I AM ALL FOR COST RESTRAINTS, BUT NOT WHOLLY ON THE BACKS OF PHARMACIES (WHO BAILED OUT MEDICARE PART D BY NOT GETTING PAID FOR MONTHS WHILE MEDICARE GOT THEIR DUCKS IN A ROW.) THE GOVERNMENT IS SUPPOSED TO SUPPORT SMALL BUSINESSES, NOT RUN US INTO THE GROUND.

WHO WILL SUFFER? PHARMACIES AND PATIENTS WHO CANT FIND QUALITY CARE. IT COSTS US ANYWHERE FROM $8-10.00 OVERHEAD TO PROCESS A PRESCRIPTION. THE AMP CALCULATIONS ARE CALCULATED TO PAY US UNDER THE COST WE PAY FOR THE MEDICATION. IS IT REALLY A HARD BUSINESS DECISION TO DROP MEDICAID? NOT AT THOSE COSTS.

PLEASE CALCULATED AMP FAIRLY SO I CAN STAY IN BUSINESS AND GIVE MY MEDICAID PATIENTS THE SERVICE THEY DESERVE.

KEVIN L. ARNOLD
VILLAGE DRUGS
MUSCLE SHOALS, AL 35661
KLARNOLD1@AOL.COM
256 381 8060

Submitter : **Miss. Amy Stroman** **Date: 02/07/2007**

Organization : **Student, Ohio Northern University**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Jeffrey Peterson **Date:** 02/07/2007

Organization : Parson's Canby Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Impact on small pharmacies

Collection of Information Requirements

Collection of Information Requirements

CMS must employ a complete definition on the cost to dispense a prescription

GENERAL

GENERAL

The Definition of 'Dispensing Fee' does not reflect the true costs to pharmacies to dispense 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 billing information; and other real costs, such as rent, utilities and mortgage payments.

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

Organization : Krogers

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Jennifer Kidwell **Date:** 02/07/2007

Organization : OPA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Leslie Norwalk

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Tom Nameth **Date:** 02/07/2007

Organization : Discount Drug Mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Mrs. Ashley Updike** **Date: 02/07/2007**

Organization : **Kroger Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Pharmacies are already struggling to make ends meet, please don't hurt the health care of America!

Submitter : Mr. Marc Pupillo **Date:** 02/07/2007

Organization : PharmD Student

Category : Drug Industry

Issue Areas/Comments

Background

Background

Paying a pharmacy less than what they paid is ridiculous. How are we supposed to provide the care every patient needs when a pharmacy will be forced to understaff and cut corners. In the long run, this will only lead to increased cost to the patient who will not receive the benefit of having a properly run pharmacy.

Collection of Information Requirements

Collection of Information Requirements

Pay a fair dividend.

GENERAL

GENERAL

Paying a pharmacy less than what they paid is ridiculous. How are we supposed to provide the care every patient needs when a pharmacy will be forced to understaff and cut corners. In the long run, this will only lead to increased cost to the patient who will not receive the benefit of having a properly run pharmacy. PAY A FAIR DIVIDEND.

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

Organization : **Ohio Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do 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 : Henry Armbruster **Date:** 02/07/2007

Organization : Henry Armbruster

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

On July 1, CMS plans to begin reimbursing for generics based on Average Manufacturers Price (AMP), which it proposed in a regulation released Dec. 15. Community pharmacies, both chains and independents, will lose money on virtually every one of those prescriptions. The Government Accountability Office (GAO) says that community pharmacies will be paid on average 36% below their acquisition cost for every Medicaid generic drug prescription they fill under a reimbursement formula proposed by the Centers for Medicare & Medicaid Services (CMS). This would effectively put many pharmacies out of business!

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my colleagues in community pharmacy. It is estimated that the reimbursement will be far below what it actually costs many pharmacies 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.

It is not reasonable to expect pharmacies to lose money on each Medicare prescription. Nor is it reasonable to force pharmacies to choose between taking a loss on prescriptions and refusing to provide service to persons in need.

Submitter : **Ms. Lisa Karsten** **Date: 02/07/2007**

Organization : **Kindred Pharmacy Services**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As a practicing registered pharmacist and consultant pharmacist in both
Florida and Massachusetts, these proposed reimbursement changes are beyond frightening. LTC pharmacies can barely survive when providing pharmacy services that are patient focused. This dramatic decrease in reimbursement will affect patient care. We will not be able to afford to provide the services that the alternate care patients require. We are a class of pharmacists that are heavily regulated and now again being punished becasue we are being lumped into groups such as outpatient hospital pharmacies and mail order who DO NOT provide the level of care and services that the LTC industry provides. (and I may add that these special services are mandated by CMS). LTC pharmacies should not be included in this act and we should have our reimbursement stay at the current levels. Many of the Medicare Part D Plans already lump us within the retail parameters and this too is wrong.

Submitter : Mr. Troy Adair **Date:** 02/07/2007

Organization : Wal-Mart

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Line Avenue Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

AMP basis
and
Dispensing fees

GENERAL

GENERAL

AMP basis does not represent true costs to the average retail pharmacy. Please confirm the real costs that a small retail pharmacy incurs.

Medicaid/Medicare dispensing fees should be set at no less than $10 per prescription. Anything less will cause pharmacies to no longer serve medicaid/medicare patients. If you have any questions please feel free to contact me.
Thanks

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

Organization : **Ross Park Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs. Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

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

Submitter : Dr. Devin Trone **Date:** 02/07/2007

Organization : Medicap Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

PLease reconsider this killing of small rural pharmacies. Due to Medicare Part D, Or CMS cuts to the pharmacist, as I see them, My gross margin has been cut by 1/3. My rural pharmacy is in peril of failing. When I close my doors my town in Parma, Idaho will have a 30 round trip to get medicine. Medicaid/AMP cuts will be the final nail in the coffin. If this proceeds, I predict we will see 20% or more of small rural pharmacies close their doors. This will not be good for our country. Especially for our seniors and medicaid populations. It is a bad thing, mark my words.

Submitter : Mr. ANUP DOSHI **Date:** 02/07/2007

Organization : HVA PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

DEAR: Leslie Norwalk

IF THE AMP IS USED FOR PRICING REIMBURSEMENTS, I'M FOR SURE CERTAIN, THAT MY INDEPENDANT PHARMACY WILL GO OUT OF BUSINESS.

GENERAL

GENERAL

PLEASE UNDERSTAND THAT OUR REIMBURSEMENTS ARE SO BAD RIGHT NOW, THAT WE'RE BLEEDING. ANY FURTHER CUTS WILL IMMEDIATELY PUT US OUT OF BUSINESS. INDEPEDENT PHARMACIES SERVE A BIG POPULATION OF MEDICAID PEOPLE. IF WE WERE TO GO OUT OF BUSINESS, A GREAT INSERVICE AND UNJUSTICE WOULD OCCUR.

AMP PRICING IS NOT ACCURATE AT ALL!

THANK YOU

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

Organization : Discount drug Mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The AMP definition proposed under CMS-2238-P Prescription Drugs will cause tremendous harm to our pharmacies. Figures show that reimbursement will be far less than what it actually costs pharmacies to buy the drugs. I respectfully request that CMS redefine AMP to reflect what I actually pay for the product. If reimbursements do not cover costs, many independent pharmacies may be forced 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, and thereby cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more!

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

Organization : Catherine Francis

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization : Dr.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Jason Sloan **Date:** 02/07/2007

Organization : Sand Run Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Response to Comments

Response to Comments

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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 : Jeffrey Hill **Date:** 02/07/2007

Organization : Jeffrey Hill

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

CMS-2238-P-233

Submitter : **Mr. Richard MARLIN** **Date: 02/07/2007**

Organization : **Allen's Pharmaserv, Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, our pharmacy 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. Also, with each manufacturer determining the AMP we as pharmacists are at the whim of the manufacturers. Patients will suffer.

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. TOM MOWBRAY **Date:** 02/07/2007

Organization : CENTERVILLE LTC PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am an independent pharmacy owner, that specializes in unit dose packaging for mental health and mentally retarded patients in group homes and mental health agencies throughout Western Ohio. I am amazed that CMS would cut our prices on generic meds, while the population I service continues to need more forms, documentation and stringent and expensive packaging systems for their meds. We may be forced to exclude certain drugs or certain patients from our service if these price in fact do take effect. There are not many pharmacies who wish to take care of this population, i certainly hope CMS takes another look at this pricing and comes up with something that is fair

Submitter : **Mr. Dustin Melton** **Date: 02/07/2007**

Organization : **Pearman Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

DRA of 2005

Collection of Information Requirements

Collection of Information Requirements

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics. These pharmacies may have access to rebates and price concessions that may not be available to community pharmacy. Consequently, APhA is concerned that AMP may be set at a rate lower than what community pharmacy can purchase generic drug products.

Furthermore, the proposal does not address dispensing fees, thereby allowing States to continue to determine the "reasonable" dispensing fee they are required to pay pharmacists. APhA is concerned that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a $4 dispending fee when studies indicate that the average cost to dispense a medication is approximately $10.

GENERAL

GENERAL

If this proposed rule goes into effect the I am not sure what will happen to independent pharmacies like the one in this community. AMP is based on what Manufacturers sell to wholesalers and then the wholesaler has to make their money before the pharmacy can purchase it. I did read recently that 6 out of 10 of the top 100 drugs used in America the pharmacy would be selling the drugs below what it costs them to dispense them. I have a bad feeling that if this proposed rule is to go into effect because falsly increase AWP's by a third party when Pharmacists are the ones going to be the ones hurting along with the patients. I can see Pharmacists moving patients from cheaper generic medications in exoensive brand medications because of the increase in dispensing fees and profits. I would hate to see it go that way but when you loose money the you must make a choice to keep the doors open. Please take these comments in consideration. Thank you for your time.

Submitter : **Miss. Julie Tapocsi** **Date: 02/07/2007**

Organization : **Ohio Pharmacist Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mrs. Amy Hatley **Date:** 02/07/2007

Organization : Mrs. Amy Hatley

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Ashley Kanuckel **Date:** 02/07/2007

Organization : Ms. Ashley Kanuckel

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Sharon Steinkirchner **Date:** 02/07/2007

Organization : Ms. Sharon Steinkirchner

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to many pharmacies. 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 most 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 : Dr. Timothy Sizemore **Date:** 02/07/2007

Organization : Holzer Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Close to 70% of my business is medicaid claims. We would be forced out of business due to inability to pay staff and expenses. We have a total staff of approximately 30 people who are excellent at what they do and could be force out of work by this proposal. Some of our staff are forced by circumstance to use medicaid services to provide healthcare for there family. This could prevent them from being able to get there prescriptions at our pharmacy.

Submitter : **Dr. Jill Bogus** **Date: 02/07/2007**

Organization : **Ohio Pharmacists Association (OPA)**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Pleasc 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. Jeff Holycross **Date:** 02/07/2007

Organization : Aries Pharmacy

Category : Pharmacist

Issue Areas/Comments

Response to Comments

Response to Comments

The current definition of AMP is too ambiguous and will result in Medicaid patients being underserved. Pharmacists and pharmacies cannot accept reimbersments that are below their costs and remain viable. Any definition of AMP must allow for a reimbersment of at least the cost of the drug. Anything less will force pharmacies to not
service Medicaid clients.

Submitter : **Dr. Angela Grau** **Date: 02/07/2007**

Organization : **Kinney Drugs**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a retail pharmacist practicing in the upstate New York area for nearly eight years.

GENERAL

GENERAL

As a retail pharmacist I urge those in control of this law to realize retail pharmacy cannot survive at the current reimbursement formula proposed. Retail pharmacy has never had so much additional work put on us that receives no reimbursement financial (ex. counseling, helping customers with Medicare D questions-both coverage and formulary choices, etc...) and now they propose to cut our existing reimbursement for prescriptions filled. I feel retail pharmacists play a key role in a patient's overall healthcare management. How can we continue to give our customers so much needed help with insurance problems or medication questions when the scripts we are filling do not even generate the cost of the medication (not even taking into account payroll, real estate, etc...). I realize the cost of prescriptions is on the rise, but someone has to pay for the valuable service pharmacists provide or the quality of that service will be severely compromised. This in turn will only result in the elevation of other healthcare costs down the road. Will someone please stand up for us and realize how much we can help people, but we can't do it for free? Thank you for your time. Angela Grau, PharmD

CMS-2238-P-244 Prescription Drugs

Submitter : Mr. PAUL ZIPP **Date & Time:** 02/07/2007

Organization : Mr. PAUL ZIPP

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Using Manufacturer Wholesale Price will put independents out of business and shrink profits so much at chain pharmacies that prices on everything else will have to go up to compensate. Economic disaster (inflation, etc)

Submitter : Dr. Heather Wolcott **Date:** 02/07/2007

Organization : Star Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

If Medicaid reimburses at AMP, our pharmacy will not be adequately reimbursed for generic drug products or pharmacist services. Pharmacies can not afford to take a loss when filling prescriptions. We need to be paid for services and if pharmacies aren't adequately reimbursed then our pharmacy can not afford to accept or fill patient prescriptions covered by Medicaid.

Submitter : Dr. John Nguyen **Date:** 02/08/2007

Organization : Dr. John Nguyen

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I'm hoping that those that have the ability to control and determine the fate of my business and my patient's quality of life take into account what it takes to run my business. NCPA has finished their annual survey on the cost to dispense and it cost roughly $13 to fill a prescription in California. Plese take that into account. My drug store is in a rural area and it would be a huge problem for many of my elderly to drive an additional 20mins down the mountain to retrieve their medicine. Some have trouble making it to my pharmacy and it may be only 5 mins away. I'm just trying to earn an honest living by doing the best job I can to service my community. This new AMP model is forcing my community to use the only alternative they have to me...hour long wait times, terrible customer service, terrible pharmaceutical care, higher cost out of pocket and the negatives can continue on and on. If you really want to know what impact this will have, you should survey people who use independent pharmacies. Before owning my pharmacy, I use to work at the major chains. I can tell you that they have good people working for them, but their constant need to make a bigger profit manifest itself in poor pharmacy service. I remember I didn't have enough time to take a bite out of my sandwich so you can understand how patients are generally neglected at most chain stores. I didn't want to, but it was the nature of the beast. My though process was...fill fast, fill accurately and don't kill anyone. Customer service...no. Customer anything...no. Just don't kill anyone. That's how the majority of all the pharmacist who work at chains feel. I couldn't keep doing that and felt there should be a better way. So, I went out and made that better way happen. I bought my own pharmacy. In a short period of time I've been able to have a positive influenee on many of my patient's lives, but I fear this will come to a halt with the AMP model. I don't need to make millions and billions like the chains, I just need to keep making a difference in my patients lives. I'm just asking for the ability to better someone's quality of life. I know that the goverment won't flinch if my store closes, but it's not the goverment I'm worried about. Who will eventually pay for this AMP model? It'll hurt me, but I can find a job and start over from bankrupcy. It's really going to hurt all the people who depend on me to coordinate their pharmaceutical care. Many of my patients count on me to arrange everything about their medicines because they don't understand or they aren't able to do so. Do you think the stressed out pharmacist at any chain is going to take the 20mins to counsel them about their drugs? I was one of those pharmacist once and the answer is NO. Not because they don't want to, but because 2 pharmacist can't fill 500 prescriptions and have time to talk to anyone at great length. You can't do that volume and care. By implementing this AMP model, you are essentially taking the last line of help away from those who needed it the most....my patients. I hope you consider what I've written here and I hope you really research the economical impact you will have on all independent pharmacies. I hope you also strive to understand what pharmacies like mine have done to better the lives of many people. I hope you understand that we run on a very thin margin as it stands and we offer so many services now that we don't get paid for. Please survey and talk to those that use independent pharmacies. Please see how important it is to them to continue to have an independent pharmacy to go to. Thank you for your time. John Nguyen Pine Cone Drug

Submitter : Dr. John Nguyen **Date:** 02/08/2007

Organization : Pine Cone Drug

Category : Pharmacist

Issue Areas/Comments

Background

Background

I'm hoping that those that have the ability to control and determine the fate of my business and my patient's quality of life take into account what it takes to run my business. NCPA has finished their annual survey on the cost to dispense and it cost roughly $13 to fill a prescription in California. Plese take that into account. My drug store is in a rural area and it would be a huge problem for many of my elderly to drive an additional 20mins down the mountain to retrieve their medicine. Some have trouble making it to my pharmacy and it may be only 5 mins away. I'm just trying to earn an honest living by doing the best job I can to service my community. This new AMP model is forcing my community to use the only alternative they have to me...hour long wait times, terrible customer service, terrible pharmaceutical care, higher cost out of pocket and the negatives can continue on and on. If you really want to know what impact this will have, you should survey people who use independent pharmacies. Before owning my pharmacy, I use to work at the major chains. I can tell you that they have good people working for them, but their constant need to make a bigger profit manifest itself in poor pharmacy service. I remember I didn't have enough time to take a bite out of my sandwich so you can understand how patients are generally neglected at most chain stores. I didn't want to, but it was the nature of the beast. My though process was...fill fast, fill accurately and don't kill anyone. Customer service...no. Customer anything...no. Just don't kill anyone. That's how the majority of all the pharmacist who work at chains feel. I couldn't keep doing that and felt there should be a better way. So, I went out and made that better way happen. I bought my own pharmacy. In a short period of time I've been able to have a positive influence on many of my patient's lives, but I fear this will come to a halt with the AMP model. I don't need to make millions and billions like the chains, I just need to keep making a difference in my patients lives. I'm just asking for the ability to better someone's quality of life. I know that the goverment won't flinch if my store closes, but it's not the goverment I'm worried about. Who will eventually pay for this AMP model? It'll hurt me, but I can find a job and start over from bankrupcy. It's really going to hurt all the people who depend on me to coordinate their pharmaceutical care. Many of my patients count on me to arrange everything about their medicines because they don't understand or they aren't able to do so. Do you think the stressed out pharmacist at any chain is going to take the 20mins to counsel them about their drugs? I was one of those pharmacist once and the answer is NO. Not because they don't want to, but because 2 pharmacist can't fill 500 prescriptions and have time to talk to anyone at great length. You can't do that volume and care. By implementing this AMP model, you are essentially taking the last line of help away from those who needed it the most....my patients. I hope you consider what I've written here and I hope you really research the economical impact you will have on all independent pharmacies. I hope you also strive to understand what pharmacies like mine have done to better the lives of many people. I hope you understand that we run on a very thin margin as it stands and we offer so many services now that we don't get paid for. Please survey and talk to those that use independent pharmacies. Please see how important it is to them to continue to have an independent pharmacy to go to. Thank you for your time. John Nguyen Pine Cone Drug

Submitter : **Mrs. Dona McGuire** **Date: 02/08/2007**

Organization : **Ohio Pharmacists Assoc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

? 2007 Ohio Pharmacists Association
2155 Riverside Drivc
Columbus, Ohio 43221-4052
voice: (614) 586-1497
fax: (614) 586-1545
e-mail: info@ohiopharmacists.org

Submitter : Emily Zura **Date:** 02/08/2007

Organization : Ohio Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. Luke Henry **Date:** 02/08/2007

Organization : Dr. Luke Henry

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacist, I see everyday how expensive Rx drugs are. I understand that CMS is trying to curb costs, which is understandable. However, the current proposed plan with AMP is NOT the appropriate way. The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many pharmacies 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. This shows that this issue has not been well thought out, and will not save money as intended, but rather will negatively impact patient care.

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. Bryan Leland **Date:** 02/08/2007

Organization : Walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Sally Thompson **Date:** 02/08/2007

Organization : Klein's Pharmacy & Orthopedic Appliances, Inc.

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Rob Schuster **Date:** 02/08/2007

Organization : OPA

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

We have spent the last few weeks in class learning about the proposed legislation. The problem is not the idea of cost containment, the problem lies in where you're trying to contain the cost. Retail stores are barely profitable as is, while manufacturer's margins are 3-5 x that of top Fortune 500 companies. Continue the efforts to cut costs, but I urge you to not cut the legs out from under retail. We are a wonderful resource, especially for those on limited budgets. We are often the closest thing many poverty level folks get to a doctor, so please let us continue to work in a profitable environment. If you want to cut costs, you need to go higher than the retail level, look at the manufacturers.

Submitter : Dr. Stephen House **Date:** 02/08/2007

Organization : University of Cincinnati (PharmD Candidate)

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Nicholas Michel **Date:** 02/08/2007

Organization : University of Cincinnati College of Pharmacy, OPA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it refleets 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. David Noday **Date:** 02/08/2007

Organization : Kids-N-Cures Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

MY NAME IS DAVID NODAY I GRADUATED FROM OHIO NORTHERN UNIVERSITY IN 1982.I HAVE BEEN A PHARMACIST FOR 25 YEARS, AND HAVE WORKED IN BOTH RETAIL AND CLINICAL SETTINGS. I CURRENTLY OWN 2 RETAIL INDEPENDENT PHARMACIES CALLED KIDS-N-CURES, WE HAVE A NICHE PHARMACY THAT SERVES THE NEEDS OF SPECIAL CHILDREN,MANY OF WHOM HAVE MEDICAID AS THEIR ONLY SOURCE OF INSURANCE.

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Megan Vozar **Date:** 02/08/2007

Organization : University of Toledo College of Pharmacy

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Holli Fultz **Date:** 02/08/2007

Organization : University of Cincinnati

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Submitter : Miss. Amy Seiler **Date:** 02/08/2007

Organization : OPA

Category : Individual

Issue Areas/Comments

Background

Background

Pharmacy Student, working in retail

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Cynthia Widmaier **Date: 02/08/2007**

Organization : Haggen, Inc

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed rule does not address our grocery pharmacy concerns that tbe new reimbursement formula will not adequately reimburse pharmacies for generic drug products or pharmacist services (dispensing fee).

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-servicc pharmacies, hospital outpaticnt pharmacies, and outpatient clinies. These pharmacies may have access to rebates and pricc concessions that may not be available to grocery and community pharmacy. Consequently, l am concerned that AMP may be set at a rate lower than l can purchase generic drug products.

Furthermore, the proposal does not address dispensing fees, thereby allowing States to continue to determine the "reasonable" dispensing fee they are required to pay pharmacists. l am concerned that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a $4 dispending fee when studies indicate that the average cost to dispense a medication is approximately $10.

l believe that a more effective way to reduce healthcare costs is to aggressively use the medication management skills of the community pharmacist. The pharmacist should be incentivized to improve the health outcome for patients by coordinating care with the patient's physicians, eliminating unnecessary medications or substituting lower cost therapeutically equivalent medications, and most importantly, incentivized to spend time with the patient on a regular basis to educate and monitor proper prescription drug usage.

Submitter : **Mrs. Brianne Baloga** **Date: 02/08/2007**

Organization : **Mrs. Brianne Baloga**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

CMS-2238-P"

GENERAL

GENERAL

As a pharmacy student and pharmacist as of June 2007, I am very concerned about how CMS is calculating generic drug reimbursement through AMP (Public Law 109-171).
AMP is NOT a pharmacy's actual acquisition cost for medications. A pharmacy will not be able to stay in business and provide community pharmacy services to an expanding Medicare/Medicaid patients with dismal reimbursements at this level. In addition, the report mentions nothing about a reasonable dispensing fee. Dispensing fees help pharmacists compensate for falling reimbursement rates. A poorly calculated AMP will give providers, patients, and other uninformed persons the idea that AMP is reflective of the price that pharmacies pay for medications. AMP does not provide a pharmacy with adequate reimbursement due to poor calculations and lack of a dispensing fee. To gain access to lower acquisition costs requires special contracts that only larger buying groups can attain. Community pharmacies are at a loss compared to hospital/clinic organizations, PBMs, and mail-order pharmacies. These pharmacies may have access to rebates and price concessions that may not be available to community pharmacy. If CMS wants Medicaid and Medicare patients to have access to community pharmacies, then they need to support the community pharmacy. Studies and years of experience have shown our nation that when drug profiles are not comprehensively monitored or patients do not have local access to medications, they end up at the hospital spending more CMS money than if they would have had their medications dispensed and monitored by a community pharmacist.

Thank you for hearing my voting voice.

Very Sincerely,

Brianne Baloga Doctor of Pharmacy Candidate 2007

CMS-2238-P-262 Prescription Drugs

Submitter : VICKY LUCCO **Date & Time:** 02/08/2007

Organization : VICKY LUCCO

Category : Other Health Care Professional

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is

currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

CMS-2238-P-263 Prescription Drugs

Submitter : Mr. CHRIS TOLLIVER **Date & Time:** 02/08/2007

Organization : OHIO PHARMACIST'S ASSOC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

BASICALLY AMP WILL REDUCE OUR REIMBURSEMENT SO LOW THAT WE WILL BE CARRYING INVENTORY AND ACTUALLY LOSING 30-35% WHEN WE GIVE IT TO
TO THE PATIENT. WE ARE UNABLE TO BUY IT AT THE TERMS YOU ARE PROPOSING. I FEEL YOU WILL SEE A DRASTIC REDUCTION IN PHARMACIES
WILLING TO PROVIDE SERVICES TO THIS POPULATION IF THIS IS PASSED-NOT BECAUSE OF OVER-ZEALOUS BUSINESS PRACTICES BUT SHEER SURVIVAL.WHY DO YOU THINK SO MANY PHARMACIES HAVE CLOSED DOORS OR SOLD TO BIGGER BUSINESSES? THE INVENTORY WE CARRY IS EXTREMELY COSTLY AND NEEDS TO HAVE AN ADEQUATE PROFIT MARGIN AND DEFINITELY NOT A NEGATIVE MARGIN AS THIS PROPOSAL WILL HAVE. ALSO YOU NEED TO FACTOR IT THAT WE ARE THE LAST HEALTH CARE PROFESSIONAL TO SEE THE PATIENT PRIOR TO HIM OR HER TAKING THEIR MEDICATION. IS THIS THE PERSON YOU WANT TO DRIVE OUT OF BUSINESS? THANK YOU,CHRIS TOLLIVER

CMS-2238-P-264 Prescription Drugs

Submitter : Miss. Heather Groeschen **Date & Time:** 02/08/2007

Organization : University of Cincinnati 2007 PharmD Candidate

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Samuel Coletta **Date:** 02/08/2007

Organization : Avenue Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

The continued loss of revenue from inequitable reimbersements on medicare part d prescriptions and the continued under reimbersement proposed by GAO.

GENERAL

GENERAL

How about working to correct the take-it -or leave-it contracts that the PBM's force and that are protected by antitrust laws.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Studies performed by Grant Thornton, LLP, used data from more than 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. The study showed that the national average cost of dispensing is $10.50 per prescription. It also will say costs vary significantly from state to state, ranging from an average of $8.50 per prescription in Rhode Island to $13.08 in California.

Submitter : **Date: 02/08/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Tell CMS the following:

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what the pharmacy actually pays for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Date: 02/08/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : RUTH LIGHT **Date:** 02/08/2007

Organization : RUTH LIGHT

Category : Other Health Care Professional

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

he proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

GENERAL

GENERAL

he proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Sara Hermiller **Date:** 02/08/2007

Organization : Sara Hermiller

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Pleasc 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 : Mimi Hart **Date:** 02/08/2007

Organization : Hart Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am an independent pharmacy owner. Many of my Medicaid patients are mentally ill and require that I deliver their medication to their homes in medisets - neither service for which I get paid. If I cannot even get paid what the drugs cost me, I cannot continue to provide these services and many of these patients who are currently in group or supervised homes will have to be intitutionalized. I know my position is not unique and I ask that you consider what other repercussions- both monetary and emotional may come from this decision. Thank you

Submitter : Mr. Dan Stange **Date:** 02/08/2007

Organization : Health Alliance of Greater Cincinnati

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Date: 02/08/2007**

Organization : **Georgia Department of Community Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-272-Attach-1.DOC

Georgia Department of Community Health
Comments to CMS-2238-P
Medicaid Program: Prescription Drugs

Provisions of the Proposed Regulation

Definition of Multisource Drugs
The revised definition of multiple source drugs requiring at least one other covered outpatient drug which is pharmaceutically and therapeutically equivalent and is available in the U.S. market place is a very positive change.

Prompt Pay Discounts
The customary prompt pay discounts extended to wholesalers should be included in the AMP calculation defined in Section 6001(c). The inclusion of these discounts in the determination of the AMP price is critical to obtain a more accurate price. The challenge with the inclusion of these discounts is the timing of the information and its availability for the inclusion at the time the AMP price must be reported to CMS. The application of historical trending should be allowed, but it should undergo close scrutiny/auditing by CMS.

Mail Order and Retail Class of Trade Definition
Mail order pharmacies should be excluded from the retail class of trade definition for purposes of calculation of AMP. The purchasing power of mail order pharmacies and package sizes utilized in mail order pharmacy practice could greatly skew the reported price and the subsequent FUL. Additionally, inclusion of mail order pharmacy in the retail class of trade would further prevent Medicaid agencies from being able to use AMP pricing as a method of pharmacy provider reimbursement. Few Medicaid agencies utilize mail order as an avenue of dispensing medications to their populations. Hence, inclusion of an unobtainable price in the calculation of AMP whose purpose would be for use by Medicaid agencies is not appropriate.

Exclusion of PBM Prices
The average manufacturer price calculation should exclude PBMs who are acting as wholesalers or mail order pharmacies. Additionally, PBM rebates, discounts, as well as service or administrative fees charged by PBMs to manufacturers should not be included in the AMP calculation. AMP should reflect the average price paid by retail pharmacies or wholesalers for drugs distributed to the retail pharmacy class of trade. Retail pharmacies do not benefit from any of the PBM discounts or rebates mentioned above. Therefore, these factors should be excluded from the AMP calculation. However, should CMS decide to include mail order pharmacies in its definition of "retail class of trade," then PBM's acting as wholesalers and or mail order pharmacies would by default need to have their purchase discounts included in the calculation of AMP. Again, CMS is highly

discouraged from including mail order pharmacies (whether associated with a PBM or not) in the definition of retail class of trade.

While the exclusion of PBM rebates and discounts would result in higher AMP prices and impact manufacturers' drug rebate liability, it would also create a price that is more realistic of the average manufacturer price to pharmacies and wholesalers. This makes the AMP more appropriate as it gets included in the FUL pricing as well as making options for pharmacy reimbursement based on AMP more feasible.

Purpose of AMP
AMP now has two primary purposes. One purpose is the basis for which Medicaid rebates are calculated. The other purpose is a component in the calculation of the FUL prices. CMS states that "AMP should be calculated to reflect the net drug price recognized by the manufacturer, inclusive of any price adjustments or discounts provided directly or indirectly by the manufacturer." The DRA also changes the basis of the FUL price calculations to 250% of AMP. Putting these pieces together, Medicaid agencies must recognize that AMP is artificially low and reflects discounts to which retail pharmacies are not privy. Neither is Medicaid privy to the extent of these discounts. The difficulty is that Medicaid must somehow estimate these "price adjustments and discounts" and compensate for these factors when reimbursing pharmacy providers. AMP should not include discounts and other price adjustments not readily available to the retail pharmacy class of trade.

Estimate of Discounts
To make AMP meaningful, the use of rolling average estimates of all lagged discounts given by manufacturers to retail pharmacy class of trade purchasers should be allowed in the determination of AMP prices. Due to the potential fluctuation of these prices and the negative impact on accuracy of the FUL pricing and any other state-defined use of AMP as a reimbursement strategy, these estimates must be allowed. The use of a 12 month rolling average estimate of all lagged discounts to drug purchasers should be applied to both monthly and quarterly reported AMPs.

FUL Inclusion and Determination
The revision to the criteria for FUL inclusion from the presence of three therapeutically and pharmaceutically equivalent multiple source drugs to two such drugs is very positive. CMS should incorporate this methodology for purposes of establishing FULs for multiple source drugs.

FUL calculations should include customary prompt pay discounts extended to retail pharmacy drug purchasers. The method proposed to utilize the least costly therapeutic equivalent identified at the NDC-9 level is acceptable given the prudent measure of checking to make sure the AMP is not less than X percent of the next highest AMP for that drug. The appropriateness of the 30% proposed is not known at this point, and its rationale is not readily apparent from the document.

Submitter : Ms. Sherri Heiman **Date:** 02/08/2007

Organization : Ms. Sherri Heiman

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Jeff Lurey **Date:** 02/08/2007

Organization : Georgia Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

This is a terrible Rule. If this Rule is implemented unchanged, it will be devastating to community pharmacy and the patients these pharmacies serve. Reimbursement rates to community pharmacies are already at rock-bottom. To further decrease these rates, especially in the area of genric drugs, would force many small independent pharmacies out of business. In many rural areas, small independent pharmacies are the only source of healthcare in the community. It makes no sense to drive these businesses out of existence. Additionally, to decrease the reimbursements on generics makes even less sense. Generics offer the only real chance to save money on prescriptions and this rule would act as a deterrent for pharmacies to switch to generics. If anything, incentives to increase generic utilization should be promoted, not the opposite as this rule does. We should be adopting rules that encourage the use of generics by offering additional incentives and we should also be encouraging pharmacists through incentives to provide medication therapy management (MTM) to their patients.

Submitter : PENNY RUNYON **Date: 02/08/2007**

Organization : PENNY RUNYON

Category : Other Health Care Professional

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Submitter : Mr. KEN WARMAN **Date:** 02/08/2007

Organization : WARMAN'S PRESCRIPTION SERVICE

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am an independent pharmacy owner (for 20 yrs) and I am baffled as to why the federal governmental agencies all hate pharmacists. The proposal to pay at AMP is ludricrice- I will lose money on every generic Rx that I fill. Why are pharmacists not allowed to make a profit any longer? Why don't we base your salaries on the GMP and inflation rates from 20 years ago? That seems a fair as basing our reimbursement on something that we can't achieve. We are the ones on the "front lines" helping patients wade thru all of the Part D and managed care messes, and we get rewarded for that by cutting our reimbursements. Get a clue!!

Submitter : Ms. Rebecca Vierling **Date:** 02/08/2007

Organization : University of Cincinnati College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect. This is a serious issue that can hurt medicaid recipients and pharmacies. Thank you for your time.

Submitter : Mrs. Julie Salomone **Date:** 02/08/2007

Organization : Klein's Community Health Center Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. ANITA DAVIS **Date:** 02/08/2007

Organization : KLEINS PHARMACY

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. armand derousseau **Date:** 02/08/2007

Organization : medical city dallas hospital

Category : Pharmacist

Issue Areas/Comments

Background

Background

The specific NDC number of a stocked drug changes frequently throughout the year based on prices, back-orders, availability, and contract changes. When a pharmacist enters a medication order, they don't know what brand is presently on hand. To build all the possible NDC options into our computer systems for selection of the one on hand would bog down order entry efficiency and lead to increasing medication errors.

Collection of Information Requirements

Collection of Information Requirements

NDC number information is unknown at the time of order entry.
A manual look up would greatly decrease efficiency.
Our systems don't allow for the downloading of this information as items are billed.

GENERAL

GENERAL

Not feasible from the vantage point of available labor.
Not economically feasible.
Will create non-compliance and inaccuracy if these obstacles are ignored.
Will cost more to implement than will be saved through refunds.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Will require massive data base building.
Will still not bring identity of the available drug to the pharmaicst at time of order entry.
Will slow down all processes.
Don't have capability to transmit NDC even if we knew the NDC.

Response to Comments

Response to Comments

Not feasible from the vantage point of available labor.
Not economically feasible.
Will create non-compliance and inaccuracy if these obstacles are ignored.
Will cost more to implement than will be saved.

Submitter : Mr. Eric Schmitz **Date:** 02/08/2007

Organization : Ohio Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Date: 02/08/2007**

Organization :

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. JEFFREY LIGHT **Date:** 02/08/2007

Organization : KLEINS MEDICAL EQUIPMENT

Category : Health Care Provider/Association

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Miss. Michelle Chaffins **Date:** 02/08/2007

Organization : OPA/ CMS

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

GENERAL

GENERAL

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. We need to keep the market fair and profitable for all types of business.

Response to Comments

Response to Comments

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

Submitter : Mrs. Cynthia Dapore **Date:** 02/08/2007

Organization : Mrs. Cynthia Dapore

Category : Pharmacist

Issue Areas/Comments

Background

Background

If the Government Accountability Office is correct in predicting that Community Pharmacies will lose 36% on each prescription filled, I am definitely against this bill. I work for an independent Pharmacy which strives to give customer service by giving the appropriate amount of time to each individual customer. You can expect us to stay in business if our reimbursement is below our cost. Please don't support this docket.

Thank you for your consideration.

Cindy Dapore, Rph

GENERAL

GENERAL

I'm sorry. I must have filled in the wrong box. I just want it to be known that this docket would hurt a lot of pharmacies. I work for an independent which strives to give customer service and only provides items related to the medical field. We would not have any means to recoup our losses if the insurance payment was less than cost.
Again thank you for your consideration and please do NOT support this docket

Submitter : Miss. Nicole Mathers **Date:** 02/08/2007

Organization : The Ohio State University College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

If you have any questions, please contact OPA.

Submitter : Mr. Dan Knight **Date:** 02/08/2007

Organization : Uinversity of Cincinnati

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 many pharmacies to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what we 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.
Sincerely,
Dan Knight, Pharm D Candidate

Submitter : Larry Windmoeller **Date:** 02/08/2007

Organization : U of Missouri Health Care Hosptial & Clinics

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express my concern regarding the issue of providing a NDC number on a billing submission per the December 22, 2006 published proposal. The impact on such an issue is itself staggering. Health care organizations are under great, great work volume now and to add a "paperwork" process is unrealistic and not justifiable. With continued process of having multiple generic medications each with separate NDC numbers of the same medication makes this process overwhelmingly burdensome. I request this proposal not be implemented.

Submitter : **Date: 02/08/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Jonathan Nance **Date:** 02/08/2007

Organization : OPA

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

If you have any questions, please contact OPA.

Submitter : terrell mundhenk **Date:** 02/08/2007

Organization : terrell mundhenk

Category : Pharmacist

Issue Areas/Comments

Response to Comments

Response to Comments

I work in the small town of West Alexandria, ohio. Your proposed changes to AMP will drive my pharmacy out of business. The US government seems to be only interested in cutting budgets and fighting wars. It passes legislation to create more work like HIPPA and methamphetamine laws which increase costs. I do not understand what you are thinking. maybe we should just nationalize all of health care!!!

Submitter : Mr. Rod Tobias **Date:** 02/08/2007

Organization : Mr. Rod Tobias

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

Submitter : Ms. **Date:** 02/08/2007

Organization : Ms.

Category : Individual

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

he proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Date: 02/08/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. MARTIN MULLANEY **Date:** 02/08/2007

Organization : MULLANEY MEDICAL INC

Category : Pharmacist

Issue Areas/Comments

Background

Background

I have been in Pharmacy for 45 years and have not seen any AVERAGE pricing reflect any TRUE price. So what do you do but cut the FEES.
Pharmacy has not had any fee increase in decades. The so called AVERAGE cost to dispense a prescription is in excess of TEN DOLLARS.
So if you want to use a true lower cost for the product then you also must use a true average dispensing fee, OK? You can NOT expect pharmacy to eat the cost and the fee while you get pay raises!!

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Regulatory Impact Analysis

Regulatory Impact Analysis

Submitter : Mr. DAVID MAURY **Date:** 02/08/2007

Organization : griffin pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

OUR 3 PHARMACIES EMPLOY 5 FULL TIME PHARMACISTS AND 28 FULL TIME EMPLOYEES. "AMP" PLUS WHATEVER THREATENS TO CRIPPLE OUR STORES TO THE POINT OF CLOSURE. I REQUEST THAT YOU IMMEDIATELY STOP SQUEEZING THE PHARMACIES AND TAKE AN HONEST LOOK AT THE "PBM" PRACTICES THAT CONSTANTLY DECIEVE AND OVERCHARGE EMPLOYERS AND GOVERNMENT. THIS HAS GONE FAR ENOUGH IT TIME TO STOP NOW !!!!!!!!!!!!

Submitter : **Date: 02/08/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. THOMAS ARMENTROUT **Date:** 02/08/2007

Organization : PATIENT CARE PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

I'm a community pharmacist is Fairfield Ohio that provides retail pharmacy services to patients in which we also service some Medicaid patients. We have been an established business since 1980 and I have been a pharmacist since 1975

Collection of Information Requirements

Collection of Information Requirements

AMP needs to be defined so that the community pharmacist can continue to serve Medicaid patients and that it will be for a fair cost assessment of the actual cost that the retail pharmacy pays for the drugs that we provide to Medicaid patients (as well as the dispensing fee or markup must be adequate to continue to stay in business)

Regulatory Impact Analysis

Regulatory Impact Analysis

Please keep in mind the economic impact and the need for medicaid patients to have access to pharmacewutical services in whick requires a fair assessment of what really is AMP when it comes to the retail pharmacy in buying drugs to provide for their patients.

Submitter : Mr. Akram Hussein **Date:** 02/08/2007

Organization : ASP

Category : Individual

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Darren Mertz **Date:** 02/08/2007

Organization : Fred Meyer Stores/ Western Region Division, Kroger

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a pharmacist and pharmacy manager of Fred Meyer #615 at 6305 Bridgeport Way, University Place, WA 98467. I am responsible for the day to day opperations of this pharmacy. I annually review how much it costs our location to fill a prescription beyond the cost of medication based on wages, benifits, insurance, taxes, utilities, rent etc. I feel we run an efficient pharmacy.

Collection of Information Requirements

Collection of Information Requirements

I have become aware of efforts by CMS to recalculate how it reimburses pharamcists dispensing fees through my national pharmacy organization, APhA. A $4.00 dispensing fee is not a realistic number. $4.00 does not adequately reimburse my company for our efforts in the pharmacy.

GENERAL

GENERAL

I hope that my imput regarding a real world cost per prescription will have an impact on your decision for service reimbursement rates.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

As I wrote earlier, I annually review our 'cost per perscription' so we can accurately implement our competative price match policy. It is currently approximately $12.00 per prescription. We are a moderate volume pharmacy and we work efficiently.

Response to Comments

Response to Comments

If CMS goes forward with it's proposed $4.00 dispensing fee, it would be necessary to fill more prescriptions with less resources (people).

Submitter : **Molly Gates** **Date: 02/08/2007**

Organization : **University of Findlay School of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Miss. Erin Shupert** **Date: 02/08/2007**

Organization : **Miss. Erin Shupert**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator Leslie Norwalk,

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

Sincerely,
Erin Shupert, PharmD

Submitter : **Ms. george varughese** **Date: 02/08/2007**

Organization : **CVS/Pharmacy**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Joseph Sabino **Date:** 02/09/2007

Organization : Pure Service Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I operate an institutional pharmacy which provides pharmacy services to patients in long term care facilities in Ohio. The impact of lowering the drug cost compenent would be devasting to the pharmacies in this country. They are already struggling under the preseny arrangements. The AMP pricing that I have seen appears to take rebates to PBM's, hospitals, and large mail order pharmacies in to account. These are not available to even large chain operations let alone the smaller independent pharmacies. The AMP would lead to reimbursemewnt below costs and close most pharmacies in the country. The assertion that pharmacies would seek wholesale sources who would provide pharmaceuticals at these price levels is ludicrous. Implementation of this plan will negatively impact the sick and elderly by reducing availability of pharmacy services. If the government is serious about reducing drug costs, it should impose price controls on the pharmaceutical manufacturers and eliminate the unnecessaary and extravagant costs of promoting and adverttising brand name pharmaceuticals and pay providers fairly.

Submitter : **Mrs. Kara Haven** **Date: 02/09/2007**

Organization : **Mrs. Kara Haven**

Category : **Individual**

Issue Areas/Comments

Background

Background

Educator

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mrs. Mary Parsons **Date:** 02/09/2007

Organization : Mrs. Mary Parsons

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 the reimbursement will be below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. 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. 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 AMP that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect. thank you

Submitter : Mr. Tim Bradner **Date:** 02/09/2007

Organization : Rite Aid

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Acting Administrator Leslie Norwalk,
The proposed AMP definition under CMS-2238-P Prescription Drugs will
cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs. Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to
cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more. Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect. Thank you for your time.

Sincerely,
Tim Bradner
ONU Pharm.D. Candidate 2007

Submitter : zev zylberberg **Date:** 02/09/2007

Organization : Future Pharmacy

Category : Long-term Care

Issue Areas/Comments

Background

Background

We are a long term care pharmacy provider. We supply medications to people in nursing homes,homes for adults, assisted living facilities and group homes. To help these frail adults we blister package the medications. Medication Administration Reports are generated to chart that the medication is taken properly. Delivery multiple times per day and holidays to ensure the doctor's orders are done right away.

GENERAL

GENERAL

A reduction in the reimbursement for generic drugs would eliminate the only area of profitability left for pharmacy. The Brand name drugs cost alot to the pharmacy and the reimbursement is low.The difference in price between the actual cost of the drug anp the AWP is the only way cover the increased cost of a Pharmacist.(There is a severe shortage of Pharmacists)Employee Pharmacists today make over $
100,000 per year. The result of this loss of income will be the inability to have sufficient pharmacists to cover the health care needs of this country

Submitter : Dr. David Kohll **Date:** 02/09/2007

Organization : Kohll's Pharmacy and Homecare

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am the owner of 8 retail pharmacies and healthcare centers. These are my thoughts regarding the change in generic drug reimbursement.

GENERAL

GENERAL

See attachment

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

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

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

Submitter : Mr. JOSELITO DELOSSANTOS **Date:** 02/09/2007

Organization : GANANDA PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

INDEPENDENT OWNER OF A BRAND NEW PHARMACY WISHING TO ACCEPT MEDICAID CLIENTS.

Collection of Information Requirements

Collection of Information Requirements

I DO NOT KNOW WHY PRICES SHOULD BE ADJUSTED BY WE HAVE BEEN CUT QUITE A FEW TIMES ALREADY. I BELIEVE CMS SHOULD LEAVE PRICING AS THEY ARE NOW.

GENERAL

GENERAL

PLEASE BE ADVISED THAT WE HAVE BEEN DRAMATICALLY AFFECTED BY CUTS ALREADY. IF THIS PRICE ADJUSTMENT IS ABLE TO BE IMPLEMENTED I ASSURE YOU THERE WILL BE MANY PHARMACIES THAT WILL CLOSE AND MANY OTHER PHARMACIES THAT WILL NOT ACCEPT MEDICAID PRESCRIPTIONS. THIS WILL EVENTUALLY DECREASE THE QUALITY OF CARE OF MEDICAID CLIENTS AND CAUSE A MAJOR PROBLEM WITH PHARMACIES THAT WILL BE ABLE TO HANDLE THEM. I ASSURE YOU TO LOOK ELSEWHERE FOR MONETARY CUTS.

Submitter : Mr. marcus wilson **Date:** 02/09/2007

Organization : Carthage Pharmacy Services, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

" Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy s acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

" Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy s cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Submitter : Mrs. Diane Gulas **Date:** 02/09/2007

Organization : Mrs. Diane Gulas

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Scott Davis **Date:** 02/09/2007

Organization : Memorial Healthcare System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-2238-P-313-Attach-1.DOC

CMS-2238-P-313-Attach-2.DOC

Memorial Healthcare System

MEMORIAL REGIONAL HOSPITAL • JOE DIMAGGIO CHILDREN'S HOSPITAL
MEMORIAL HOSPITAL WEST • MEMORIAL HOSPITAL MIRAMAR • MEMORIAL HOSPITAL PEMBROKE

February 9, 2007

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

VIA ELECTRONIC SUBMISSION

Re: **CMS-2238-P; Medicaid Program; Prescription Drugs; 71 FR 77174; December 22, 2006; Proposed Rule**

Dear Ms. Norwalk:

Thank you for this opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed rules regarding implementation of provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs and related Medicaid rebate policies.

Memorial Healthcare System (MHS) is a multi-hospital, governmental healthcare organization located in South Florida. We are comprised of four hospitals, a freestanding nursing home, and a number of outpatient clinics and health services. For the year ended April 30, 2006, we admitted almost 75,000 patients and furnished over 630,000 outpatient visits and more than 250,000 emergency room visits. MHS is the safety-net provider of healthcare services for our market area, furnishing substantially all of the hospital and related health care services to the uninsured and underinsured population of southern Broward County, Florida.

All of our hospitals are "covered entities" as defined by section 340B of the Public Health Service Act, and we currently purchase over $16 million of drugs annually under this program for use in our hospital outpatient departments, in our qualified hospital-based clinics, and as take-home medications for our indigent patients. Without our participation in the 340B program, our capacity to adequately serve these patients would be sharply reduced.

Our concerns with the proposed rule are detailed in the attachment to this letter. In short, they are:

- the administrative and financial burden of capturing and reporting NDC codes for drugs dispensed in our facilities;
- technical and operational issues, such as rules that could cause States to impose new rebate obligations on drugs that should be exempt from State rebates; and,

Detailed Comments on Proposed Rule on Prescription Drugs

Regulatory Impact Analysis

Under separate cover (copy attached) we are submitting comments to the CMS Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development (SORA), as well as to the Office of Information and Regulatory Affairs of the Office of Management and Budget (OIRA) regarding the calculated cost of compliance with this proposed rule.

The CMS estimate of 15 seconds per claim clearly underestimates the full cost of compliance and barely covers the time required to simply transcribe the NDC codes on those bills. It includes nothing of the cost of revising current billing systems to capture and retain NDC information, update the NDC information as codes change each calendar quarter, or to identify for each drug dispensed, the actual NDC code for that particular dose.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires the adoption of standard transaction code sets as part of the administrative simplification of claims processing. The original proposal by CMS at that time (August 17, 2000) was to adopt NDC codes as the standard code set for all pharmacy items. Response to this rule indicated an average cost per hospital of more than $200,000 just to implement the change. Additional costs would be expected on an ongoing basis to maintain those systems and operate them.

In response to these comments, CMS issued revised final regulations on February 20, 2003, which eliminated the requirement that NDC codes be used. While this revision still permits them as an option (such as for retail pharmacies), CMS recognized the lack of benefit to offset the cost of this conversion in hospitals.

At a cost of just $200,000 per hospital, the total cost of implementation would reach almost $1.3 billion. The Regulatory Impact Analysis prepared by CMS indicates State and federal savings over 5 years of only $179 million related to the implementation of section 6002 of the DRA. This clearly demonstrates that the cost of implementation far outweighs any benefits to be achieved.

In addition, we believe that the cost of maintaining systems using NDC codes would be even higher than the original $200,000 estimate because of enhancements to drug dispensing and administration systems that would increase the amount of time spent on each drug dispense. Details are included in our attached comments to SORA and OIRA.

FFP: Conditions Relating to Physician-Administered Drugs

Proposed section 447.520 of these rules would compel States to require providers to submit all bills for drugs using NDC codes. Although the DRA only requires submission of data on single-source drugs and the top 20 multiple-source drugs, CMS recognizes correctly that providers and States would need to adopt a single billing system for all claims, rather than one for DRA-

specified drugs and a different system for all others. Therefore, the requirement for reporting effectively covers all billed drugs.

The requirement that hospitals provide NDC codes for each drug is not simply burdensome on hospitals, it may well be technically impossible to accomplish with accuracy without extraordinary efforts and cost.

Without repeating their comments, I would first refer to the concerns expressed by the National Uniform Billing Committee in their letter to former Secretary Donna Shalala (September 22, 2000), comments sent to former Secretary Tommy Thompson by the National Committee on Vital and Health Statistics (February 22, 2001), and by the American Hospital Association (July 1, 2002).

Unit Counts Do Not Match

National Drug Codes are 11-digit identifiers that specify the manufacturer, drug, and package size. Even for single-source drugs, there are generally multiple package sizes available. For multiple-source drugs, especially those that are commonly dispensed, the number of possible NDC codes is enormous. These codes indicate the package size *purchased*, not the package size *dispensed*. For example, NDC #55513-0057-04 represents four vials of 25mcg of Aranesp. If a dose of 25mcg were administered, reporting this NDC code would indicate 100mcg (4 x 25mcg). Currently, this dose of this drug is reported using HCPCS code J0881, 1mcg x 25 units. The technical requirements for converting units are overwhelming, and could lead States to seek rebates on erroneously counted units dispensed.

Business Process Redesign Would Be Required

The state of pharmacy technology today is such that most hospitals of any size utilize drug-dispensing machines located throughout the hospital for timely, controlled dispensing of prescribed medications. These machines are linked to pharmacy-controlled ordering systems that enable professional staff in the hospital to withdraw only the medications prescribed for a specific patient and only in the doses prescribed. Each medication is stored in a unique slot in the machine, which are filled/refilled by pharmacy staff.

In order for those machines to operate properly, medicines must be packaged in unit-dose quantities. The difference in unit-dose quantities and NDC package quantities is noted above. In addition, though, these drug-dispensing machines are used to monitor and control inventory levels. Unit dose packages used to stock these machines may be made up from multiple NDC packages, resulting in a mix of NDCs in a single machine slot.
When a nurse removes a dose of medication from a dispensing machine, that machine communicates to the billing system based on which machine slot was accessed, not based on which individual dose was removed from that slot.

If dose-specific NDC codes are required for billing, then the entire existing process would have to be redesigned. None of the options for redesign are favorable:

- Limit any one slot to only one NDC code. There is limited space available in these machines. Each machine is also very expensive, and takes up space in the hospital. The option of adding more machines to enable the use of multiple NDC codes is not physically possible.
- Purchase only one NDC code for any given drug. This would cause multiple problems. Costs would increase because competing NDC codes would not be accessed when their prices are lower. Shortages of a drug in a particular package size could cause outages in the hospital, or would require the hospital to reprogram all its machines on a regular basis to accommodate NDC changes.
- Disconnect the dispensing machines from the billing system and bill based on the unit-dose package. This would require implementing a manual billing process for all drugs, result in increased labor costs for every drug administered, and likely result in lost charges for hospitals because of the burden of capturing manual data.

These options do not even begin to address the complexities associated with NDC-specific billing for drug compounds that are mixed in the pharmacy, and which are currently billed using a single charge code in the hospital's billing system. Unbundling those compounds for billing would require untold additional staff time, and further redesign of billing systems.

Medicare Billing Requirements are Different

The proposed rule sets forth billing requirements for Medicaid programs using NDC codes. However, the Medicare program requires the use of HCPCS codes, with different units of measure. These two transaction code sets are not readily compatible. Translation can be made from NDC to HCPCS (where a HCPCS code applies), but a single HCPCS code may represent many NDC codes. Hospitals would still have to maintain two separate billing processes that are payer-specific. This is an undue burden on hospitals.

Covered Entities Should Retain the Benefit of 340B Pricing

When disproportionate share hospitals were added to the list of "covered entities" under section 340B of the Public Health Service Act, it was clearly the intent of Congress that these providers be enabled to benefit from the lower prices available for drugs in support of their demonstrated safety-net missions.

Existing law exempts from Medicaid rebates those drugs purchased by covered entities, so that manufacturers are not subjected to a "double rebate" related to those drugs.

The ability to bill the Medicaid program directly as we would any other payer is a vital part of our participation in the 340B program. Since Medicaid rates are based on cost, and cost savings we obtain are realized by the State in their payments for services furnished. Yet we are able to maintain a single, uniform billing process for all patients.

The requirement that the State pursue all available rebates could be construed to require that they pursue those rebates *directly*. This would require us to either carve out all Medicaid drug bills (and again maintain two separate billing systems) or drop out of the 340B program. Manufacturers also suggest that this requirement could cause them to totally discontinue 340B pricing to providers in order to prevent duplicate discounts. The related loss of savings on non-Medicaid patients would be devastating.

We would recommend that the proposed rules be clarified to require States to pursue only those rebates that are not already exempt under section 340B of the PHS Act.

Calculation of Average Manufacturer Price (AMP)

Sections 447.504 and 447.505 of the proposed regulations address the calculation of AWP and best price, which would, if finalized, have some effect on the calculation of prices available to covered entities under section 340B of the PHS Act. There is not sufficient detail provided, and no summary by CMS, of what the overall effect on best price would be of these proposed changes. We would request that CMS analyze the effect on 340B best prices of these proposed changes, and make changes to these proposed regulations that would retain the most favorable pricing for covered entities.

Use of 9-Digit NDC Codes

The rule proposes to require calculation of AMP based on categorizing drugs using their 9-digit NDC code identifier. This level of code, versus the full 11-digit code, excludes information on package sizes. As a result, the ability to publish 340B prices publicly is sacrificed. CMS's position that Congress did not intend the use of 11-digit codes is too limited a reading of the statute. It is not inconsistent with the DRA to calculate AMP based on 9-digit code groupings, but gather and report data at the 11-digit level of specificity for purposes of 340B pricing transparency.

Exclusion from Best Price of Certain Nominal Price Sales

Section 447.508 of the proposed regulations would exempt from best price calculations sales at a nominal price, defined as it has been previously defined. However, the proposed regulations would limit which nominal price sales are so excluded. The proposed regulation includes only *outpatient* sales to certain covered entities, the IHS and DVA.

We note that in the discussion of proposed section 447.505, CMS has already recognized that inpatient prices charged to hospitals in the 340B program are also exempt from best price calculations, based on section 1002(a) of the Medicare Modernization Act of 2003.

Our request is that CMS modify the language of proposed section 447.508 to also exempt those inpatient nominal price sales made to 340B hospitals.

COST ESTIMATE
IMPLEMENT NDC CODES FOR MEDICAID BILLING
MEMORIAL HEALTHCARE SYSTEM
HOLLYWOOD, FLORIDA

Revising Carecast			
Programming changes to report NDC codes			$250,000
Adding new compendium entries for each NDC code	# new entries	10,000	
	# pharmacies	9	
	Time each (minutes)	6	
	Total Minutes	540,000	
	Total Hours	9,000	
	Cost/hr (w/bene)	55	
	Total Cost		$495,000
Revising interfaces to Pyxis and bar-code charting			$50,000
Revising OSPAK			
Cost of canisters for each NDC code	Cost Each	$67	
	Qty	10,000	
	Cost		$670,000
Revising Pyxis			
Programming changes			
Revise billing logic			$50,000
Revise interface to Carecast			$12,000
Build Pyxis controller for new NDC entries	# new entries	10,000	
	Time each (minutes)	3	
	# of Controllers	5	
	Total Minutes	150,000	
	Total Hours	2,500	
	Cost/hr (w/bene)	45	
	Total Cost		$112,500
Training Pharmacy			
	# staff	60	
	# hrs	8	
	Cost/hr (w/bene)	55	
			$26,400
Training Nursing			
	# staff	5,000	
	# hrs	8	
	Cost/hr (w/bene)	28	
			$1,120,000

COST ESTIMATE
IMPLEMENT NDC CODES FOR MEDICAID BILLING
MEMORIAL HEALTHCARE SYSTEM
HOLLYWOOD, FLORIDA

Revising Billing Systems			
Add charge codes for each NDC code			
	# codes	10,000	
	# pharmacies	9	
	Time each (minutes)	3	
	Total Minutes	270,000	
	Total Hours	4,500	
	Cost/hr (w/bene)	100	
	Total Cost		$450,000
Revise billing system to accommodate NDC codes			$50,000
Maintenance of Pharmacy Systems			
Add staff to maintain ongoing NDC changes	# pharmacies	9	
	# shifts	1	
	# staff/shift	1	
	Annual salary/bene	82,000	
			$738,000
Total Cost			$4,023,900
# Hospitals			4
Cost per Hospital (first year)			$1,005,975
Annual maintenance cost			$738,000
Per Hospital			$184,500
5-year cost per hospital			$1,743,975

Memorial Healthcare System

MEMORIAL REGIONAL HOSPITAL • JOE DIMAGGIO CHILDREN'S HOSPITAL
MEMORIAL HOSPITAL WEST • MEMORIAL HOSPITAL MIRAMAR • MEMORIAL HOSPITAL PEMBROKE

January 30, 2007

Melissa Musotto
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-2238-P
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Katherine Astrich, CMS Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
Attention; CMS-2238-P
Room 10235
New Executive Office Building
Washington, D.C. 20503

Re: **CMS-2238-P; Medicaid Program; Prescription Drugs; 71 FR 77174; December 22, 2006; Proposed Rule**

Dear Ms. Musotto and Ms. Astrich:

I am writing to you on behalf of Memorial Healthcare System in regard to the above-captioned proposed rule issued by CMS. This rule would implement certain sections of the Deficit Reduction Act of 2005 (DRA). We are deeply concerned that the regulatory impact analysis prepared by CMS for this rule is significantly flawed for the component relating to reporting of physician-administered drugs. As explained further below, there is a great cost associated with converting to such reporting that far outweighs the projected benefit associated with that reporting. Fair representation of the full costs of conversion would provide good reason for CMS to withdraw this proposal and seek other means to achieve the DRA requirements.

Memorial Healthcare System (MHS) is a multi-hospital, governmental healthcare organization located in South Florida. We are comprised of four hospitals, a freestanding nursing home, and a number of outpatient clinics and health services. For the year ended April 30, 2006, we admitted almost 75,000 patients and furnished over 630,000 outpatient visits and more than 250,000 emergency room visits. MHS is the safety-net provider of healthcare services for our market area, furnishing substantially all of the

hospital and related health care services to the uninsured and underinsured population of southern Broward County, Florida.

Background

Section 447.520 of the proposed regulations implements section 6002 of the DRA, which requires, among other things, that information regarding utilization of physician-administered drugs be collected reported by States "...using National Drug Code [NDC] codes *unless the Secretary specifies that an alternative coding system should be used.*" [DRA §6002(a)(7)(C), emphasis added].

The key purpose of this section of the DRA is to help ensure that States are collecting the full rebates due for drug manufacturers under section 1927 of the Social Security Act.

The regulatory flexibility analysis presented by CMS in this notice makes two broad, problematic assumptions. First, it assumes that most Medicaid recipients who are furnished physician-administered drugs are also Medicare beneficiaries. Second, it assumes that the cost to implement this rule is limited to 15 cents per claim. These assumptions result in an annual cost of only $344,000 nationally, compared to annual benefits from improved rebate collections of about $36 million.

However, when these assumptions are corrected, costs to implement conversion to NDC codes and maintain ongoing changes to those codes range from $1.3 *billion* and up.

Assumptions Required for Full Implementation

The CMS analysis apparently counts only the time required to transcribe the NDC code on a bill. What it fails to count are the costs associated with:

- Revising pharmacy order-entry, packaging, and dispensing systems to be NDC-code specific;
- Training pharmacy staff to utilize NDC codes for billing in addition to inventory control;
- Training nursing and other clinical staff to utilize new codes and revised order-entry systems;
- Maintaining ongoing changes to NDC codes, which are much more frequent than changes to HCPCS codes used today; and,
- Equipping hospitals with additional dispensing and storage tools to segregate differing NDC codes related to the same drug.

Attached to this letter are our comment letter to CMS on this proposed rule and our initial estimate of the cost to convert and maintain our system to use NDC codes instead of HCPCS codes. For our four-hospital system, the cost per hospital over 5 years exceeds $1.7 million each.

In 2000, the Secretary issued final rules implementing standardized transaction codes to be used for healthcare transactions under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those rules required NDC codes as the standard code set for all pharmacy transactions.

Based on feedback from the healthcare industry, final regulations issued February 20, 2003 revoked that requirement. Feedback in part included a cost estimate of $200,000 per hospital to convert to NDC codes, or over $1.3 billion nationally. This estimate per hospital is far below our own, but the national estimate includes many hospitals smaller than ours. Yet even this low per-hospital estimate shows that the cost of implementation far outweighs CMS's estimate of benefit.

Also, CMS has estimated the Medicaid volume based on an assumption that most all Medicaid patients receiving physician-administered drugs are also Medicare patients. In such situations, for hospital-administered drugs, Medicare is the primary payer, and such drugs are not subject to Medicaid rebates.

Furthermore, a substantial portion of Medicaid recipients are under age 65 and not disabled. They include children, pregnant women, and other medically-indigent persons. The number of transactions estimated to be affected by CMS needs further reconsideration.

Finally, the estimate of benefit is also questionable.

All of our hospitals are "covered entities" as defined by section 340B of the Public Health Service Act, and we currently purchase over $16 million of drugs annually under this program for use in our hospital outpatient departments, in our qualified hospital-based clinics, and as take-home medications for our indigent patients. The savings we achieve on these purchases are included in our annual Medicare and Medicaid cost reports, providing the basis for the State to recoup its share of those savings in our Medicaid payment rates.

If we are required to file our Medicaid bills using NDC codes so that the State may directly pursue rebates, there will be *no net savings* to the State for those drugs – the savings is already being achieved. The cost-benefit analysis for our hospitals is all cost, no benefit.

Recommendation

The regulatory flexibility analysis by CMS should be replaced with a more comprehensive, accurate analysis of both costs and benefits. Transition to NDC codes is not warranted, and the Secretary should pursue use of HCPCS codes for reporting, as permitted by the DRA section emphasized above.

Submitter : Dr. danny dang **Date:** 02/09/2007

Organization : independent pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am pharmacist practicing at Congress Pharmacy, an independent entity in New York City. I completed PharmD 2004 at Long Island University,Brooklyn NY. I have dedicated all my time and knowledge to ensure and maximize my patient's health and improve their knowledge on medications and disease states. As well as interacting with health care providers to provide drug informations, treatment options as well as education and speeches to patients and health-care providers.

Collection of Information Requirements

Collection of Information Requirements

Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, GAO-07-239R, December 22, 2006

GENERAL

GENERAL

With all respects to all decision makers, I believe the new proposal medicaid out patient drug reimbursement will jeopadize pharmacist professions as well healthcare system. The proposal was unfair to pharmacists and pharmacy. We are already suffering medicare part D hassles and harrassment from medicare part D plans for slow response, inadequate eligibility, coverage, prior approval information that we spend hours to resolve on our patients behalf. We did it for free. CMS was praising pharmacists' role in helping patients. Instead of rewarding or make our tasks easier, the new policy threatens to force pharmacies out of service due to severe loss on new reimbursement by this policy GAO 07-239R. No healthcare professionals are able to sustain business if they deliver health care service at a loss. As result of this policy, more pharmacies close out, more pharmacists lose jobs, and most importantly patients are not accessible to services.

All decision makers should ask yourself a very basic question before voting, if you say Yes to below questions then you go ahead and support this policy, else I strongly urge you to vote NO.

1.> Are you able to operate a business at a loss for each service to your patients?
2.> Is there a price tag to your health? Is your health is worthless?
3.> When was the last time you or your loved ones fill(antibiotic, asthma, diabetes,etc) prescriptions at your local pharmacies to fulfill your life threatening needs, and now you decide to vote to close those pharmacies and have your prescriptions mailed to you or going distant and crowded pharmacies to bargain your lucks?

4.> How would the pharmacies service would be like when baby boomers are retired? Are you denying them to our services?

I am asking you to rationalize your thinking to make a wise decision for our society. Our society increases needs for pharmacists knowledge and expertise to assist and to improve patients care. Please do not close the chapter on our pharmacist professions.

I am happy and delighted to assist you and any officials to visit my pharmacy and others to witness services and our patients needs then you will have a better information to form a wiser decision.

On behalf of all American Citizens and pharmacy staffs, I would like to thanks for your effort to address pharmacist's concems to your colleague.

Please contact me at 718 665-6771 or email me at dannyd@congresspharmcy.com if I can help you further.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, GAO-07-239R, December 22, 2006

Response to Comments

Response to Comments

Pharmacies close-out, pharmacy staffs will be out of job, services are limited or inaccessible to patients depending on locations, more unnecessary emergencies and hospital services, while saving money by cutting pharmacy reimbursement, the insurance, tax payers and government pays more to unnecessary medical services.

Submitter : Mrs. Julie Perkins **Date:** 02/09/2007

Organization : Batson's Drug Store

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I own the only pharmacy in Elk County Kansas. I am proud that I have had the business expertise to keep my pharmacy afloat after all the changes Medicare Part D created for my rural remote pharmacy. I am writing to voice my concerns over the proposed changes to pricing and AMP. Pharmacies have already taken a HUGE brunt of the price cuts that have occured in the healthcare field in recent years. We have cut back our overhead as much as I see is possible and I greatly fear this next round. We can't take anymore! My customers will have no other option than a pharmacy that is located an hour away from their home. The amount we will be paid to dispense a prescription does not even cover what it costs to fill a prescription. I need to be able to do more than break-even on the cost of the medication. I must also receive enough money to pay for the label, the bottle, the sack, the staple, the receipt, the ink, the electricity, the employee, the heat (or air conditioner), the insurance, the delivery expense, repairs, maintenance, taxes, telephone, sewer, trash, and my time! Do you see where any of these can be eliminated? I don't. Small pharmacies can't take anymore! It may be hard to understand when you have a chain pharmacy on every corner in the large cities, but you are severely damaging rural America! Please stop this from proceeding forward!! We are going out of business at an alarming rate. I BEG YOU, PLEASE HELP!!

Submitter : Gregory Wissel **Date:** 02/09/2007

Organization : Gregory Wissel

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Ms. Teresa Robinson **Date:** 02/09/2007

Organization : Ohio Northern University Student

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Griffith VINCENT **Date:** 02/09/2007

Organization : Sterling Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I own Sterling Pharmacy, a very small pharmacy in a town of only about 2,000 people. The proposed AMP definition under CMS-2238-P Prescription drugs will cause great harm to my pharmacy. It is estimated that the reimbursment 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 actuallly pay for the product. If reimbursments do not cover costs, I may have to turn 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 pharmicies' total ingredient cost. If AMP were defined so that it covers 100% of pharmies' ingredient costs, then an adequate reimbursment could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by my pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover my costs.
If underpaid on Medicaid prescriptions, I will be forced to turn Medicaid patients away, cutting access for patients. Additionaly, the reimbursment 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.

Grif Vincent
740-869-3784

Submitter : Mr. GREGORY DIEHL **Date:** 02/09/2007

Organization : GLEN CENTER PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Congratulations! This proposed reimbursement schedule will complete the job that the insurance companies started and deal the final blow to independent retail pharmacy, perhaps even chain retail. It is fine to lump me in with mail-order so long as I am able to buy at the mail order rate.
I am willing to compete every day on a level playing surface. This legislation will surely push me out of my profession.
Include kick-backs that PBM's receive? How can you? I don't get those rebates.
Pricing updates - why not regulate the industry so they can only raise prices on the every 6 months on Jan 1st and July 1st and they need to provide 60 days advance notice. That way we won't be dispensing Rx's at a loss.
I encourage you to work on the margin you are asking us to.

Submitter : Mr. howard feder **Date:** 02/09/2007

Organization : v.g.h.pharmacy inc

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

Collection of Information Requirements

Collection of Information Requirements

The following is a summary of NCPA s suggested comments to CMS. Specific CMS requests for comment (in bold, with page reference) are followed by an NCPA response.
Inclusion of all mail order pharmacy prices in retail pharmacy class of trade. pg. 29
Public Access Defines Retail Pharmacy Class of Trade
CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be publicly accessible. Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in AMP.
NCPA recommends retail pharmacy class of trade include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies a definition that currently encompasses some 55,000 retail pharmacy locations.
Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade. pg. 31-33
Inclusion in Best Price of PBM rebates, discounts and other price concessions pg. 53
Treatment of Manufacturer coupons with regard to Best Price pg. 55
Inclusion of Direct-to-Patient Sales with regard to AMP pg. 41
AMP Must Differ From Best Price
If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.
CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.
The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the 4
market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.
For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.

GENERAL

GENERAL

Subject: plea for sanity in an insane world
Pharmacy Benefit Managers make so much money from the prescriptions they adjudicate that a PBM officer had enough money to fund his own multi-million dollar campaign for governor of New Jersey. There seems to be something wrong here. The feds are screaming that medicaid/medicare costs too much, then they turn it over to the pbms that are making so much money that a multi-million dollar fine can be easliy handled by them. one pbm is taking over another pbm for 26 billion dollars am i wrong in thinking that the 26 billion dollars will come out of our pockets? the difference in what they charge the insurance and what they pay pharmacies to dispense the medication plus the rebates they get from the drug companies for putting thier drugs on formulary is a trade secret according to them. if they had to let us know how much they were making maybe someone would wake up and put a stop to this rape of the country. don't they see that the pbms are part of the problem not the solution.
the other major component of the problem is the drug companies themselves. they pay more for lobbying, advertising, rebates both to governments and pbms, political contributions both visible and not then they pay to research the original drug. drug price has nothing to do with the cost of the actual drug. in many cases the actual cost of the drug is so low that they can afford to give it away to people who can't afford the price that the various insurances pay for them. drug companies make more money from manipulating dosage forms and making a spectrum of combination products than they do from original research into new drugs. each new dosage form and group of combo-drugs is priced as though it was an original research product.
as long as there are no controls in place for these industries, and as long as they keep supporting the people in power(who have health insurance and retirement

plans that we pay for) we will remain in the pit we have been placed in by the very people we have trusted to get us out of this mess.
this new federal initiative will be the final blow to the independant pharmacies that serve the medicaid / medicare population. the people who spend hours on the phone with the part d plans, doctors and caregivers. we can barely makeends meet now. name another profession that exists on a profit margin of less than 10%. somehow this administration thinks that the burden of high drug prices should be carried by the people making the least money from this situation. the drug companies make billions, the benefit managers have billions of dollars to take each other over, but lets take 90% od 8.4 billion from the people who make pennies and who serve the penniless.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

How PBM price concessions should be reported to CMS. pg. 33
PBM Transparency Necessary to Assess Manufacturer Rebates
PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those adjustments to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory ageney. 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 cstimates of all lagged discounts for AMP. pg. 70
AMP Must Be Reported Weekly
There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.
Use of the 11-digit NDC to calculate AMP pg 80
AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy
5
We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.
Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.
Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. The 11-digit NDC must be used when calculating the FUL.
Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients. pg. 110
CMS discusses impact on pharmacy:
? On independents: potential significant impact on small, independent pharmacies. pg. 101
? On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 (a small fraction of pharmacy revenues). pg. 108
? We are unable to estimate quantitatively effects on small pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. pg. 110
Impact on small pharmacies demonstrated by GAO findings
The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction.

Regulatory Impact Analysis

Regulatory Impact Analysis

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 stateset 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.
6
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.
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.

Response to Comments

Response to Comments

Summary of Key Points:
_ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
_ Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
_ To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
7
1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation: Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Submitter : **Phillip Sollon** **Date: 02/09/2007**

Organization : **Sollon Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

25 Years of Community based retail pharmacy.

Collection of Information Requirements

Collection of Information Requirements

Calculation of AMP
Rebates
Price changes
Costs of dispensing

GENERAL

GENERAL

I am available for more "grass roots" discussion on these topics should anyone wish to contact me.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Published readily available data

Regulatory Impact Analysis

Regulatory Impact Analysis

AMP does NOT reflect costs incurred by independent retail pharmacy.
AWP more closely is associated with true costs.
Rebates are geared to PBM's and mail-order-houses, and are not to be considered available to independent pharmacy.
Prices change daily and at the least should be updated on a weekly basis.
Documented studies show the true costs associated with dispensing.

Response to Comments

Response to Comments

Use of AMP pricing, non-conforming price-updates, and inclusion of high end rebates would be devistating to our business and put many patients at the risk of interrupted health care due to lack of availability and freedom of access to their prescription medications.

Submitter : Mr. Upendra Solanki **Date:** 02/09/2007

Organization : Mr. Upendra Solanki

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The impact of this legislation will be very dramatic. It will be a negative for patients because it will limit access to care. It will also be detrimental to care in the sense that Community Pharmacy will be impacted negatively. A large number of jobs will be lost in community pharmacy and access to the elderly and disenfranchised will be limited!

Submitter : Mr. Joe Wedig **Date:** 02/09/2007

Organization : Mr. Joe Wedig

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Mr. delane bassett** **Date: 02/09/2007**

Organization : **luling discount pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir

I own a small pharmacy in rural central texas. If your proposed reimbursement for medicaid rx's takes affect, my store will be forced to no longer accept texas medicaid. I dread seeing the affect on these old and poor people when they no longer have their medicine . Please reconsider .

Thanks,

Delane Bassett Rph

Submitter : Dr. Wiliam Valutsky **Date:** 02/09/2007

Organization : Methodist Ambulatory Surgery Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

A longer time for the rule to take effect is needed. Currently there are NO sofware programs in place to provide NDC numbers on pt bills. It would take at least a year to develop and test a program to do what is required on this proposal.

Submitter : Mr. edward salser **Date:** 02/09/2007

Organization : edwards drug co

Category : Drug Association

Issue Areas/Comments

Background

Background

i have been in retail business since 1956 and have survived be hard woprk and family
devotion to service. i note that on the horizion is a plan which will effectively no longer allow service to our community or prospects for survival.if prayer would work
i will pray that some one takes stock of what is happening. dear God.

Submitter : Mr. edward salser **Date:** 02/09/2007

Organization : edwards drug co

Category : Pharmacist

Issue Areas/Comments

Background

Background

I NOTE THAT AFTER SERVING THE PUBLIC SINCE THE 1950'S SHE SERVICE TO MY COMMUNITY WILL BE THREATENED AND MY BUSINESS PROBABLY WON'T SURVIVE
WON'T SOME SANITY PREVAIL. I IMPLORE SOMEONE WILL UNDERSTAND THE DAMAGE THAT WILL BE DONE TO RETAIL PHARMACY AND THE PERSONS THEY SERVE

Submitter : howard feder **Date:** 02/09/2007

Organization : myrtle ave. pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

Collection of Information Requirements

Collection of Information Requirements

Public Access Defines Retail Pharmacy Class of Trade
CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be publicly accessible. Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in AMP.
NCPA recommends retail pharmacy class of trade include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies a definition that currently encompasses some 55,000 retail pharmacy locations.
Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade. pg. 31-33
Inclusion in Best Price of PBM rebates, discounts and other price concessions pg. 53
Treatment of Manufacturer coupons with regard to Best Price pg. 55
Inclusion of Direct-to-Patient Sales with regard to AMP pg. 41
AMP Must Differ From Best Price
If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.
CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.
The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the
4
market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.
For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.
How PBM price concessions should be reported to CMS. pg. 33
PBM Transparency Necessary to Assess Manufacturer Rebates
PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those adjustments to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that 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.

GENERAL

GENERAL

Summary of Key Points:
_ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
_ Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
_ To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

7
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 publiely accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.
Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP. pg. 70
AMP Must Be Reported Weekly
There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.
Use of the 11-digit NDC to calculate AMP pg 80
AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy
5
We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.
Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.
Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. The 11-digit NDC must be used when calculating the FUL.

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS discusses impact on pharmacy:
? On independents: potential significant impact on small, independent pharmacies. pg. 101
? On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 (a small fraction of pharmacy revenues). pg. 108
? We are unable to estimate quantitatively effects on small pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. pg. 110
Impact on small pharmacies demonstrated by GAO findings
The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.
The impact on independent pharmacies also cannot be mitigated by an increase in stateset 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.
6
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.
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.

Response to Comments

Response to Comments

Summary of Key Points:
_ The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
_ Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
_ To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
7
1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Submitter : howard feder **Date:** 02/09/2007

Organization : howard feder

Category : Individual

Issue Areas/Comments

Background

Background

Subject: plea for sanity in an insane world
Pharmacy Benefit Managers make so much money from the prescriptions they adjudicate that a PBM officer had enough money to fund his own multi-million dollar campaign for governor of New Jersey. There seems to be something wrong here. The feds are screaming that medicaid/medicare costs too much, then they turn it over to the pbms that are making so much money that a multi-million dollar fine can be easliy handled by them. one pbm is taking over another pbm for 26 billion dollars am i wrong in thinking that the 26 billion dollars will come out of our pockets? the difference in what they charge the insurance and what they pay pharmacies to dispense the medication plus the rebates they get from the drug companies for putting thier drugs on formulary is a trade secret according to them. if they had to let us know how much they were making maybe someone would wake up and put a stop to this rape of the country. don't they see that the pbms are part of the problem not the solution.
the other major component of the problem is the drug companies themselves. they pay more for lobbying, advertising, rebates both to governments and pbms, political contributions both visible and not then they pay to research the original drug. drug price has nothing to do with the cost of the actual drug. in many cases the actual cost of the drug is so low that they can afford to give it away to people who can't afford the price that the various insurances pay for them. drug companies make more money from manipulating dosage forms and making a spectrum of combination products than they do from original research into new drugs. each new dosage form and group of combo-drugs is priced as though it was an original research product.
as long as there are no controls in place for these industries, and as long as they keep supporting the people in power(who have health insurance and retirement plans that we pay for) we will remain in the pit we have been placed in by the very people we have trusted to get us out of this mess.
this new federal initiative will be the final blow to the independant pharmacies that serve the medicaid / medicare population. the people who spend hours on the phone with the part d plans, doctors and caregivers. we can barely makeends meet now. name another profession that exists on a profit margin of less than 10%. somehow this administration thinks that the burden of high drug prices should be carried by the people making the least money from this situation. the drug companies make billions, the benefit managers have billions of dollars to take each other over, but lets take 90% od 8.4 billion from the people who make pennies and who serve the penniless.

Submitter : **Mr. Richard De Vere** **Date: 02/09/2007**

Organization : **Dismukes Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Under the proposed reimbursement regulations outlined in this proposal, I will have to take one of two actions. I will either have to discontinue my participation in the medicaid vendor drug program or I will have to close the pharmacy entirely. Since 90% of We must be reimbursed at a fair price for our products and services or all of us will suuffer.

Submitter : **Mr. steven nelson** **Date: 02/09/2007**

Organization : **Okeechobee Discount Dugs and Big Lake Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Pharmacy Owner for over 25 years, In the profession for over 37 years. Extremely active in the community and served on over 15 boards.Only Pharmacy in Okeechobee County to provide delivery service to shut ins.

Collection of Information Requirements

Collection of Information Requirements

AMP reduction on reinbursement on prescriptions. Particularly generic drugs.

GENERAL

GENERAL

Please reversc this bill, and get off the backs of pharmacy. Go after thc PBM's/Insurance companies and drug manufactures who are making record wind fall profits. All us to make a "fair and descent" living!!!

Response to Comments

Response to Comments

Would drive us out of business.

Submitter : Thomas Cory **Date:** 02/09/2007

Organization : Standard Pharmacy

Category : Drug Association

Issue Areas/Comments

Background

Background

Adjusted Medicaid Reimbursement to Pharmacies

Collection of Information Requirements

Collection of Information Requirements

Redefine AWP

GENERAL

GENERAL

See Attachment - failure to make adjustments to the proposl cluld result in dcminished accessibility of the Medicaid population

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See GAO Report - Talk to a community pharmacist

CMS-2238-P-332-Attach-1.PDF

CMS-2238-P-332-Attach-2.PDF

CMS-2238-P: Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005

As promised, NCPA is providing an outline of our position regarding CMS-2238-P, the agency rule which will redefine Average Manufacturers Price (AMP) for use as a Federal Upper Limit (FUL) in the Medicaid program. The move to AMP will result in a significant reduction in Medicaid reimbursement for multiple source generic medications. NCPA will be submitting a comprehensive set of comments on behalf of community pharmacy, however it is our desire for the Centers for Medicare & Medicaid Services (CMS), the agency that runs the Medicaid program, to receive a significant number of comments from the pharmacy community.

This outline is provided so that community pharmacy's comments will have a more unified theme in order to magnify their impact. Please review the rule and these suggested comments and then submit your own comments to CMS from your perspective.

Comments can be submitted electronically, by mail, by express mail and by hand or courier. Full details are outlined on pages 2-4 of the proposed rule. The proposed rule can be found on the CMS website at: http://www.cms.hhs.gov/MedicaidGenInfo/downloads/AMP2238P.pdf.

NCPA suggests you submit your comments electronically by visiting http://www.cms.hhs.gov/eRulemaking. **PLEASE REMEMBER: Your comments must be received by CMS no later than 5 p.m. on February 20, 2007.** Comments should also be addressed to Acting Administrator Leslie Norwalk.

NCPA comments reference the recently released Government Accountability Office (GAO) report on Medicaid Federal Upper Limits (GAO-07-239R) which can be found at http://www.gao.gov/new.items/d07239r.pdf.

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:

> "The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower

> 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.

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

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

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.—pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP—pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

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

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110

CMS discusses impact on pharmacy:

- On independents: potential "significant impact on small, independent pharmacies."—pg. 101
- On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 ("a small fraction of pharmacy revenues").—pg. 108
- "We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark 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.

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.

Summary of Key Points:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.

2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*

3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Submitter : **Mr. Dennis Foreman** **Date: 02/09/2007**

Organization : **Wal-Mart Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Administrator Leslie Norwalk, I would like to make some comments on the pending definition of AMP for retail pharmacy medicaid reimbursement.

Collection of Information Requirements

Collection of Information Requirements

1. The formula for AMP-based Federal Upper Limits (FUL) in the proposed rule will not cover pharmacy acquisition costs for multiple source generic medications. 2. AMP was never intended to serve as a basis for reimbursement. 3. To be an appriopriate benchmark, AMP must be difined to reflect 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 the way that brick and mortar pharmacies are publicly accessible. 3. Reporting AMP at 11 digit NDC level to ensure accuracy on a weekly basis. 4. Employ a complete definition of cost to dispense which on average is $10.50.

Submitter : Mr. STUART FELDMAN **Date:** 02/09/2007

Organization : CROSS RIVER PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

REIMBURSEMENT

GENERAL

GENERAL

I DON'T KNOW HOW MUCH LONGER WE CAN HOLD ON. FORTUNATELU WE ARE IN A RELATIVELY HIGH INCOME BUSINES ARE AND DO A RELATIVELY SMALL % OF MEDICARE RX'S..HOWEVER MY MAJOR FEAR IS THAT IF THE GOVT ALLOWS THE SEVERE DOWNWARD SPIRAL OF PHARMACY REIMBURSEMENT VIA THE WAC FORMULA IT WILL NOT BE VERY LONG BEFORE ALL OF THE PROVATE PBM'S FOLLOW SUITE. IT WILL THEN BE IMPOSSIBLE TO CONTINUE TO DO BUSINESS AS THE ONLY COMMUNITY PHARMACY IN OUR AREA. THE GOVT NEEDS TO TAKE A LOOK AT THE REAL COSTS OF DOING PHARMACY BUSINESS, STOP SELLING OUT TO THE BIG PLAYERS AND LISTEN TO THOSE WHO ARE PROVIDING HEALTH CARE.

Submitter : **Mr. Charles Moore** **Date: 02/09/2007**

Organization : **Charlie's U-Save Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The use of AMP as currently defined as the basis for the reimbursement of the cost of generic drugs for Medicaid patients will reduce payment for those drugs to a level where my pharmacy will not be able to provide them to Medicaid patients. The AMP was designed as a way for drug manufacturers to report what they are charging for their product to CMS,and is to their advantage to report the lowest prices they charge(which are NOT available to the retail pharmacy providers), since the lower the cost, the lower the rebates they have to pay. To be accurate for the retail pharmacy sector, the prices charged to classes of trade such as the VA, mail order pharmacy, and direct to the consumer programs by the drug manufacturers must be excluded from the AMP calculation. The drug manufacturers will not give retail pharmacy the same low prices, or the rebates they give to these classes of trade, and any reimbursement from CMS/Medicaid that is based on those prices will be much lower than the the net cost of goods available to my retail business. My business has already felt the impact of low dispensing fees and low reimbursement from the Medicare D drug plans(our net profit was down $40,000 from 2005, which means NO profit for 2006), and as you are well aware, the SSI disability people and senior Medicaid eligible people have been moved into the Medicare D plans. To further reduce the reimbursment for the remaining Medicaid recipients to a level where as a business man I can no longer afford to accept the Medicaid contract will limit the availability of pharmacy services to the patients in my area. My pharmacy is the only independent pharmacy in a 40 mile radius that offers not only prescriptions, but other health related services to the Medicaid clients in our area. The health needs of thosc patients will not be served in a timely fashion if their last remaining access to pharmaceutical care is limited by forcing independent(and chain) pharmacies to refuse Medicaid contracts, or go out of business if they accept them. I have spent all my pharmacy career trying to build a business that I could pass on to the next generation of independent pharmacists, and between Medicare D, and AMP reductions to reimbursement and am seeing all of those aspirations evaporate before my eyes! Please take into consideration the report of the GAO and the impact AMP will have on reimbursement to retail pharmacy, as well as the cost of dispensing survey information that places the national average overhead cost(not including ingredients) at $10.50 per prescription. A fair AMP figure can be arrived at, but ALL of the factors effecting retail pharmacy have to be part of the computation to make it accurate!

Submitter : Joyce Miller **Date:** 02/09/2007

Organization : Joyce Miller

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Mr. David Seaman** **Date: 02/09/2007**

Organization : **Community Care Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Acting Administrator Leslie Norwalk,

The proposed AMP definition under CMS-2238-P will cause great harm to the operation of my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pahrmacy to purchase the drugs we dispense. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, we will no longer be able to serve Medicaid patients. It is estimated that as defined, AMP will only cover about half the market price of generic drugs purchaed. I ask that AMP be defined so that it covers 100% of my pharmacies acquistion costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away. My pharmacy included.

Please issue a clear definition of Average Manufacturers Price that covers my pharmacies acquistion costs. The definition must be issued as soon as possible before AMP takes effect as I am concerned that it will have negative financial and social effects.

Submitter : **Date: 02/10/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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 2than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006. -GAO-07-239R p.4

This finding validates community pharmacy s contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates

AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report Medicaid Drug Rebate Program Inadequate Oversight Raises Concerns about Rebates Paid to States (GAO-05-102).

However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in Best Price but should not be included in AMP.

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

3

GENERAL

GENERAL

Small retail pharmacies are being picked on for no reason. These pharmacies are the backbone of your medicare prescription drug program. Your proposed rules will make reimbursement levels so low that these small businesses will lose money on every transaction. Large insurance companies have enjoyed double digit

growth in their profits from your program while small providers are struggling to stay in business. We are on the front lines of the health care industry and why CMS has chosen to put small pharmacies out of business is a mystery. We have given out medicine to senior citizens and low income people without getting paid. What does CMS have against us? Comments by CMS suggesting that pharmacies can make up the loss in revenue by sale of other items is ludicrous and insulting. Small pharmacies get 90 percent of thier business from prescription sales. How can they stay in business when losing money on every transaction. Why does CMS allow Large PBM companies to run its medoicare program with no intervention while scrutinizing small pharmacies to the point of irrationality. These large PBM's have been sued for shady business practices in at least 12 to 15 states. wHY HAVE YOU TRUSTED THEM WITH YOUR PROGRAM. wHY DO YOU PROPOSE TO GET 90 PERCENT OF THE MONEY FOR YOUR CUTBACKS FROM THE BACKS OF SMALL PHARMACY OWNERS WHO HAVE ALREADY SUFFERED EVERY TYPE OF CUT KNOWN TO MANKIND AND HAVE BEEN GOING OUT OF BUSINESS LIKE WILDFIRE. We have supported CMS in all thier efforts only to be cut and cut and cut and cut. Small pharmacies sometimes dispense a 500 dollar medicine for less than one dollar profit. Why are you trusting PBM's who are juggling menufacture discounts and playing the spread game to make it appear as they are saving you money when in truth they are averaging close to 20 dollars profit on every prescription while giving the retail pharmacy approximately one dollar per prescription. I ask you to reconsider these cuts and save the small independent pharmacy

Submitter : Dr. Tony Cassar **Date:** 02/10/2007

Organization : Dr. Tony Cassar

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed rate of AMP will provide margins result in pharmacies to be able to operate at best at break-even or probably result in substantial operating loses.

GENERAL

GENERAL

First, forgive me if I am not responding correctly. It is my first time.

I own an independent community pharmacy. I oppose proposed used of AMP to change reimbursement rates to pharmacies. Current state of community pharmacy is challenging at best. My margins, particularly since Medicare D implementation, have dropped dramatically compared to what I was receiving from Medicaid. We spend a substantial amount of time helping patients and doctors navigate the new Medicare plans and their formularies. We, unlike chain drug stores, make investments directly in the community by supporting community organizations and hiring locally. In addition we come in early, stay late, and deliver to clients who have difficulty with aceess.

Our current situation is that we simply make little or no margin at all brand name medication. For example, I provided $804 worth of medication to a patient and only received $6 margin. Hardly covering the carrying cost of such medicaiton, this was truly a losing prosition.

Instead of slashing payments for generic medication, which is what would occur with the proposed change to AMP, we should be encouraging it. Is is the use of generics that allow us to survive. Loss of indpendent community pharmacies will mean a real challenge to access in the most vulnerable communities as well as oligopolies of large pharmacy chains.

I support the review of why medication is so expensive, but reducing reimbursement to pharmacy is looking at the wrong player in the pipeline. It is like forcing gas station owners to reduce the price to consumers using price controls. Pharmacy does not control over costs of either medication or insurance to pay for them. Why isn't any concerted effort being made to take on the huge lobbying of PHARMA and the insurances. Independent pharmacy is certainly not posting the gains that you will find in these market sectors.

Submitter : **Date: 02/10/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I work at an independent pharmacy where about 75% of our customers are on Medicare Part D. The problem is that the dispensing fees that we receive do not cover the costs of providing pharmacy services ...things like labor, computers, delivery services, inventory control, rent, utilities, insurance, etc. A typical $2.50 dispensing fee we receive per perscription for our typical 100 perscriptions a day doesn't even cover the labor cost of a single pharmacist, let alone any of the other costs mentioned about.

If we want quality pharmaceutical health care delivery to continue in this country, then the rules must be changed. Otherwise we will drive all the independent and community pharmacies out of business and at the same time allow record profits for health insurers, PBMs and drug manufactures.

Imagine a future without local pharmacies to provide advice, guidence, and answers concerning medication issues. The 1-800 call centers in India and China havc been great for the computer industry but not so great for the millions of American computer users.

Yes, we need to make sure that we provide drug benefits for our aging population at reasonable costs, but we also need to ensure that the future health care system we create is one that we really want. I want a future where I'll be able to go to my local pharmacy ... and I hope you do too.

Submitter : **Dr. Thomas Buford** **Date: 02/10/2007**

Organization : **Leoni Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Leoni Pharmacy is an independent retail pharmacy that has been in continuous operation for 103 years. I have owned the business since 1987. Approximately 22% of all prescriptions we fill are for Medi-Cal (California Medicaid) patients.

Collection of Information Requirements

Collection of Information Requirements

Calculation and use of AMP for reimbursement.

GENERAL

GENERAL

I implore you to reconsider the implementation of AMP in its current form. The effect on community retail pharmacy and the patients we serve would be devastating and permanent.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Information used in responding to the proposed regulations was collected from internal operating documents as well as financial statements.

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposal to include mail order pharmacy in the same class of trade as retail pharmacy is inappropriate. Mail order pharmacies are not publicly accessible like community retail stores are, and, more importantly, have access to pricing and manufacturer rebates that community retail pharmacy does not have access to. While manufacturer's commonly give rebates, these rebates have never been paid to, or received by community retail pharmacy. AMP must accurately reflect what is actually paid by community retail pharmacy for multi-source generic drugs. Perhaps mail order pharmacies should have their own version of AMP, reimbursing them at their cost. But to include their costs in retail pharmacy's AMP calculation is completely inappropriate. Additionally, AMP's must be updated weekly to be able to accurately reflect cost changes that occur on a daily basis by manufacturers. To report these changes less frequently is disregarding reality. Multi-source generic products have price fluctuations, both up and down, that necessitates weekly updates. Also, CMS must include a complete and accurate definition on the cost to dispense. The definition must include valuable pharmacist time that is required to care for medicaid patients and fill their prescriptions. This should include counseling, phone calls, faxes, e-mails, contacts with Medi-Cal and PBM's, overhead costs associated with running a business, and a reasonable profit. Business that does not remain profitable closes, thus a reasonable profit must be included in the dispensing fee definition. The GAO has stated that the currently proposed AMP calculation would result in community retail pharmacy being paid 36% below acquisition cost. No amount of dispensing fee would cover this shortfall. Both the AMP and the dispensing fee need to be realistic. All price concessions, rebates, or other discounts given by manufacturers must excluded from AMP for retail pharmacy, since community retail pharmacy is excluded from receiving these manufacturer perks. All mail-order and PBM pricing must be excluded from the AMP, as both are extended special manufacturer pricing that is not available to retail pharmacy, and mail-order pharmacies and PBM's are not publicly accessible as retail pharmacy is. AMP must be reported using the full 11 digit NDC number; using only 9 digits would not accurately reflect the cost of the drug being dispensed to the patient.

Response to Comments

Response to Comments

If CMS implements these proposals to AMP, my pharmacy's profit would decline by approximately 70%. Medi-Cal patients would no longer be profitable for us to serve, and not only would I have to stop accepting Medi-Cal patients, but because of the decrease in prescription volume, I would have to lay off employees as well. I am not sure at this point if I would be able to stay open under this scenario, but at the very least I would have to evaluate whether or not my return on investment would warrant closing my store and redeploying assets elsewhere. I find it absolutely absurd that CMS is proposing a reimbursement reduction of this magnitude while their own assesment says that the impact would be significant on small, independent pharmacies. CMS' own estimates put the 'savings' at $2 billion by 2011: this equates to the average pharmacy seeing a decrease in profit of roughly $35,000 annually. I assure you this is not a small fraction of my profit. My store is staffed appropriately right now for the number of patients and prescriptions we fill. To offset that $35,000 loss, I would have to let go two employees. With two fewer employees, we could no longer provide appropriate care for our patients. Additionally, the GAO findings show that the proposed rule would cause small independent pharmacies to lose 36% on each transaction. No business can continue when losing money on every transaction. No increase in volume can make up for this loss. There isn't 36% worth of fat to be cut out of my operation.

Submitter : **Date: 02/10/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Reimbursments to Pharmacies

Collection of Information Requirements

Collection of Information Requirements

36% lower payments!

GENERAL

GENERAL

Less enrollment in Pharmacy Colleges, more shortage of pharmacists, rejection of state and federal funded " careless programmes" and and eventually " Death of Pharmacist" profession!

Regulatory Impact Analysis

Regulatory Impact Analysis

Currently, Independent Pharmacies are struggling hard, Centralization, forceful mail orders, big corporate's globalisation---ALL are destroying the traditional American values! Greed by the " Big Fish" will eventually lead to the "law of jungle" without social and intellectual values..a phenomenon which Europe has long ago rejected!

Submitter : **Mr. James Pennington** **Date: 02/10/2007**

Organization : **Seaside Family Pharmacy, L.L.C.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Not completely sure of info desired for this section, but will proceed with personal "background". I am a community pharmacy owner with much at stake, thus keen interest in the way prescription reimbursements are affected by referenced docket:CMS-2238-P. I have 34 years experience in the retail drug store industry, but just 9 months as an owner of my own business. My store is small and convenient to a fairly large community of seniors and younger families (70/30 mix). We offer traditional pharmacy services to our clients including free delivery. We accept all medicare part d plans.
Our business is progressing as expected and if the trend continues we should have 2007 sales of approximatly $1.8 million (97% of that will be from prescription sales and about 90% of rx sales are from third parties such as medicare part d plans and other insurance plans). Now for the bad news. It will be very difficult for my small operation (4 employees including self) to break even in 2007!

Please see general comments.

GENERAL

GENERAL

It is obvious that my business must at least break even for me to continue to remain open and to provide what I believe is an essential service to my community So, my commentary to you is simply a request to allow me the opportunity to continue to provide service to my community and jobs for at least 4 people. How can you help?

1. Allow me and other independent pharmacy owners a level playing field. Not fair to allow rebates/discounts etc to PBMs, Ins. company pharmacies and government agencies and not to the independent business owner. Why not just get rid of the complicated and difficult to regulate rebate system (which invites or even demands conflict of interest). To the drug manufacturer...just submit your best price. If it is fair as compared to others..you will be on the formularies.

2. Regulate the PBMs and insurance companie's contracts with retail pharmacy. Currently independent pharmacies are handed a take it or leave it contract for services and have only the choice of having that business or not having it (remember, 90 % of my business is via third party contracts). Please keep in mind that these contracts are designed by companies, some of whom are under investigation in 20 or more states for using 'questionable business practices'...this a matter of congressional record.

3. Considering item #2., a GAO study recently determined that the average cost to dispense a prescription is $10.50. I would appreciate your consideration of this information when considering reimbursements for medicare/medicaid rx's. What would be wrong with a simple system (no rebates/discounts(kickbacks))that prices each prescription at net cost (*not AWP) + $10.50??? Simple to administer, regulate and oversee.

Thank you.

J.D, Pennington, Pharmacist

Submitter : Mr. Jaroslaw Palylyk **Date:** 02/10/2007

Organization : Rx Care Pharmacies Inc.

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

Background

Background

We are a long term care pharmacy servicing skilled, assisted living, and group home facilities for the mentally retarded

Collection of Information Requirements

Collection of Information Requirements

The proposed legislation and the reduction of the cost basis reimbursement to pharmacies for medicaid recipients will be devastating to both the patient as well as the pharmacies servicing those patients. The time and effort involved in filling prescriptions in special compliant unit dose packaging, checking for any interactions and finally for delivery will never ever be covered by the proposed fees and costs associated with the proposed legislation. Please reconsider the issues, speak to the pharmacy leaders across the country and the health care workers associated with the facilities serviced to understand all the issues in a much more realistic way.

Submitter : Mr. JEFF NEIDIG **Date:** 02/10/2007

Organization : MEDI-WISE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. Anna D'Andrea **Date:** 02/10/2007

Organization : OPA

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Attention: Acting Administrator Leslie Norwalk.

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Thank you for your time,

Dr. Anna D'Andrea, PharmD

Submitter : Mr. Mark Baychuk **Date:** 02/10/2007

Organization : Vitality Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I own a retail pharmacy close to Lij and Schneiders and the proposed cost will be devasting to my pharmacy. We supply services like compounding for children, which at this time is not reimbursed already, we have 2 drivers which are out all day delivering to the hospital and to the elderly in the neighborhood, we also go as far as picking up food for the elderly if needed in bad weather. We supply a large amount of surgicals, and injectables also. The cost of doing all this is enormous and the constant increase in the cost of insurance for health, vehicles and pharmacy raise as much as 18 percent per year. The cost of rent is enormous. The amount all insurances are reimbursing are steadily decreases as also you are proposing. Our utilitys increase each year also. So with all this happening to pharmacys ,does any one think a pharmacy can surive in this environment? Instead of a decrease in payments the pharmacys there needs to be INCREASES. So please stop this because the needs of all our communties will be negatively affected by this.

Submitter : Mr. Dennis Blank **Date:** 02/10/2007

Organization : Mr. Dennis Blank

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AMP has of yet been to show an accurate provider product cost. Until such, as well as how the current product basis of cost relates to the cost of service provided, it should not even be cosidered as as a new structure for reimbursement. AMP is so low, it will eliminate prescription providers, and as a net result, reduce needed drug therapy services to the public. STOP before irreversable damage is done to the society.

Submitter : wilton youngblood **Date:** 02/10/2007

Organization : lowe's marketplace pharmacies

Category : Pharmacist

Issue Areas/Comments

Background

Background

I WISH THE GOV. WOULD GO AFTER THE MANUFACTURERS FOR LOWER COSTS INSTEAD OF ALWAYS COMING TO THE RETAIL OUTLETS FOR PRICE CUTS. IT COSTS US ABOUT $9.44 TO ACTUALLY FILL A RX TODAY. IT IS DIFFICULT FOR US TO OBTAIN DRUGS FROM COMPANIES OUTSIDE THE LARGE WHOLESALERS, SO IT MAKES IT DIFFICULT TO BUY AT SOME CHEAP-CHEAP GENERIC PRICE. THANKS, W.E. YOUNGBLOOD DIRECTOR OF PHCY OPERATIONS LOWE'S MARKETPLACE PHARMACIES.

GENERAL

GENERAL

SEE BACKGROUND

Submitter : Mr. Timothy Kirk **Date:** 02/10/2007

Organization : Bedford Pharmacy, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. scott palmer **Date:** 02/10/2007

Organization : A & P PHARMACY, INC

Category : Pharmacist

Issue Areas/Comments

Background

Background

GOVERNMENT NEEDS TO UNDERSTAND THAT THE COST OF FILLING A PRESCRIPTION GOES WELL BEYOND THE COST OF THE DRUG. EACH PHARMACY MUST EMPLOY ANCILLARY STAFF TO WAIT ON THE CUSTOMER, TO ANSEWER THE PHONE, TO FAX AND PHONE THE DR. FOR CLARIFICATION, REFILL REQUESTS, AND INSURANCE ISSUES. THE PHARMACIST MUST HAVE TIME TO COMMUNICATE WITH THE CUSTOMER TO MAKE SURE THEY UNDERSTND THEIR MEDICATION, IT'S PURPOSE, WHEN TO TAKE, POSSIBLE EFFECTS AND SIDE EFFECTS, AND WHAT THEY SHOULD EXPECT FROM THEIR MEDCIINE. WITH MAIL ORDER NOT HAVING TO DEAL WITH THE PUBLIC PER SE, AND PRIMARILY RELYING ON WRITTEN TEXT TO COMMUNICATE WITH THE CONSUMER, WE AT THE RETAIL LEVEL ARE LEFT WITH THE RESPONSIBILITY OF HAVING TO PROVIDE VALUBLE INTELLIGENCE TO THE CONSUMER WHILE NOT RECEIVING THE UNFAIR COST DISCOUNTS THEY DO. THEY DO NOT HAVE TO DEAL WITH INSURANCE, FOR IN FACT THEY REPRESENT INSURANCE. THE COST OF HEALTHCARE MUST TAKE INTO ACCOUNT MORE THAN JUST A SIMPLE COST OF THE DRUG.

Submitter : Dr. SUZANA GIFFIN **Date:** 02/10/2007

Organization : CENTRAL CARE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

If AMP is to accuratly serve both purposes CMS must define AMP to reeflect the actual cost paid by the retail pharmacy, excluding all rebates and price concessions not available to retail pharmacy.All rebates and price concessions are appropriatly included in "Best price" but should not be included in AMP. An accurate definition of AMP and BEst Practice will set an accurate baseline for reimbursement.This will ensure use of more affordable generics, thus saving money for the healthcare system while promoting effective patient care.
Community pharmacists as I serve not only as dispensing pharmacies, but we provide complete patient medication management and help patients, especially elederly stay compliant with their medications so they don't end up in the hospitals -thus reducing cost to CMS- also we prevent patients from harmful drug - drug interactions as we know not only their medication history, but also their entire medical history and serve as guardians for patients and a doubel check for physicians.

I ask CMS to seriously take community pharmacists comments and NCPA's comments before doing something so detrimental to our patients, our community and our country.

Regulatory Impact Analysis

Regulatory Impact Analysis

If AMP is to accuratly serve both purposes CMS must define AMP to reeflect the actual cost paid by the retail pharmacy, excluding all rebates and price concessions not available to retail pharmacy.All rebates and price concessions are appropriatly included in "Best price" but should not be included in AMP. An accurate definition of AMP and BEst Practice will set an accurate baseline for reimbursement.This will ensure use of more affordable generics, thus saving money for the healthcare system while promoting effective patient care.
Community pharmacists as I serve not only as dispensing pharmacies, but we provide complete patient medication management and help patients, especially elederly stay compliant with their medications so they don't end up in the hospitals -thus reducing cost to CMS- also we prevent patients from harmful drug - drug interactions as we know not only their medication history, but also their entire medical history and serve as guardians for patients and a doubel check for physicians.

Submitter : **Michael Krusling** **Date: 02/10/2007**

Organization : **Mike's Batavia Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am the owner operator of a small semi-rural independent pharmacy. Current proposed lesgislator will put me out of business, and will have a negative impact on my customers, especially those customers receiving medicaid services.

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. kevin feicht **Date:** 02/10/2007

Organization : Mr. kevin feicht

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. KEVIN GAHM **Date:** 02/10/2007

Organization : GAHM'S PHARMACY II, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

THE PROPOSED DEFINITION OF AMP UNDER CMS-2238-P PRESCRIPTION DRUGS WILL CAUSE GREAT HARM TO MY PHARMACY. IT IS ESTIMATE THAT THE REIMBURSEMENT WE WILL RECEIVE WILL BE FAR BELOW WHAT IT ACTUALLY COSTS MY PHARMACY TO PURCHASE THESE MEDICATIONS. I RESPECTFULLY REQUEST THAT CMS REDEFINE AMP SO THAT IT REFLECTS WHAT I ACTUALLY PAY FOR THE PRODUCT. IF REIMBURSEMENTS DO NOT COVER COSTS, I AND MANY OTHER RETAIL PHARMACIES MAY BE FORCED TO TURN AWAY THEIR MEDICAID PATIENTS WITHOUT MEDICATIONS THEY NEED. IN A POOR RURAL ENVIRONMENT SUCH AS MINE, THIS WOULD BE DEVASTATING TO MY BUSINESS, MY EMPLOYEES, AND MY PATIENTS. A PROPER DEFINITION OF AMP IS THE FIRST STEP TO SOLVING THE PROBLEM. I UNDERSTAND THAT THE SECRETARY OF HEALTH AND HUMAN SERVICES HAS BEEN GIVEN ALOT OF LEEWAY IN DEFINING AMP. I ONLY ASK THAT AMP BE AN ACCURATE PORTRAYAL OF PHARMACIES' TOTAL INGREDIENT COST SO THAT AN ADEQUATE REIMBURSEMENT MAY BE OBTAINED. AS IT IS CURRENTLY DEFINED, AMP IS ESTIMATED TO ONLY COVER HALF OF THE MARKET COST PAID BY COMMUNITY PHARMACIES. CURRENTLY, EACH MANUFACTURER DEFINES AMP DIFFERENTLY, AND WITHOUT PROPER DEFINITION, MEDICAID REIMBURSEMENTS WILL NOT DOVER PHARMACY AQUISITION COSTS. UNDERPAID PHARMACIES WILL BE FORCED TO TURN MEDICAID PATIENTS AWAY, CUTTING ACCESS TO NEEDED MEDICATIONS TO MANY POOR, ESPECIALLY IN RURAL ENVIRONMENTS SUCH AS MINE. ADDITIONALLY, THE CUTS WILL COME EXCLUSIVELY FROM GENERIC DRUGS, SO UNLESS AMP IS CORRECTLY DEFINED TO COVER AQUISITION COSTS, AN INCENTIVE WILL BE GIVEN TO DISPENSE MORE EXPENSIVE BRAND NAME MEDICATIONS THAT COULD ACTUALLY END UP COSTING MEDICAID MORE THAN LOWER PRICE MORE COST EFFECTIVE GENERIC DRUGS.PLEASE ISSUE A CLEAR DEFINITION OF AVERAGE MANUFACTERS PRICE THAT COVERS COMMUNITY PHARMACY AQUISITION COSTS AS SOON AS POSSIBLE, BEFORE THIS AMP STATUTE TAKES EFFECT, TO PREVENT COMMUNITY PHARMACIES FROM TURNING AWAY MEDICAID PATIENTS AND LIMITING ACCESS TO MUCH NEEDED MEDICATIONS FOR THE POOR.

Submitter : **Mr. Dale Tinker** **Date: 02/10/2007**

Organization : **New Mexico Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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

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

Summary

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

Collection of Information Requirements

Collection of Information Requirements

?447.504 Determination of AMP
Defining Retail Pharmacy Class of Trade
Inclusion of Medicaid Sales
Discounts, Rebates and Price Concessions

?447.510 Requirements for Manufacturers.
Market Manipulation
Claw-back
Pricing Lag
Severe Price Shifts
Record Keeping

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

GENERAL

GENERAL

See attachment for comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachment for comments

Regulatory Impact Analysis

Regulatory Impact Analysis

See attachment for comments

New Mexico Pharmacists Association Comments

February 20, 2007

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

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

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

Summary

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

§447.504 Determination of AMP

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

forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

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

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given

by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

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

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

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

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

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29."

Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to 1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers

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

§447.510 Requirements for Manufacturers.

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

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter

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

discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

[3] §447.510(d)(2)

AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

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

Record Keeping

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

Additional Comments

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

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

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

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

Sincerely,

Dale Tinker
Executive Director
New Mexico Pharmacists Association
2716 San Pedro, NE, Suite C
Albuquerque, New Mexico 87110

cc. Members of Congress in New Mexico

Response to Comments

Response to Comments

See attachment for comments

CMS-2238-P-356-Attach-1.RTF

Submitter : **Ms. Heather Pasquale** **Date: 02/10/2007**

Organization : **CVS/pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a Pharmacist, district manager for a chain drig store and on the Ohio State Board of Pharmacy. The proposed AMP rule will have a detrimental effect on pharmacy.

GENERAL

GENERAL

Community pharmacies, both chains and independents, will lose money on virtually every one of those prescriptions. The Government Accountability Office (GAO) says that community pharmacies will be paid on average 36% below their acquisition cost for every Medicaid generic drug prescription they fill under a reimbursement formula proposed by the Centers for Medicare & Medicaid Services (CMS). This would effectively put many pharmacies out of business! Please consider a different alternative as this will have a negative effect on pharmacies. With the increase in senior population, losing pharmacies due to loss of profits will have a negative impact on healthcare overall. We need the pharmacies to remain open. The drug manufactors make over 15% profit and community pharmacy makes 2%, why is every rule aimed at community pharmacy.

Submitter : **Dr. Richard de Blaquiere** **Date: 02/10/2007**

Organization : **White Cross Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I have several general comments that pertain to this legislation.

First, I think that any part of this legislation that is based on Pharmacy Benefit Manager (PBM)data is unusable considering the nature of PBMs. These companies are continually in legal battles over their practices. This is why state governments have had to enact transparency laws in many cases. PMB's have also not lived up to their promises. In particular, PBMs have touted their ability to contain prescription drug costs. Obviously, their would not be a need for any deficit reduction measures if PBMs had actually been successful at this.

Second, This legislation is misguided. It is aimed at reducing costs from the very sector of the pharmaceutical sector that has actually saved costs. In addition, it doesn't actually reduce the cost of any drug, it simply reduces the reimbursement to the provider. While this may save the government money, it is not actually reducing price. The impact of this will be an incentive to dispense a more expensive medication and the further deterioration of prescription drug healthcare.

Submitter : Mr. Suresh Wattamwar **Date:** 02/10/2007

Organization : Sure drugs

Category : Pharmacist

Issue Areas/Comments

Background

Background

AMP: Payment for the prescription drugs based on proposed AMP.

Regulatory Impact Analysis

Regulatory Impact Analysis

Proposed regulation is a windfall for the closed doore pharmacies at the cost of the retail pharmacists. The formula should be based on 3 seperate catagories like Closed door pharmacies, Hospital & nursing home Pharmacies and Retail pharmacies. Each one should be reembursed based on their AMP. The market place has diffrent prices for each groups and each one should be based on their purchase prices. The other solution will be asking the manufacturrs to charge average price but same to every one like every place in the world. It is important that your desion should be based on the understanding of place of a retail pharmacy in the patients mind and the result of your action on the existance of the retail pharmacies.
Thank you.

Submitter : Mr. Kenneth Wingate, RPh **Date:** 02/10/2007

Organization : Mr. Kenneth Wingate, RPh

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. daniel christensen **Date:** 02/10/2007

Organization : pssny

Category : Pharmacist

Issue Areas/Comments

Background

Background

I have been practicing community pharmacy in upstate ny for 32 years. The pharmacy is progressive doing only health and wellness items. We deliver quality care and deliver to patients' homes. Medicaid clientele are a large portion ofthe business because the chains won't bother with high maintenance people and stock the little used or expensive pharmaceuticals and surgical supplies (braces home equipment) that require extra time and effort.

Collection of Information Requirements

Collection of Information Requirements

The proposed reimbursement reductions will jeopardize my job. My employer is cut to the bone now, the first thing to go would probably be home delivery... we cannot charge medicaid recipients a delivery charge! These aren't just numbers on paper, they represent peoples lives and certainly my way of life and means to make a living and pay my my taxes.....which in NY are certainly another topic. Pharmacies simply cannot stand further erosion of what little profit is available now.

Submitter : Dr. Jarrod Grossman **Date:** 02/10/2007

Organization : Columbus Rx West

Category : Health Care Professional or Association

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Date: 02/11/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Pharmacists have been "on the front line" of Medicare Part D implementation. We have had to be the ones helping our customers make the decisions about which plan, the ones to explain the finer details of the plan when something doesn't go the way it was supposed to (ie higher copays, deductibles etc), and the ones having to hear all the complaints from customers about their plans. Yet, pharmacy reimbursement keeps taking a hit with lower and lower rates. We take great care of our customers and so that means having to let some prescriptions leave the store at a loss to us because our customers are loyal to us and we feel obligated to allow the loss. I feel that by continuing to cut reimbursement to pharmacies you are going to be hurting the very face of pharmacy, and eventually, there will be a downfall in the retail profession. Then who is going to monitor/help all the millions of people who depend on our advice and service. For once, don't take the cost of rising prescription drugs out on the people who only deliver the finished product to the patients. The insurance companies aren't going broke like pharmacies are, and neither are the drug companies.

Submitter : Mr. lewis glantz **Date:** 02/11/2007

Organization : stop and shop pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

the issue is note the cost submitted by pharmacys. the issue is the cost involved with pbms and the drug manufacturing industry.look at the profit the pbms are making. with todays technology the gov should have the ability to bill directly for medicar part d and eliminate the hundrerds of millions that the pbms are making. the govt should also get reductions for the drug companys for the overprice drugs

Submitter : Mr. HUGH BONNORONT **Date:** 02/11/2007

Organization : BUNNY'S PHARMACY INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

THE PROPOSED DEFINITION OF COST UNDERR CMS-2238P WILL BE LESS THAN
WHAT WE HAVE TO PAY OUR SUPPLIERS. THE DEFINITION SHOULD BE 100% OF THE NORMAL AQUISITION COST. PLEASE REDEFINE WHAT AQUISITON
COST IS.

Response to Comments

Response to Comments

MEDICAID PAYS OUR PHARMACY FOR FILLING PATIENT PRESCRIPTIONS & SUPPLIES. IF PAYMENT IS LESS THAN OUR COST WE WILL NO LONGER BE ABLE TO CONTINUE THIS SERVICE.

Submitter : Mr. TRAVIS OKULEY **Date:** 02/11/2007

Organization : OKULEY'S PHARMACY INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AMP PRICING FOR GENERIC PRESCRIPTION DRUGS WILL PUT US OUT OF BUSINESS. PLEASE CONSIDER REVISING!!! WE WILL BE FORCED NOT TO PARTICIPATE IN MEDICAID PROGRAMS. THIS WILL GREATLY AFFECT MANY OF OUR PATIENTS.

Submitter : **Mr. Richard Lau** **Date: 02/11/2007**

Organization : **Briarmill Phaarmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications.

Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.

To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will accomplished by:

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy.

Submitter : Mrs. KIEU OKULEY **Date:** 02/11/2007

Organization : OKULEY'S PHARMACY & HOME MEDICAL

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

PLEASE REVISE AMP PRICING FOR GENERIC DRUGS. WE WILL NOT BE ABLE TO CONTINUE BEING A MEDICAID PROVIDER. THIS WILL GREATLY AFFECT MANY PATIENTS IN OUR AREA.

Submitter : Mr. Charles Rohrbaugh **Date:** 02/11/2007

Organization : Sunrise Pharmacy, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I believe the idea of an AMP is acceptable. My only issue is lumping mailorder and hospital pharmacies in with retail pharmacies. The above mentioned Pharmacies receive generous price breaks from wholesalers and manufacturers alike, thus their AMP should be calculated separately from other retail Pharmacies. That would give more legitamate 'target' prices for government purposes without unduly penalizing retail pharmacy.

Retail Pharmacies are unfairly restricted by regulations that are waived for Hospital and Mailorder Pharmacies that drive the cost to dispense up, besides already paying higher prices for the drugs we sell.

I support the AMP, but only if Hospital and mailorder pharmacy pricing is removed from the equation. Thanks.

Submitter : **Brad Wood** **Date: 02/11/2007**

Organization : **Whiston Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am mailing to regards to CMS-2238-P. I am a retail pharmacist working in an independent pharmacy which serves a very high number of both medicaid and medicare customers.

GENERAL

GENERAL

I am very much concerned that the proposed AMP-based formula will not cover even our acquisition costs for many of the multiple-source generic medications. My understanding of AMP is that it never was intended to serve as a basis for reimbursements and in order to do so it would have to be redefined to reflect the actual cost paid by retail pharmacies. Please reconsider this proposal as it certainly does not serve the best interest of the medicare/medicaid population who rely on the relationships and professional services provided by retail pharmacies or the retail pharmacies themselves who may find themselves unable to remain viable with the proposed reimbursements. Thank you.

Submitter : **Dr. James Bowman** **Date: 02/11/2007**

Organization : **Moose Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I work in rural independent community pharmacy that serves numerous Medicaid patients. Please read my general comment below and realize that such a change would either force us to stop accepting Medicaid or switch patients to brand name medications that would sky rocket the price of Medicaid more so than now.

GENERAL

GENERAL

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

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

2. AMP should not be a benchmark for reimbursement because it never reflects the actual cost of a retail pharmacy's acquisition cost. The AMP price reflects rebates paid by manufacturers to third party payers such as Medicaid, Caremark, Medco, and Express Scripts. These rebates are unavailable to retail pharmacies. The acquisition cost of mail order pharmacies owned by third party payers like Caremark and Medco are also reflected in the AMP, but should not because these pharmacies are not open to the general public and only accessible by people covered under these payers. Furthermore, mail order pharmacies are extended special prices that are not extended to publicly traded pharmacies like CVS, Walgreens, and privately owned pharmacies.

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

Respectfully,
James Bowman

Submitter : **Dr. Joseph Reina** **Date: 02/11/2007**

Organization : **J Rx Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Dr. Joseph Reina, PharmD. I am a 25 year old pharmacist. I am a graduate from St. John's University College of Pharmacy and Allied Health Professions. I am also a member of APha. I would like to comment on the proposed CMS regulation to change pharmacy re-imbursement to a formula based on AMP. I am currently opening a new independent pharmacy and it is very scary. It was always my dream to do so because I love being a pharmacist and I grew up in a family retail business so it is a combination of two passions. What has become very scary is that I recently started to sign contracts with insurance companies I found out that based on some of their re-imbursement rates I can actually lose money dispensing a prescription. I am not too sure about how Medicaid re-imbursement rates are now because although I have worked in a pharmacy for over seven years, when you work for a large chain you do not really learn anything about the 'business'. What I do know is that if these proposed regulations go into affect, independent pharmacies will not be able to survive. When you do the numbers they just do not add up. How can you run a business if the largest portion of it, in this case prescriptions, only breaks even on the actual cost of the product and you do not even take the cost of running the business into consideration? This is a real shame because the owners of independent pharmacies are people like me. People who love the job and know that they can provide so much more for their patients if they are allowed to do so, which in chain pharmacies is impossible. At the same time that it is my pleasure to provide these services, it is just impossible to do if I can not make money. After all I believe everyone is entitled to make a living.

Submitter : Mr. Fabian Estrada **Date:** 02/11/2007

Organization : APhA, Pharmacy student

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Reimbursing pharmacists only 250% of the generic drug price according to the average manufacturer seems low. The state is trying to focus on reducing medication costs by reducing what the state should pay. From my experience in counseling patients at the retail level, I notice that about 50% of patients do not use their medications correctly. The state wants to focus on reducing costs, but why not focus on improving the patient's health by assuring that they are using their medications correctly. Many patients claim that their doctors do not explain the proper way to use prescriptions. I believe that healthcare expenditures would decrease for the state if the state focused on patient education and medication compliance. The state may pay less for each prescription dispensed, but if the patient is not using them correctly this may lead to hospital costs increasing which may increase the number of prescriptions per patient in the long run. Also, many pharmacies can order medications for next day delivery if the patient needs it. But who will cover the fee charged to the pharmacy for the delivery, not the state. Should the patient wait until the pharmacy's regular order date? What if the medication is rarely used but needed to maintain life? I agree that cutting costs is important, but please don't try to superficially fix this problem and let it resuface later. Instead, attack the problem from the root. Patient education on proper usage and compliance is key to ultimately reducing costs for the state. Although results will not be immediate.

Submitter : **Mr. David Isaacs** **Date: 02/11/2007**

Organization : **Giant Eagle Pharmacy/Diabetes Care Center**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I have been a pharmacist in the Cleaveland, Ohio area for 32 years, working mostly in inner-city and inner-ring suburbs

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Sam Scuderi **Date:** 02/11/2007

Organization : PSSNY

Category : Pharmacist

Issue Areas/Comments

Background

Background

Pharmacists have always been paid using the AWP. This is going to change and create a health care crisis.

GENERAL

GENERAL

I am against using amp as the new standard of payment. This can only lead to more community pharmacies closing because of the reduced payments for medicaid and medicare prescriptions.Because of the reduced payment using the amp standard chain pharmacies will cut back on the clerical help and add an additional burden to pharmacists. Some pharmacies may not to be able to fill medicaid or medicare prescriptions because of the lower payment for generic drugs. Generic pharmaceutical organizations have encouraged pharmacists to dispense generic drugs when and where possible depending on how the prescription is written. Even the federal governemt felt this would save medicare patients substantial savings. However,in light of the new amp reimbursement standard, how can pharmacy survive?

Submitter : **Nancy Faust** **Date: 02/11/2007**

Organization : **Nancy Faust**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

CMS-2238-P has a provision to use the Average Manufacturer's Price (AMP) as the reimbursement for prescription medications. This is an unreasonable plan since a pharmacy cannot purchase medications at this cost. If the cost of the medication is greater than the reimbursement, then pharmacies and the pharmacists will no longer be available to serve the public in health care. The only way that a pharmacist is compensated for his/her expertise is through the sale of the medications that are dispensed. It is irrational to expect a pharmacy to dispense medications with little or no compensation and continue be a viable part of health care.

Submitter : Corinne Garza **Date:** 02/11/2007

Organization : Hicksville Pharmacy and Home Medical

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Legislators,

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Sincerely,
Corinne Garza R.Ph.
Hicksville Pharmacy and Home Medical
116 E High St
Hicksville, OH 43526
Telephone (419) 542-6218

Submitter : **Mr. Jackson Bray** **Date: 02/11/2007**

Organization : **Capital Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Using AMP to price Medicaid Rx will result in loss of profit on these rx to a negative figure. If this results we will have to stop participating in then Medicaid program. We can not contiune to supplement government programs at a negative profit margin. We pay our taxes and can not be asked to supplement government programs that can not manage their money.

Submitter : Mr. Mark Ebner **Date:** 02/11/2007

Organization : Klein's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mrs. Melody Peak **Date:** 02/11/2007

Organization : Mrs. Melody Peak

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Submitter : **Ms. Bryan Peak** **Date: 02/11/2007**

Organization : **Ms. Bryan Peak**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

Submitter : Mr. Edward Schreiner **Date:** 02/11/2007

Organization : Stoll's Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment for my complete comments.

CMS-2238-P-382-Attach-1.DOC

#382

February 11, 2007

R.E. Comments concerning CMS-2238-P: Implementing the Medicaid Drug Rebate Program provision of the Deficit Reduction Act of 2005

To Whom It May Concern,

I am a registered pharmacist practicing in a small, family-owned independent pharmacy in Waterbury, Connecticut. My pharmacy has been in business in downtown Waterbury, CT for over sixty years. A large portion (>25%) of the prescriptions filled at my pharmacy are reimbursed under the Medicaid program.

As currently written, the implementation of AMP-based FULs for use in the Medicaid program will have a devastating impact on my ability to continue operating my pharmacy. As you are aware, AMP-based FULs will not cover retail pharmacy acquisition costs for an extensive number of multiple-source generic medications. In the latest GAO report (GAO-07-239R), the GAO specifically finds that the estimated AMP-based FULs in their 77 drug sample were, on average, 36% lower than the average retail pharmacy acquisition costs for the first quarter of 2006. The report indicates that, in the majority of instances, the formula for AMP-based FULs in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic drugs. These finding illustrate my belief that AMP is not appropriate as a baseline for reimbursement unless it is redefined to reflect realistic pharmacy acquisition costs.

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 pharmacies, such as my own, will consider closing completely, as this reimbursement mechanism will have a devastating impact on my ability to service a large Medicaid patient population. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name drugs, thus driving Medicaid costs even higher.

AMP is now to serve two distinct and contrary purposes: 1) as an index for manufacturer rebates paid to states, and 2) as a baseline for pharmacy reimbursement. 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 GAO-05-102 "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concern About Rebates Paid to States".

If AMP is to accurately serve both purposes and to be an appropriate benchmark, **CMS MUST define AMP to reflect the actual cost paid by retail pharmacies**. This will be accomplished by; (1) excluding all rebates and price concessions made by manufacturers that are NOT available to retail pharmacies, (2) excluding all mail order facilities and PBM pricing from AMP calculation (*Mail order facilities and PBMs are extended special prices from manufacturers that are not available to retail pharmacies and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible),* and (3) reporting AMP at the 11-digit NDC level to ensure accuracy, as suggested by

CMS. All rebates and price concessions are appropriately included in the definition of "Best Price" but should not be included in AMP.

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade (which should include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass-merchants and supermarket pharmacies), it should include and exclude components according to their impact on the actual acquisition costs paid by retail pharmacies. CMS rightly excludes manufacturer rebates to state Medicaid programs, the Department of Defense under TRICARE and the VA program. Rebates paid to PBMs and mail order facilities should also be excluded in calculating AMP as these rebates are not available to the retail pharmacy class of trade. Should manufacturers include PBM/mail-order rebates in AMP calculations, the AMP would be driven below available market price, thus undermining FUL and shrinking the rebates states receive.

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

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 or rebates. The impact on participating pharmacies also cannot be mitigated by an increase in state-set dispensing fees. It is 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 that used data from over 23,000 community pharmacies and 832 million prescriptions to determine cost dispensing figures). As indicated by this study, increases in state-set dispensing fees may address the true cost of dispensing but will have no impact on negating the discrepancy between the proposed AMP and actual drug acquisition cost at the retail pharmacy level.

In conclusion, I strongly request that CMS change the definition of AMP to reflect actual acquisition cost paid by the retail pharmacy class of trade. All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculation. An AMP-based reimbursement that underpays retail pharmacy will have dire consequences for patient care and access.

Sincerely Submitted,

Edward Schreiner, R.Ph.
Stoll's Pharmacy, Inc.
185 Grove Street
Waterbury, CT 06710

Submitter : **Logan Davis** **Date: 02/12/2007**

Organization : **Samford University**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics.

These pharmacies may have access to rebates and price concessions that may not be accessible to community pharmacy. Consequently, community pahrmacists are concerned that AMP may be set at a rate lower than what community pharmacy can purchase generic drug products.
The proposal does not address dispensing fees and continues to let States determine the 'reasonable' dispensing fee they are required to pay pharmacists. We are concerned that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a $4 dispending fee when studies indicate that the average cost to dispense a medication is approximately $10.

My home county is Sumter County, Alabama. This county is in the poor, rural black belt of Alabama. There are two pharmacies in this county and both are independent pharmacies. They will not be able to accept Medicaid prescriptions if the changes in this proposal are made. These patients will experience an even further reduction of total health and their lack of health care will cost the Medicaid system even more by increasing emergency room visits.

Please see attached documents for the study outlining cost of dispensing, the GAO report, and the National Community Pharmacy Association's comments on this issue.

CMS-2238-P-383-Attach-1.PDF

CMS-2238-P-383-Attach-2.PDF

CMS-2238-P-383-Attach-3.PDF

383

Grant Thornton LLP

National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies

Executive Summary

January 2007

Grant Thornton

Prepared for:

The Coalition for Community Pharmacy Action (CCPA)

NATIONAL COST OF DISPENSING (COD) STUDY
FINAL REPORT
JANUARY 26, 2007

Executive Summary

A. Objective and Overview of the National Cost of Dispensing Study

Grant Thornton LLP was engaged by the Institute for the Advancement of Community Pharmacy (IACP), doing business as the Coalition for Community Pharmacy Action (CCPA) on behalf of the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), to perform an independent study to identify and quantify the costs incurred by pharmacies across the United States in dispensing prescriptions. The primary purpose of the study was to provide a comparative analysis of dispensing costs across all states and types of payers, including Medicaid. To perform this study, Grant Thornton partnered with The MPI Group.

Data were submitted for over 24,400 pharmacies, of which 23,152 provided complete and usable data and are included in the computations shown in this report. The survey requested data for the six months from March through August of 2006, a period selected to avoid any unusual, one-time expenses that some pharmacies may have incurred during the implementation of Medicare Part D. The 23,152 pharmacies reported filling more than 832 million prescriptions during this time, of which over 65 million – or 7.8% – were paid by Medicaid. National computations include data from all states.

The Cost of Dispensing Model uses five cost elements, which are explained in detail in the full report:

- Prescription department salaries and benefits
- Other prescription department costs
- Facilities costs
- Other store/location costs
- Allocated corporate overhead, where applicable

The overall cost of dispensing for all prescriptions reported by the pharmacies was computed first. The cost of dispensing specific to Medicaid prescriptions was then calculated by adjusting the overall COD to reflect differences in time required to fill Medicaid prescriptions, as reported by pharmacists, and the interest costs associated with carrying Medicaid receivables.

This report focuses on four views of the overall COD and the Medicaid COD:

- Cost of dispensing on a per-prescription basis.
- Cost of dispensing on a per-store basis (that is, every store is counted equally, regardless of its prescription volume).
- Cost of dispensing for prescriptions filled by stores in rural locations and in urban locations.
- Cost of dispensing on a per-prescription basis and a per-store basis by state.

The full report provides detailed information about development of the survey instrument, distribution and tabulation of surveys, review of the data, confidentiality considerations, and the computational model for determining the cost of dispensing.

It should be noted that Grant Thornton did not conduct an audit of these data. Accordingly, with the publication of this report, our findings are not to be understood to express an audit or limited assurance opinion in accordance with auditing standards generally accepted in the United States of America.

B. Summary of Findings

Most charts in the report show cost of dispensing (COD) in two ways – per prescription and per pharmacy. One reason these numbers can vary significantly is that high-volume pharmacies typically have a lower COD than low-volume pharmacies. Therefore, the COD per prescription can be lower than the COD per pharmacy because lower-cost prescriptions make up a larger proportion of the population used to compute the COD. On the other hand, the COD per pharmacy treats every pharmacy equally, regardless of its prescription volume; a lower-volume, higher-cost pharmacy has the same impact on the COD per pharmacy as a higher-volume, lower-cost pharmacy. The COD per pharmacy provides the reader with information about the costs of the stores, regardless of how many prescriptions each one dispensed.

The overall COD was calculated for more than 832 million prescriptions dispensed by 23,152 pharmacies in all 50 states, the District of Columbia and Puerto Rico. The average (mean) overall COD per prescription was $10.50; the average overall COD per pharmacy was $12.10. This difference indicates there are substantial variations in the number of prescriptions filled per pharmacy and that pharmacies with the greatest volume of prescriptions have significantly lower dispensing costs compared with pharmacies with the lowest volumes. It is apparent that total prescription volume is a key variable related to a pharmacy's cost of dispensing.

Overall Cost of Dispensing					
	Frequency	**Mean [3]**	**Median [4]**	**25th Percentile [5]**	**75th Percentile [5]**
COD per prescription [1]	832,377,163	$10.50	$9.86	$8.48	$11.70
COD per pharmacy [2]	23,152	$12.10	$10.86	$9.07	$13.50

1. Weighted data by volume of prescriptions; each prescription COD as one value (i.e., a pharmacy with 5,000 prescriptions has 5,000 values in the array of COD data).
2. Unweighted data; each pharmacy's COD as one value, regardless of the pharmacy's prescription volume.
3. Mean is the average value
4. Median is the midpoint value of responses
5. Percentiles: The 25th percentile is the value below which 25% of responses fall. The 75th percentile is the value below which 75% of responses fall.

The Medicaid cost of dispensing was similarly computed for more than 65 million prescriptions filled by the 22,123 pharmacies that reported Medicaid prescriptions and for which a Medicaid COD could be computed. The national average COD was $10.51 per prescription and $12.81 per pharmacy. The average COD for Medicaid prescriptions does not differ significantly from the overall COD shown in the table above. However, the Medicaid COD per pharmacy is $0.71 higher

than the overall COD per pharmacy, suggesting that lower-cost, higher-volume pharmacies fill a disproportionately greater percentage of Medicaid prescriptions. As noted below, this may also be affected by lower-cost rural pharmacies' filling more Medicaid prescriptions than urban stores on a per-pharmacy basis.

	Frequency	Mean	Median	25th Percentile	75th Percentile
Medicaid COD per prescription [1]	65,037,250	$10.51	$9.87	$8.52	$11.62
Medicaid COD per pharmacy [2]	22,123[3]	$12.81	$11.22	$9.36	$14.06

1. Weighted data by volume of Medicaid prescriptions for which a Medicaid COD could be computed; each Medicaid prescription COD as one value.

2. Unweighted data; each pharmacy's Medicaid COD as one value, regardless of its Medicaid prescription volume.

3. 1,029 pharmacies reported no Medicaid prescription volume and/or did not provide sufficient information to compute a Medicaid COD.

Of the 23,152 pharmacies in the database, 19,811 were classified as urban and 3,185 as rural by matching the stores' zip codes with Metropolitan Statistical Areas (156 pharmacies could not be classified by MSA). Rural stores' overall COD and Medicaid COD, per prescription, were approximately 8% below the COD's of urban pharmacies, but the overall prescription volume, per store, was about the same for both the urban and rural pharmacies. On the other hand, rural pharmacies filled 55% more Medicaid prescriptions per store than urban pharmacies. The majority of the 8% difference in COD between urban and rural pharmacies with comparable prescription volumes appears to be caused by lower payroll costs in rural stores.

Survey respondents were asked to estimate the average work time for all activities required to dispense a prescription for each type of payer – Medicaid, Medicare Part D plans, other third-party plans, and customers with no third-party payer. Survey respondents for which a Medicaid COD could be computed reported that, on average, prescriptions paid by Medicare Part D are the most time-consuming (12.5 minutes), followed by Medicaid (11.7 minutes), other third-party payers (10.6 minutes) and prescriptions paid directly by customers (8.7 minutes).

Similarly, the survey asked respondents to report the average time to receive payment for Medicaid, other third-party (including Medicare Part D), and customer-paid prescriptions. The responses for Medicaid varied significantly from one state to another, but on average, the pharmacies reported receiving payment from Medicaid 19.9 days after billing, compared with 23.7 days for other third parties (including Medicare Part D). On a state-by-state basis, the survey shows that Medicaid programs' days to pay range from a high of 50.6 days average (30 days median) in Illinois to a low of 9.9 days average (10 days median) in Texas. The COD model used in this study added approximately $.01 per day to the COD for each day payment was outstanding, based on the average prescription selling price and interest rates applicable during the study period.

The full report, for which this is the Executive Summary, presents more detailed data nationally and for most states. State-level information for Alaska, the District of Columbia, Hawaii, Maine, North Dakota, and Puerto Rico is omitted, either because the number of pharmacies for which complete data were submitted was very small or due to confidentiality concerns if the data were presented fully.

Service Providers and Sponsors for Cost of Dispensing Study

Grant Thornton LLP

Grant Thornton LLP is the U.S. member firm of Grant Thornton International, one of six global accounting, tax and business advisory organizations. Grant Thornton is the leading accounting firm serving mid-cap, small-cap and privately held companies and other organizations, and is a preferred provider of specialist financial, tax and advisory services.

Today, Grant Thornton is represented by over 519 offices in major cities in 112 countries, and by more than 20,000 personnel throughout the world. Grant Thornton has 50 offices throughout the United States; clients are served by over 400 partners and nearly 5,000 U.S. personnel.

The MPI Group

The MPI Group, Inc. is a Cleveland, Ohio based research firm which is rapidly becoming one of the world's fastest-growing, most respected management intelligence firms, completing surveys, studies and white papers for organizations around the globe. MPI is currently at work on projects in industries ranging from manufacturing to information technology to distribution to healthcare, on topics ranging from performance benchmarks to financial process metrics to customer value analysis and ROI.

CCPA

The Coalition for Community Pharmacy Action (CCPA) is an alliance between the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), which together represent more than 55,000 community pharmacies. CCPA's mission is to ensure that patients have continued access to affordable medicines and prescription care from their trusted and accessible health professional - the community pharmacist.

CCPA's sponsorship of this project was made possible by a significant financial contribution from the Community Pharmacy Foundation. The Community Pharmacy Foundation's primary purpose is to assist community pharmacy practitioners by providing resources for research and development to encourage new capabilities and continuous improvements in the delivery of patient care. CCPA acknowledges the generosity of the Foundation and its directors for this support.

NCPA

The National Community Pharmacists Association (NCPA), founded in 1898, represents the nation's community pharmacists, including owners of more than 24,000 pharmacies, more than 68,000 pharmacists and more than 280,000 full-time employees. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines.

NACDS

The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 37,000 pharmacies, employ 114,000 pharmacists, and fill more than 2.3 billion prescriptions yearly. Other members include more than 1,000 suppliers of products and services to the chain drug industry.

CMS-2238-P: Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005

As promised, NCPA is providing an outline of our position regarding CMS-2238-P, the agency rule which will redefine Average Manufacturers Price (AMP) for use as a Federal Upper Limit (FUL) in the Medicaid program. The move to AMP will result in a significant reduction in Medicaid reimbursement for multiple source generic medications. NCPA will be submitting a comprehensive set of comments on behalf of community pharmacy, however it is our desire for the Centers for Medicare & Medicaid Services (CMS), the agency that runs the Medicaid program, to receive a significant number of comments from the pharmacy community.

This outline is provided so that community pharmacy's comments will have a more unified theme in order to magnify their impact. Please review the rule and these suggested comments and then submit your own comments to CMS from your perspective.

Comments can be submitted electronically, by mail, by express mail and by hand or courier. Full details are outlined on pages 2-4 of the proposed rule. The proposed rule can be found on the CMS website at: http://www.cms.hhs.gov/MedicaidGenInfo/downloads/AMP2238P.pdf.

NCPA suggests you submit your comments electronically by visiting http://www.cms.hhs.gov/eRulemaking. **PLEASE REMEMBER: Your comments must be received by CMS no later than 5 p.m. on February 20, 2007.** Comments should also be addressed to Acting Administrator Leslie Norwalk.

NCPA comments reference the recently released Government Accountability Office (GAO) report on Medicaid Federal Upper Limits (GAO-07-239R) which can be found at http://www.gao.gov/new.items/d07239r.pdf.

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:

> "The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower

> 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.

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

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

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.—pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP—pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

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

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.—pg. 110

CMS discusses impact on pharmacy:

- On independents: potential "significant impact on small, independent pharmacies."—pg. 101
- On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 ("a small fraction of pharmacy revenues").—pg. 108
- "We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark 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.

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.

Summary of Key Points:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.

2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*

3. Reporting AMP at the 11-digit NDC level to ensure accuracy

383-P

CMS-2238-P: Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005

As promised, NCPA is providing an outline of our position regarding CMS-2238-P, the agency rule which will redefine Average Manufacturers Price (AMP) for use as a Federal Upper Limit (FUL) in the Medicaid program. The move to AMP will result in a significant reduction in Medicaid reimbursement for multiple source generic medications. NCPA will be submitting a comprehensive set of comments on behalf of community pharmacy, however it is our desire for the Centers for Medicare & Medicaid Services (CMS), the agency that runs the Medicaid program, to receive a significant number of comments from the pharmacy community.

This outline is provided so that community pharmacy's comments will have a more unified theme in order to magnify their impact. Please review the rule and these suggested comments and then submit your own comments to CMS from your perspective.

Comments can be submitted electronically, by mail, by express mail and by hand or courier. Full details are outlined on pages 2-4 of the proposed rule. The proposed rule can be found on the CMS website at: http://www.cms.hhs.gov/MedicaidGenInfo/downloads/AMP2238P.pdf.

NCPA suggests you submit your comments electronically by visiting http://www.cms.hhs.gov/eRulemaking. **PLEASE REMEMBER: Your comments must be received by CMS no later than 5 p.m. on February 20, 2007.** Comments should also be addressed to Acting Administrator Leslie Norwalk.

NCPA comments reference the recently released Government Accountability Office (GAO) report on Medicaid Federal Upper Limits (GAO-07-239R) which can be found at http://www.gao.gov/new.items/d07239r.pdf.

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

AMP-based FULs will not cover pharmacy acquisition costs for multiple-source generic medications. In their latest report, the GAO specifically finds:

> "The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower

#383-C

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

December 22, 2006

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*

Dear Mr. Chairman:

Spending on outpatient prescription drugs in Medicaid—the joint federal-state program that finances medical services for certain low-income adults and children—has accounted for a substantial and growing share of Medicaid expenditures.[1] Medicaid's total spending on outpatient prescription drugs grew from $4.6 billion in fiscal year 1990 to $40 billion in fiscal year 2004—or from 7.0 to 14.2 percent of Medicaid's total expenditures for medical care. State Medicaid programs do not directly purchase prescription drugs; instead, they reimburse retail pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries.[2] For some outpatient multiple-source prescription drugs, state Medicaid programs may only receive federal matching funds for reimbursements up to a maximum amount known as a federal upper limit (FUL).[3,4] Required by law as a cost-containment strategy, FULs are calculated as 150 percent of the lowest price for a drug, from among the

[1]Medicaid consists of 56 distinct programs created within broad federal guidelines and administered by state Medicaid agencies. The 56 Medicaid programs include one for each of the 50 states; the District of Columbia; Puerto Rico; and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, and the Virgin Islands. Hereafter in this report, we use "state Medicaid programs" to refer to these 56 programs.

[2]Retail pharmacies are licensed nonwholesale pharmacies that are open to the public.

[3]FULs must be established for each multiple source drug for which there are three or more therapeutically equivalent drug products. 42 U.S.C. § 1396r-8(e)(4) (2000). Therapeutically equivalent drug products can be substituted with the full expectation that they will produce the same clinical effect as the prescribed drug.

[4]By regulation, FULs apply to multiple-source prescription drugs that the Food and Drug Administration considers to have at least three therapeutically equivalent versions and at least three manufacturers or suppliers. 42 C.F.R. § 447.301 and 447.332 (2005).

prices published nationally in three drug pricing compendia.[5] State Medicaid programs have the authority to determine their own reimbursements to retail pharmacies[6] for covered outpatient multiple-source prescription drugs, as long as those reimbursements do not exceed established FULs in the aggregate.

The Deficit Reduction Act of 2005 (DRA) included provisions that changed the methodology for calculating FULs.[7] Beginning January 1, 2007, a drug's FUL will be based on the average manufacturer price (AMP). AMP represents the average of prices paid to manufacturers by wholesalers for a drug distributed to the retail pharmacy class of trade, including retail pharmacies, and is typically less than any of a drug's published prices in the three pricing compendia. Each therapeutically equivalent version of a multiple-source drug has an AMP, and beginning January 1, 2007, a drug's FUL will be calculated as 250 percent of the lowest AMP from among a drug's therapeutically equivalent versions. The Congressional Budget Office estimated that when implemented, AMP-based FULs could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010 and by about $11.8 billion from 2007 to 2015.[8]

Though representing a potential cost saving measure for Medicaid, the change in FUL calculation methodology—using AMP instead of the lowest published price—has raised concerns among retail pharmacies serving Medicaid beneficiaries. Drug manufacturers are required to report AMP data on their drugs to CMS. Because these data are not publicly available, retail pharmacies cannot determine what the relationship will be between AMP-based FULs and the prices the pharmacies pay to acquire these drugs.[9]

Because of your interest in the potential effects of the AMP-based FULs on retail pharmacies, you requested information on how AMP-based FULs will compare with retail pharmacy acquisition costs. We estimated what the AMP-based FULs would have been if they had applied in 2006 and compared them with average retail pharmacy acquisition costs from 2006 for frequently used and high expenditure multiple-source outpatient prescription drugs in Medicaid.

---

[5]The Centers for Medicare & Medicaid Services (CMS), the agency that oversees Medicaid, identifies which drugs are subject to FULs. The Deficit Reduction Act of 2005 also included additional provisions relating to Medicaid reimbursement of outpatient prescription drugs.

[6]Many state Medicaid programs require retail pharmacies to dispense the lower cost therapeutically equivalent version of a drug to Medicaid beneficiaries when one is available. Under these mandatory generic substitution policies, the higher cost version of the drug remains available to beneficiaries if the prescribing physician receives prior authorization. In cases when retail pharmacies are authorized to dispense the higher cost version of the drug, the FUL does not apply.

[7]Pub. L. No. 109-171, § 6001, 120 Stat. 4, 54-59 (2006) (to be codified at 42 U.S.C. § 1396r-8).

[8]Congressional Budget Office Cost Estimate. S. 1932, Deficit Reduction Act of 2005. January 27, 2006.

[9]The price a retail pharmacy pays to acquire a drug from a manufacturer or wholesaler is known as a pharmacy's drug acquisition cost.

To estimate the AMP-based FULs and compare them with average retail pharmacy acquisition costs, we used first quarter 2006 Medicaid utilization data[10] to select a sample of multiple-source outpatient prescription drugs subject to Medicaid FULs. To develop our sample, we identified the 50 drugs that were the most frequently used—that is, represented 53 percent of the outpatient prescription drugs subject to FULs and dispensed to Medicaid beneficiaries in the first quarter of 2006—and the 50 drugs that were the highest expenditure—that is, accounted for 56 percent of Medicaid spending on outpatient prescription drugs subject to FULs in the first quarter of 2006,[11] with some drugs overlapping the two categories. Our resulting sample contained 77 multiple-source outpatient prescription drugs, which comprised 27 frequently used prescription drugs in Medicaid, 27 high expenditure prescription drugs in Medicaid, and 23 prescription drugs that overlapped both categories.

We obtained AMP data from the Centers for Medicare & Medicaid Services (CMS), which requires manufacturers to report AMP data within 30 days of the end of every calendar quarter. We obtained the average retail pharmacy acquisition cost data for the first quarter of 2006 from IMS Health, which obtains these data on sales transactions from approximately 100 manufacturers and over 300 distribution centers, including drug wholesalers and chain warehouses. These manufacturers and distribution centers are responsible for over 85 percent of total market dollar volume. IMS Health projects these data to represent national average acquisition costs for each drug in our sample in the first quarter of 2006.[12] The average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual acquisition costs because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers.[13]

For each of the 77 drugs in our sample, we estimated what the AMP-based FULs would have been had they applied in 2006. Using AMP data from the first quarter of 2006, we followed DRA provisions and selected the lowest AMP for each group of therapeutically equivalent versions and multiplied those AMPs by 250 percent. We did not exclude any outlier AMP data in order to be consistent with how CMS officials told us they will be implementing DRA provisions beginning January 1, 2007. We

[10]Medicaid utilization data reported to CMS include information on the total number of units and dollar amount for which state Medicaid programs reimbursed retail pharmacies for covered drugs dispensed to Medicaid beneficiaries. As of July 2006, when we selected our sample, utilization data from Iowa, Minnesota, New Jersey, and Rhode Island were not included because these states had not reported their Medicaid utilization data for the first quarter of 2006.

[11]In ranking drugs by their share of Medicaid expenditures for multiple-source outpatient prescription drugs in the first quarter of 2006, we excluded any dispensing fees paid to pharmacies as a part of state reimbursement formulas. Each state pays pharmacies, for each prescription dispensed, a professional dispensing fee intended to cover the pharmacy's labor and overhead costs, such as pharmacists' salaries, drug packaging, rent, and utilities.

[12]For any given drug, the acquisition costs of individual pharmacies may be higher or lower than the national average.

[13]These rebates may vary as retail pharmacies negotiate their rebates based on various factors, including the type of drug, manufacturer, and volume of purchases. In addition, they can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis.

compared these estimated AMP-based FULs with average retail pharmacy acquisition cost data from the first quarter of 2006 for the 77 drugs in our entire sample and for each of the three categories of drugs our sample comprises—the frequently used drugs, the high expenditure drugs, and the drugs that overlapped both categories.[14] In order to assess the extent to which AMP-based FULs are likely to vary over time, we also examined the variation in lowest AMPs for the drugs in our sample from the third quarter of 2005 through the third quarter of 2006. We determined that the data used were sufficiently reliable for our purposes. For more detail on our scope and methodology, see enclosure I. The list of 77 drugs we reviewed is included in enclosure II. We performed our work from July 2006 through November 2006 in accordance with generally accepted government auditing standards.

Results in Brief

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.

Though the difference between AMP-based FULs and retail pharmacy acquisition costs was in some cases sizable, the extent of this difference may change because of several factors, including the quarter-to-quarter variation in AMPs used to set FULs as well as the presence of rebates that retail pharmacies may obtain from drug manufacturers and wholesalers. To the extent that the utilization of multiple-source outpatient prescription drugs by retail pharmacies remains similar in 2007 and later to the utilization patterns captured in our sample of drugs for the first quarter of 2006, the gap between estimated first quarter 2006 AMP-based FULs and pharmacy acquisition costs could persist, once the AMP-based FULs are implemented in 2007. However, to the extent that the cost-containment measures of the AMP-based FULs influence pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset.

[14]In our comparison of the AMP-based FULs and retail pharmacy acquisition costs, we did not consider dispensing fees.

In reviewing a draft of this report, CMS disagreed with our finding that the AMP-based FULs were lower than the average retail pharmacy acquisition costs for most of the 77 drugs in our sample. In particular, CMS had significant concerns with our estimates of both pharmacy acquisition costs and AMP-based FULs and stated that our findings had not accounted for changes in these two variables that are likely to take place after DRA provisions are implemented in January 2007. In our view, we used the most complete, accurate data sources available at the time of our analysis for our purposes—to estimate both retail pharmacy acquisition costs and AMP-based FULs, had the latter applied in the first quarter of 2006. Furthermore, in our draft report we identified the limitations of the data sources used in our estimates and acknowledged that the difference between retail pharmacy acquisition costs and AMP-based FULs could change following implementation of DRA provisions in 2007. Only after AMP-based FULs are implemented in 2007 will there be an opportunity to determine the extent to which these FULs facilitate both cost-effective Medicaid drug expenditures and adequate reimbursement for retail pharmacies.

Background

Medicaid is a joint federal-state entitlement program that finances medical services for certain low-income adults and children.[15] While federal guidelines require that all state Medicaid programs offer certain basic benefits, each state Medicaid program determines the extent to which it will cover optional benefits. Outpatient prescription drug coverage is an optional benefit that all state Medicaid programs have elected to include in their Medicaid benefit packages. State Medicaid programs do not directly purchase drugs; instead they reimburse retail pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries. For some outpatient multiple-source prescription drugs, state Medicaid programs may only receive federal matching funds for reimbursements up to a maximum amount known as a FUL.

Medicaid Federal Upper Limits

FULs were first established in 1987 as a cost-containment strategy in an effort to limit the amount that Medicaid could reimburse retail pharmacies for certain multiple-source outpatient prescription drugs.[16] FULs have been established for multiple-source drugs that have at least three manufacturers or suppliers and CMS publishes a list of drugs that have FULs in the State Medicaid Manual.[17] FULs are expressed on a

---

[15]Within guidelines established by federal statutes, regulations, and policies, each state (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program.

[16]52 *Fed. Reg.* 28,648 (July 31, 1987). Legislation was enacted in 1990 making the application of FULs a statutory requirement. (Pub. L. No. 101-508, sec. 4401(a)(3), § 1927(f)(2), 104 Stat. 1388, 1388-143 (to be codified, as amended by DRA § 6001(a)(1)–(2), 120 Stat. 54-55, at 42 U.S.C. § 1396r-8(e)(4)).

[17]In addition, FULs are only established when multiple-source drugs are listed as "A" rated-drug products—that is, that the Food and Drug Administration (FDA) considers to be therapeutically equivalent to other pharmaceutically equivalent products—in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*. This list is commonly known as the Orange Book and identifies drug products approved on the basis of safety and effectiveness by FDA.

per-unit basis—for example, per tablet. As of first quarter 2006, the list included more than 500 multiple-source drugs.[18]

CMS determines the FUL for a multiple-source outpatient prescription drug by grouping a drug's therapeutically equivalent versions together and setting a FUL for each group. Each of a drug's therapeutically equivalent versions has several published prices associated with it, including the average wholesale price (AWP),[19] wholesale acquisition cost (WAC),[20] and direct price (DP).[21] All of these prices are published in each of the three national drug pricing compendia—First DataBank, Medi-Span, and Red Book—which use different methods for determining these published prices. The lowest published price for a FUL group—that is, a drug—may be any one of these three prices, and this can vary depending on the FUL group. Until provisions in DRA take effect January 1, 2007, CMS sets a FUL by identifying a drug's therapeutic equivalent with the lowest price—either AWP, WAC, or DP—in any of the three national drug pricing compendia, and multiplying that price by 150 percent.

A state's total reimbursements for Medicaid prescription drugs subject to FULs must not exceed, in the aggregate, the payment levels established by the FULs over a year. States may exceed the FUL for an individual prescription drug as long as their aggregate expenditures for all prescription drugs subject to FULs do not exceed the amounts that are calculated using the rate established by the FUL.

State Medicaid programs consider several methods for reimbursing pharmacies for multiple-source prescription drugs. In general, states base their Medicaid reimbursements to a retail pharmacy for a covered outpatient prescription drug on the lowest of the following: a state's best estimate of retail pharmacies' acquisition costs for the drug;[22] the usual and customary charge of the retail pharmacy that dispensed the drug;[23] the FUL for the drug, if applicable; or the state's maximum allowable cost (MAC) for the drug,[24] if applicable. When the FUL for a drug is not the

---

[18]Transmittal No. 37, Federal Upper Limit Drug List, November 20, 2001. Federal Upper Limit (FUL) Changes to Transmittal No. 37, June 23, 2006.

[19]AWP is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies.

[20]WAC is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions.

[21]DP as published by First DataBank represents the manufacturer's published catalog or list price for a drug product to nonwholesalers. DP does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions.

[22]States may establish their own methodologies for estimating retail pharmacies' drug acquisition costs. Most states in the first quarter of 2006 chose to estimate these costs by taking a percentage discount from the AWP.

[23]The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy.

[24]States that administer MACs publish lists of selected multiple-source drugs with the maximum price at which the state will reimburse for those medications. Pharmacies generally do not receive payments that are higher than the MAC price. The MAC lists differ from the FUL list, as states have more

lowest of these four amounts, Medicaid typically reimburses pharmacies at a rate lower than the FUL.

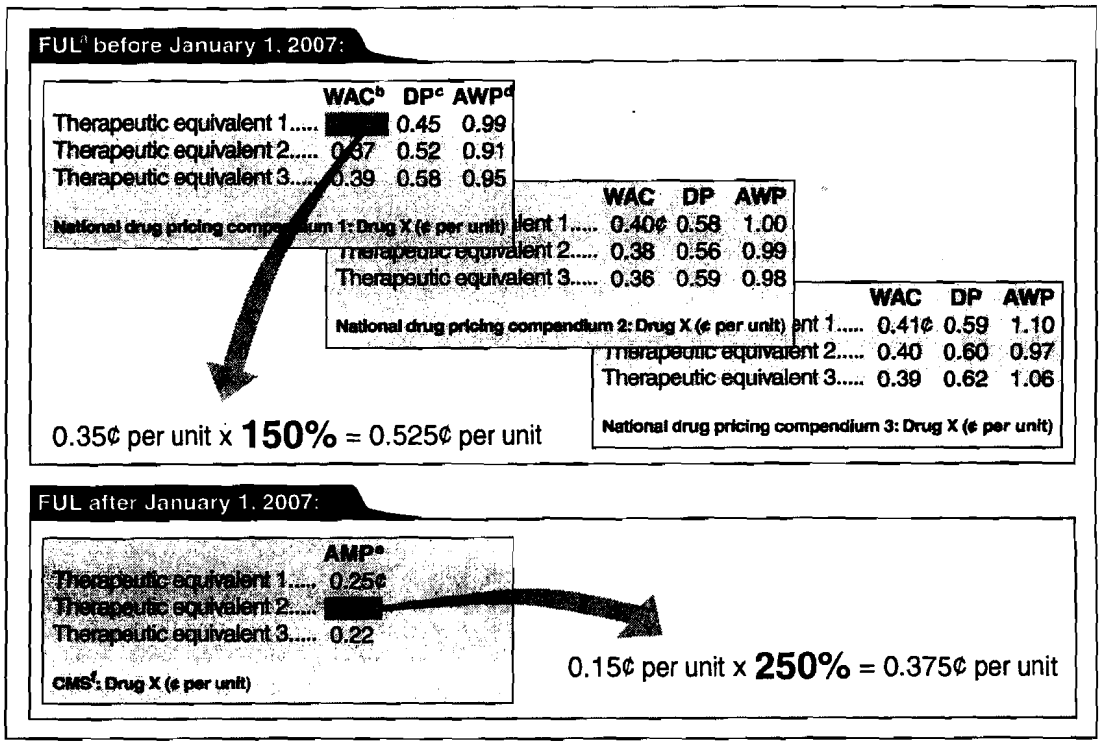
Deficit Reduction Act of 2005 and Medicaid FULs

DRA modified the methodology used to set FULs for certain multiple-source outpatient prescription drugs for Medicaid.[25] Rather than 150 percent of the lowest published price of the therapeutically equivalent versions, starting January 1, 2007, DRA required that CMS calculate FULs as 250 percent of the lowest AMP among a drug's therapeutically equivalent versions. AMP data are collected by CMS and are not publicly available. (Fig. 1 illustrates how Medicaid FULs are calculated before and after DRA provisions take effect January 1, 2007.)

discretion in determining what drugs to include on their MAC lists. Generally, state MAC lists include more drugs, and establish lower reimbursement prices, than the FUL list. As of first quarter 2006, 43 states administer MACs.

[25]DRA § 6001,120 Stat. 54-59.

Figure 1: Illustration of FUL Methodology Before and After January 1, 2007



Source: GAO.

Note: The drug pricing compendia in fig.1 are published by First DataBank, Medi-Span, and Red Book.

[a]FUL is the federal upper limit for reimbursement of certain Medicaid outpatient prescription drugs.

[b]WAC is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions.

[c]DP as published by First DataBank represents the manufacturer's published catalog or list price for a drug product to nonwholesalers. DP does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions.

[d]AWP is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies.

[e]AMP represents the average of prices paid to manufacturers by wholesalers for a drug distributed to the retail pharmacy class of trade, including retail pharmacies.

[f]CMS is the agency that oversees Medicaid.

DRA included additional provisions relating to prescription drugs. One provision changed the criteria under which FULs must be established. Until January 1, 2007, FULs must be established for multiple-source drugs for which there are three or more therapeutically equivalent products.[26] Beginning on January 1, 2007, the DRA provides that FULs be established for multiple-source drugs for which there are at least two therapeutically equivalent products.[27] DRA also mandated several changes relating to

[26]42 U.S.C. § 1396r-8(e)(4) (2000).

[27]DRA § 6001(a)(1), 120 Stat. 54 (to be codified at 42 U.S.C. § 1396r-8(e)(4)).

the AMP. For example, DRA required that prompt payment discounts be excluded when manufacturers calculate AMP. DRA also required the Secretary of Health and Human Services to make manufacturers' reported AMP data available on a monthly basis to states, and to post those amounts on a Web site accessible to the public beginning July 2006.[28] These requirements were established in order to give states pricing information that was not previously available to consider in setting reimbursement amounts.

Estimated AMP-Based FULS Were Lower Than Average Pharmacy Acquisition Costs for Most Drugs in our Sample

For most of the 77 drugs in our sample, the AMP-based FULs we estimated using AMP data from the first quarter of 2006 were lower than average retail pharmacy acquisition costs for the same period. In particular, the percentage difference between the estimated AMP-based FULs and average retail pharmacy acquisition costs was more pronounced for high expenditure drugs than it was for frequently used drugs. Though lowest AMPs can vary notably from quarter to quarter, when we estimated what AMP-based FULs would have been using several quarters of AMP data we found that that these estimated FULs were also lower than average retail pharmacy acquisition costs for most of the drugs—and in particular the high expenditure drugs—in our sample. Furthermore, the difference between AMP-based FULs and retail pharmacy acquisition costs could change following the implementation of DRA provisions in January 2007, to the extent that retail pharmacies acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers.

Based on First Quarter 2006 Data, AMP-Based FULs Were Lower Than Average Acquisition Costs, with Difference Most Pronounced for High Expenditure Drugs

The AMP-based FULs we estimated using first quarter 2006 AMP data were lower than the average retail pharmacy acquisition costs for the same period for most—59 out of 77—of the drugs in our sample. The estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for our entire sample of drugs.[29] Further, for 43 of the 77 drugs, we found that the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies. While the estimated AMP-based FULs were lower than average retail pharmacy acquisition costs for our entire sample of drugs, this difference was most pronounced for the 27 high expenditure drugs, compared with the 27 frequently used drugs and with the 23 drugs that were both high expenditure and frequently used in our sample.

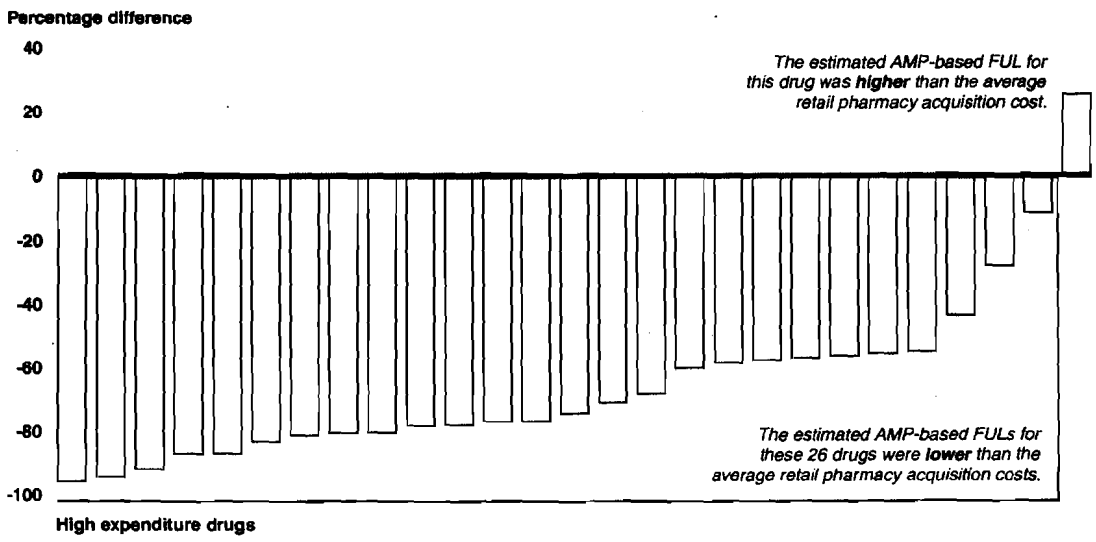
[28]While CMS released AMP data to states starting in July of 2006, the implementation of the provision requiring AMP data to be posted on a publicly available Web site has been delayed until January 1, 2007.

[29]Excluding statistical outliers from our analysis resulted in a less than 1 percent change in the average percent difference between average retail pharmacy acquisition costs and estimate AMP-based FULs.

High Expenditure Drugs

For 26 of the 27 high expenditure drugs in our sample, the AMP-based FULs we estimated using first quarter 2006 data were lower than the average retail pharmacy acquisition costs for this period (see fig. 2). The estimated FULs for these 27 drugs were, on average, 65 percent lower than average retail pharmacy acquisition costs.[30] We also found that for 21 of the 27 high expenditure drugs, the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies.

Figure 2: Comparison of Estimated AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 27 High Expenditure Outpatient Drugs in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

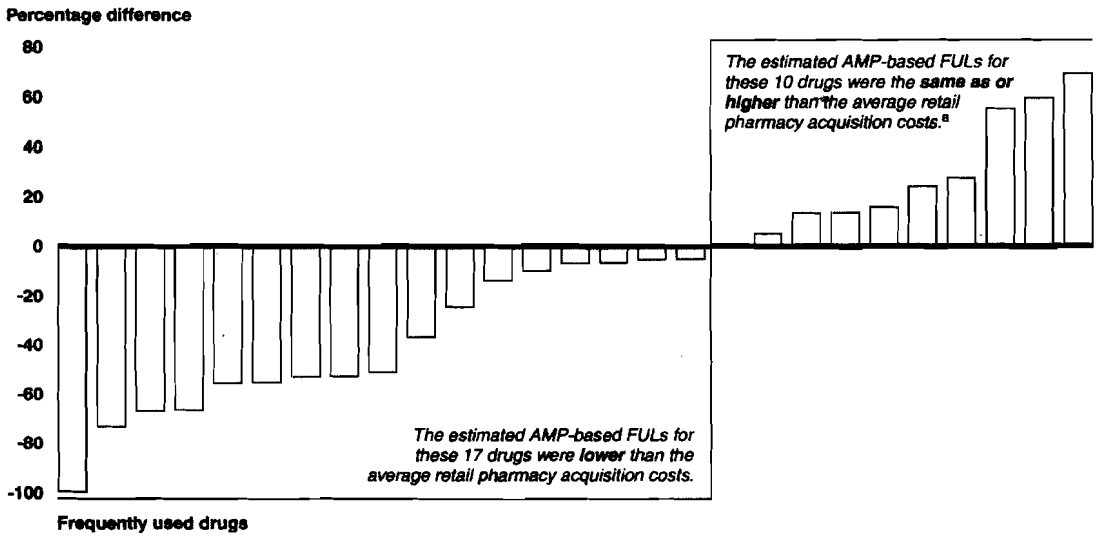
Frequently Used Drugs

For 17 of the 27 frequently used drugs in our sample, the AMP-based FULs we estimated using first quarter 2006 data were lower than the average retail pharmacy acquisition costs for this period (see fig. 3). For these 27 frequently used drugs, the estimated AMP-based FULs were, on average, 15 percent lower than average retail pharmacy acquisition costs.[31] We also found that for 11 of the 27 frequently used drugs, the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies.

[30]In the first quarter of 2006 the average acquisition cost per unit for the 27 high expenditure drugs in our sample was $0.49.

[31]In contrast with the average acquisition cost per unit for the 27 high expenditure drugs in our sample—$0.49—the average acquisition cost per unit for the 27 frequently used drugs was $0.05 in the first quarter of 2006.

Figure 3: Comparison of Estimated AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 27 Frequently Used Outpatient Drugs in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

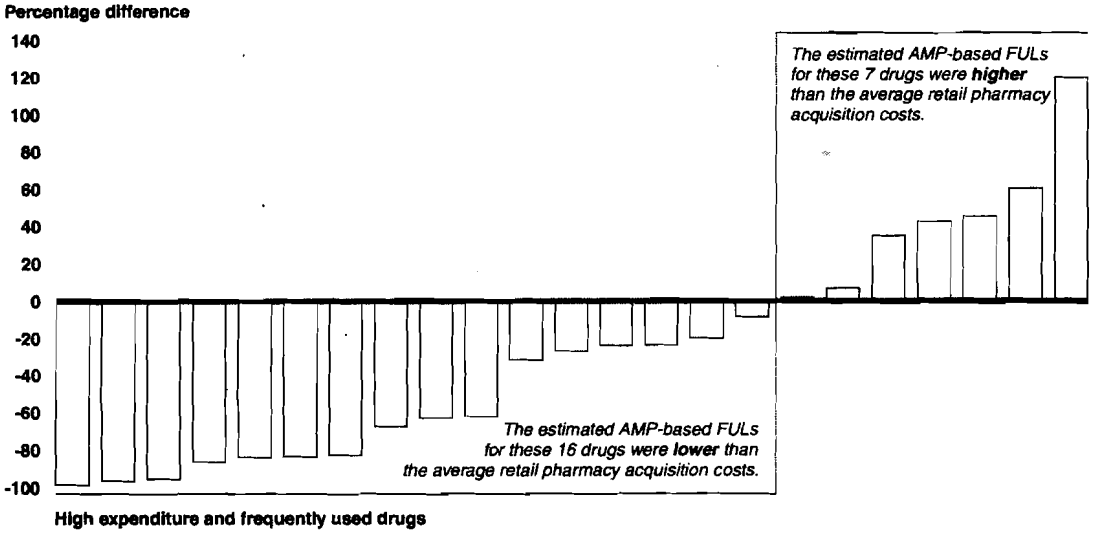
[a]One drug had an estimated AMP-based FUL the same as the average retail pharmacy acquisition cost.

High Expenditure and Frequently Used Drugs

For 16 of the 23 drugs that were both high expenditure as well as frequently used, the AMP-based FULs we estimated using first quarter 2006 AMP data were lower than the average retail pharmacy acquisition costs for this period (see fig. 4). Further, the estimated AMP-based FULs for the 23 drugs were, on average, 28 percent lower than average retail pharmacy acquisition costs.[32] We also found that for 11 of these 23 drugs the estimated AMP-based FULs fell below the lowest acquisition costs available to retail pharmacies.

[32]For the 23 high expenditure and frequently used drugs, the average acquisition cost per unit was $0.08.

Figure 4: Comparison of AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 23 Outpatient Drugs That Were Both High Expenditure and Frequently Used in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

Though Lowest AMPs Can Vary Over Time, AMP-Based FULs Estimated for Several Quarters Were Also Lower Than Acquisition Costs

Our comparison of estimated AMP-based FULs and average retail pharmacy acquisition costs involves AMP data that can vary notably from quarter to quarter. In particular, we found variation in the lowest AMPs—which will set AMP-based FULs, beginning January 1, 2007—for the 77 drugs in our sample. For example, from the first of quarter 2006 through the second quarter of 2006,

- 36 of the 77 drugs had a median increase of 33 percent in their lowest AMPs;
- 11 of the 77 drugs had no change in their lowest AMPs; and
- 30 of the 77 drugs had a median decrease of 33 percent in their lowest AMPs.

Similarly, the lowest AMPs for the 77 drugs in our sample varied from quarter to quarter over the period covering the third quarter of 2005 through the third quarter of 2006. Despite this variation in lowest AMP values, when we estimated what AMP-based FULs would have been in each of several quarters—namely, the fourth quarter of 2005 through the second quarter of 2006—we found that the estimated FULs for each of these quarters were also lower, on average, than average retail pharmacy acquisition costs from the first quarter of 2006.[33] Even if we made the comparison using the quarter—from among the fourth quarter of 2005 through the second quarter of 2006—in which each drug's estimated AMP-based FUL was the highest, the

[33]This analysis assumes that first quarter 2006 acquisition costs are a valid proxy for acquisition costs in the fourth quarter of 2005 and the second quarter of 2006.

estimated AMP-based FULs for 49 of the 77 drugs remained lower than first quarter 2006 average retail pharmacy acquisition costs. Across our entire sample of 77 prescription drugs, the estimated AMP-based FULs were 12 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006. This analysis also showed differences across the three groups of drugs in our sample:

- For the high expenditure drugs, AMP-based FULs for 24 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 41 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

- For frequently used drugs, AMP-based FULs for 10 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 11 percent higher, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

- For the high expenditure and frequently used drugs, AMP-based FULs for 15 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 4 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

Difference between AMP-Based FULs and Retail Pharmacy Acquisition Costs Could Change Following Implementation of DRA Provisions in 2007

Though the difference between AMP-based FULs and retail pharmacy acquisition costs in the first quarter of 2006 was in some cases sizable—on average 65 percent for the high expenditure drugs in our sample—it is important to recognize that the extent of this difference may change, because of several factors. These factors include the quarter-to-quarter variation in the AMPs used to set FULs, the DRA-required change in the definition of AMP that excludes prompt payment discounts from the calculation of AMPs, which may increase AMPs, and the presence of rebates that retail pharmacies may obtain from drug manufacturers and wholesalers that may lower retail pharmacy acquisition costs. In addition, because FULs apply to state Medicaid program aggregate expenditures for relevant outpatient multiple-source drugs in a year, states may reimburse for some drugs in excess of the FULs as long as these higher reimbursements are offset by others that are below the FULs.

Furthermore, the difference we found between AMP-based FULs and retail pharmacy acquisition costs also reflects the particular multiple-source outpatient prescription drugs pharmacies purchased and dispensed to Medicaid beneficiaries in the first quarter of 2006. To the extent that in 2007 and in future years this utilization remains similar to the utilization captured in our sample of drugs for the first quarter of 2006, the gap we found could persist. However, to the extent that the cost-containment measures of the AMP-based FULs influence retail pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset. Only after AMP-based FULs are implemented in

2007 will there be an opportunity to determine the extent to which these FULs are facilitating both cost-effective Medicaid drug expenditures and adequate reimbursements for retail pharmacies.

Agency and Other External Comments

CMS reviewed a draft of this report and provided written comments, which are reproduced in enclosure III. CMS disagreed with our finding that the AMP-based FULs were lower than the average retail pharmacy acquisition costs for most of the 77 drugs in our sample. In particular, CMS had significant concerns with our estimates of both pharmacy acquisition costs and AMP-based FULs and stated that our findings had not accounted for changes in these two variables that are likely to take place after DRA provisions are implemented in January 2007. In our view, we used the most complete, accurate data sources available at the time of our analysis for our purposes—to estimate both retail pharmacy acquisition costs and AMP-based FULs, had the latter applied in the first quarter of 2006. Furthermore, in our draft report we identified the limitations of the data sources used in our estimates and acknowledged that the difference between retail pharmacy acquisition costs and AMP-based FULs could change following implementation of DRA provisions in 2007.

In its written comments, CMS raised issues regarding our estimates of retail pharmacy acquisition costs, our estimates of AMP-based FULs, and our discussion of the impact of DRA provisions:

Our Estimates of Retail Pharmacy Acquisition Costs

CMS stated that our draft report did not provide source documents or evidence of how IMS Health arrived at the acquisition costs used in our comparison. Our draft report explained that IMS Health collects acquisition cost data from actual sales transactions from manufacturers and distribution centers, which represent over 85 percent of total market dollar volume, and projects these data to represent national average acquisition costs. We could not provide CMS with the acquisition cost data used in our analysis because, while they are commercially available, they are proprietary. Specifically, our data use agreement with IMS Health prohibits us from releasing its data to third parties, such as CMS.

CMS also questioned the validity of our estimation of retail pharmacy acquisition costs because we did not account for the rebates retail pharmacies may receive from wholesalers and manufacturers. In our draft report we stated that the IMS Health data did not account for such rebates, and we identified this as a limitation of our analysis. However, as CMS officials acknowledged to us, there are no known data sources of pharmacy acquisition costs of multiple-source outpatient prescription drugs that account for rebates. Identifying rebates is difficult because retail pharmacies negotiate their rebates based on various factors and can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis. We have amended our report to clarify these issues.

Our Estimates of AMP-Based FULs

CMS stated that in estimating the AMP-based FULs for our analysis we did not exclude outlier AMP data. According to CMS, excluding outlier AMP data could have "significantly" raised our estimates of AMP-based FULs for many multiple-source outpatient prescription drugs. As we stated in our draft report, we did not exclude outlier AMP data from our analysis because, during the course of our work, CMS officials indicated that they would not exclude any outlier AMP data when they begin calculating AMP-based FULs in January 2007. To be consistent with the methodology CMS indicated the agency will use when implementing DRA provisions, we did not exclude outlier data from our estimates of AMP-based FULs. However, in their comments, CMS indicated that they intend to address outlier AMP data, as appropriate, in calculating the AMP-based FULs.

During the course of our work we identified outliers in the AMP data underlying the FULs for several drugs in our analysis. However, excluding these outliers did not significantly reduce the gap we found between the estimated AMP-based FULs and retail pharmacy acquisition costs. We have amended our report to include this information. We agree with CMS's revised approach to publish clear criteria for (1) identifying and excluding outliers from the AMP data that underlie each FUL group and (2) identifying which therapeutically equivalent versions of each drug are nationally available and should thereby be considered when setting the FUL.[34]

Potential Impact of DRA on Retail Pharmacy Acquisition Costs and AMP-Based FULs

CMS stated that our analysis did not account for several ways in which DRA may affect retail pharmacy acquisition costs and the AMP-based FULs. CMS suggested that our estimation of retail pharmacy acquisition costs will likely not reflect such costs after the implementation of DRA provisions in January 2007. CMS expects that the AMP-based FULs implemented as a result of DRA will drive retail pharmacies to fill more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs—thereby reducing these pharmacies' acquisition costs. In CMS's view, our study erroneously assumed that pharmacies' utilization of multiple-source outpatient prescription drugs—and therefore pharmacy acquisition costs—will remain unchanged after the implementation of DRA. While we estimated average pharmacy acquisition costs for the multiple-source outpatient prescription drugs in our sample using utilization and cost data from the first quarter of 2006, we also acknowledged in our draft report that retail pharmacies could change their utilization of multiple-source outpatient prescription drugs in 2007 and later to lower their acquisition costs. Specifically, our draft report stated that "to the extent that the cost-containment measures of the AMP-

[34]In a media release dated December 15, 2006, CMS indicated that it will publish in the *Federal Register* a proposed rule to implement provisions of the Deficit Reduction Act of 2005 that highlights proposed changes in the payment for certain drugs in the Medicaid program. See http://www.cms.hhs.gov/apps/media/fact_sheet.asp (December 15, 2006).

based FULs influence pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset."

CMS also pointed out that our study did not include an analysis of how retail pharmacies could mitigate the effects of AMP-based FULs by filling more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs. However, as part of our analysis, we compared estimated AMP-based FULs to the lowest available acquisition cost for each of the multiple-source outpatient prescription drugs in our sample. As we reported in our draft, for most the drugs in our sample—43 of 77—the estimated AMP-based FUL fell below the lowest acquisition cost available to retail pharmacies.

CMS had concerns that in estimating the AMP-based FULs we used AMP data that included customary prompt payment discounts, even though DRA requires their exclusion from AMP beginning in 2007. According to CMS, prompt payment discounts decrease AMPs, and so using AMP data that include such discounts will decrease AMP-based FULs. In our view, the impact of excluding prompt payment discounts from the AMP data we used to estimate AMP-based FULs is unclear. In our previous work, we have found that prompt payment discounts are, on average, 2 percent of the sales transactions to which they apply.[35] However, we have also reported that manufacturers vary in the purchasers to whom they offer prompt payment discounts and whether they include these discounts in their calculations of AMP. Therefore, attempting to account for prompt payment discounts for all of the multiple-source outpatient prescription drugs in our analysis would have, in some cases, overstated the impact of these discounts on our estimates of AMP-based FULs. We agree with CMS that the changes in the definition of AMP as required by DRA will likely increase AMP-based FULs. However, our previous work suggests that excluding prompt payment discounts from the calculation of AMP-based FULs would not have offset the gap we reported between retail pharmacy acquisition costs and estimated AMP-based FULs. In our report, we have clarified the issue of prompt payment discounts and its impact on our analysis.

In addition to their concerns related to the estimates used in our draft report, CMS noted that our analysis did not address existing state cost containment efforts, such as MAC programs, to reduce Medicaid reimbursements for outpatient prescriptions drugs. While the relationship between AMP-based FULs and state Medicaid cost containment efforts is a valid comparison, the issue was beyond the scope of our report, which compared estimated AMP-based FULs to retail pharmacy acquisition costs.

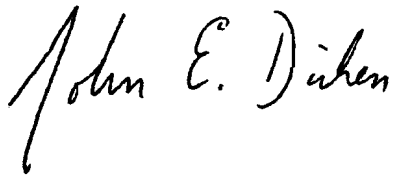
[35]See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

Finally, we agree with CMS that changing the basis of the FUL from the AWP to the AMP was a step in the right direction towards achieving savings for the federal government on Medicaid expenditures for multiple-source outpatient prescription drugs. However, these savings should be achieved while ensuring that reimbursements to retail pharmacies are adequate to provide Medicaid beneficiaries access to multiple-source outpatient prescription drugs. As we stated in our draft report, only after AMP-based FULs are implemented in 2007 will there be an opportunity to determine the extent to which these FULs facilitate both cost effective Medicaid drug expenditures and adequate reimbursement for retail pharmacies.

CMS also provided technical comments that we incorporated as appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its date. We will then send copies of this report to the Administrator of CMS and other interested parties. The report will also be available at no charge on GAO's Web site at http://www.gao.gov. If you or your staff have any questions about this report, please contact me at (202) 512-7119 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs can be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure IV.

Sincerely yours,



John E. Dicken
Director, Health Care

Enclosures—4

Scope and Methodology

To examine the relationship between the Medicaid federal upper limits (FUL) estimated using first quarter 2006 average manufacturer price (AMP) data and the average retail pharmacy acquisition cost for frequently used and high expenditure drugs in Medicaid, we used first quarter 2006 Medicaid utilization data from the Centers for Medicare & Medicaid Services (CMS)[36] to select the 50 most frequently used and the 50 highest expenditure multiple-source outpatient prescription drugs in Medicaid subject to FULs.[37] Combined, these two lists comprised a sample of 77 unique drugs representing 53 percent of Medicaid prescriptions and 56 percent of Medicaid expenditures for drugs subject to the FUL in the first quarter of 2006.[38] We obtained the list of drugs subject to the FUL from CMS and, because the AMP-based FULs were not available during the course of our work, estimated what the AMP-based FULs would have been using AMP data from the first quarter of 2006 for each of the 77 drugs.

Our analyses are limited to multiple-source outpatient prescription drugs that were subject to FULs for the first quarter of 2006 and do not include those drugs that may be added to the FUL list beginning January 1, 2007, per the expanded multiple-source definition in the Deficit Reduction Act of 2005 (DRA). Additionally, we compared corresponding AMP data with retail pharmacy acquisition cost data for each drug in our sample by National Drug Codes (NDC).[39]

To estimate FULs under the AMP-based methodology, we first extracted AMP data for the first quarter of 2006 for each of the 77 drugs in our sample from CMS's Medicaid Drug Rebate Initiative (MDRI) system. CMS requires manufacturers to report AMP data within 30 days of the end of every calendar quarter. We then selected the lowest AMP for the first quarter of 2006 for each group of therapeutically equivalent drugs and multiplied it by 250 percent. These AMP data do not account for the impact of the DRA-required change in the definition of AMP which excludes

[36]Medicaid utilization data reported to CMS include information on the total number of units and dollar amounts reimbursed for each drug. As of August 2006 when we selected our sample, Iowa, Minnesota, New Jersey, and Rhode Island had not reported their Medicaid utilization data for the first quarter of 2006.

[37]For drugs subject to the FUL, Medicaid covered 32.9 million prescriptions that were dispensed to Medicaid beneficiaries at retail pharmacies in the first quarter of 2006.

[38]Drugs with the same name but different strengths, forms (such as capsules or tablets), or package sizes were counted separately as unique drugs.

[39]NDCs are the universal product identifiers for drugs for human use. The Food and Drug Administration assigns the first segment of the NDC, which identifies the firm that manufacturers, repackages, or distributes a drug; the second segment identifies a specific strength, dosage form, and formulation for a particular firm; and the third segment identifies package size. A single drug can have multiple NDCs associated with it. For example, a drug made by one manufacturer, in one form or strength, but in three package sizes would have three NDCs. Three-segment NDCs are denoted by 11 digits while two-segment NDCs are denoted by 9 digits, and do not account for package size.

prompt payment discounts.[40] In addition, in estimating the AMP-based FULs, we did not exclude any outlier AMP data in order to be consistent with how CMS officials told us they will be implementing DRA provisions beginning January 1, 2007. Nonetheless, during the course of our work, we examined the AMP data underlying each FUL group for the presence of statistical outliers.

To determine retail pharmacies' acquisition costs for the 77 drugs, we purchased national average retail pharmacy acquisition cost data from IMS Health for the first quarter of 2006. IMS Health obtains these data on sales transactions from approximately 100 manufacturers and over 300 distribution centers, including drug wholesalers and chain warehouses. These manufacturers and distribution centers are responsible for over 85 percent of total market dollar volume. IMS Health projects these data to represent national average acquisition costs for each drug in our sample in the first quarter of 2006.[41] The average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual average acquisition costs because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers.[42] We calculated an average acquisition cost for each drug by weighting the acquisition cost for each therapeutically equivalent drug by its Medicaid expenditure for first quarter 2006.[43]

To compare the estimated AMP-based FULs to the average retail pharmacy acquisition costs for each of the 77 drug groups in our analysis, we calculated the percentage difference between the AMP-based FUL and (1) the average of acquisition costs for all therapeutically equivalent drugs within a group and (2) the average acquisition cost for the lowest cost therapeutically equivalent drug within a group. We also calculated the percentage difference of the AMP-based FUL to the average acquisition cost and minimum acquisition cost separately for the 27 high expenditure drugs, 27 frequently used drugs, and 23 drugs that were considered both high expenditure and frequently used.

---

[40]In our previous work we found that prompt payment discounts are, on average, 2 percent of the sales transactions to which they apply. However, we have also reported that manufacturers vary in the purchasers to whom they offer prompt payment discounts and whether they include these discounts in their calculations of AMP. Therefore, attempting to account for prompt payment discounts for all of the multiple-source outpatient prescription drugs in our analysis would have, in some cases, overstated the impact of these discounts on our estimates of AMP-based FULs. See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

[41]For any given drug, the acquisition costs of individual pharmacies may be higher or lower than the national average.

[42]These rebates may vary as retail pharmacies negotiate their rebates based on various factors, including the type of drug, manufacturer, and volume of purchases. In addition, they can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis.

[43]We calculated a weighted average acquisition cost to account for Medicaid prescription drug utilization patterns.

We also assessed the extent to which AMP-based FULs are likely to vary over time by examining the variation of the lowest AMPs that would be used to set the estimated FULs for each of the 77 drugs in our sample from the third quarter of 2005 through the third quarter of 2006. Additionally, we compared the highest estimated AMP-based FUL from the fourth quarter of 2005 through the second quarter of 2006 to the average retail pharmacy acquisition cost for the first quarter of 2006 for each of the 77 drugs. We also performed this comparison separately for the 27 high expenditure drugs, 27 frequently used drugs, and 23 drugs that were considered both high expenditure and frequently used.

To assess the reliability of the AMP data, we reviewed relevant documentation regarding the construction and reporting of data extracted from CMS's MDRI system. To assess the reliability of the IMS Health average retail pharmacy acquisition cost data, we reviewed relevant documentation regarding the construction and reporting of the data supplied. We determined that the data used were sufficiently reliable for our purposes.

We performed our work from July 2006 through November 2006 in accordance with generally accepted government auditing standards.

Enclosure II

Percentage of Medicaid Prescriptions and Expenditures for 77 Medicaid Outpatient Prescription Drugs GAO Reviewed, First Quarter 2006

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Acetaminophen Codeine Phosphate 300-30mg	Tablet	1.2	14	0.5	49
Acetaminophen Hydrocodone Bitartrate 500-5mg	Tablet	3.2	2	0.5	47
Acetaminophen Hydrocodone Bitartrate 500-7.5mg	Tablet	0.9	27	N/A	N/A
Acetaminophen Hydrocodone Bitartrate 500-10mg	Tablet	0.6	43	1.1	17
Acetaminophen Hydrocodone Bitartrate 750-7.5mg	Tablet	0.6	45	N/A	N/A
Acetaminophen Oxycodone HCl 325-5mg	Tablet	1.2	17	N/A	N/A
Acetaminophen Propoxyphene Napsylate 650-100mg	Tablet	1.1	19	0.6	42
Albuterol 0.9mg/inh	Aerosol	3.7	1	1.8	9
Albuterol Sulfate 0.083mg/ml	Solution	1.8	4	2.0	6
Alprazolam 0.25mg	Tablet	0.6	38	N/A	N/A
Alprazolam 0.5mg	Tablet	0.9	26	N/A	N/A
Alprazolam 1mg	Tablet	0.8	29	N/A	N/A
Amoxicillin 125/5mg/ml	Suspension	1.9	3	0.5	50
Amoxicillin 500mg	Capsule	1.6	5	N/A	N/A
Amoxicillin Clavulanic Acid 400/5mg/ml-57/5mg/ml	Suspension	N/A	N/A	1.9	7
Atenolol 25mg	Tablet	0.6	40	N/A	N/A

Enclosure II

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Atenolol 50mg	Tablet	0.8	33	N/A	N/A
Baclofen 10mg	Tablet	N/A	N/A	0.7	30
Baclofen 20mg	Tablet	N/A	N/A	0.6	41
Betamethasone Dipropionate Clotrimazole 0.05-1%	Cream	N/A	N/A	0.8	23
Carbamazepine 200mg	Tablet	N/A	N/A	0.6	45
Carisoprodol 350mg	Tablet	0.6	44	0.8	24
Cephalexin 500mg	Capsule	1.0	22	0.7	36
Ciprofloxacin HCl 500mg	Tablet	0.5	49	N/A	N/A
Clonazepam 0.5mg	Tablet	1.3	11	0.7	29
Clonazepam 1mg	Tablet	1.1	18	0.9	21
Clonidine HCl 0.1mg	Tablet	1.0	24	N/A	N/A
Cyclobenzaprine HCl 10mg	Tablet	1.0	23	0.7	34
Diazepam 5mg	Tablet	0.6	42	N/A	N/A
Fluoxetine HCl 20mg	Capsule	1.0	21	0.7	33
Fluoxetine HCl 40mg	Capsule	N/A	N/A	1.2	16
Folic Acid 1mg	Tablet	1.2	15	N/A	N/A
Furosemide 20mg	Tablet	0.9	28	N/A	N/A
Furosemide 40mg	Tablet	1.4	7	N/A	N/A
Gabapentin 100mg	Capsule	N/A	N/A	0.7	32
Gabapentin 300mg	Capsule	0.7	36	5.1	1
Gabapentin 400mg	Capsule	N/A	N/A	1.3	12
Gabapentin 600mg	Tablet	N/A	N/A	4.2	2
Gabapentin 800mg	Tablet	N/A	N/A	2.0	5
Glimepiride 4mg	Tablet	N/A	N/A	0.5	46

Enclosure II

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Glyburide 5mg	Tablet	N/A	N/A	0.8	26
Glyburide Metformin HCl 5mg	Tablet	N/A	N/A	1.1	18
Hydrochlorothiazide 25mg	Tablet	1.5	6	N/A	N/A
Hydroxyzine HCl 25mg	Tablet	N/A	N/A	0.8	27
Ibuprofen 400mg	Tablet	0.6	46	N/A	N/A
Ibuprofen 600mg	Tablet	1.1	20	N/A	N/A
Ibuprofen 800mg	Tablet	1.4	8	N/A	N/A
Levothyroxine Sodium 0.05mg	Tablet	0.6	47	N/A	N/A
Lisinopril 10mg	Tablet	0.8	32	0.6	44
Lisinopril 20mg	Tablet	0.7	37	0.6	39
Lisinopril 40mg	Tablet	N/A	N/A	0.6	40
Lorazepam 0.5mg	Tablet	1.3	10	0.9	20
Lorazepam 1mg	Tablet	1.2	16	1.3	13
Lorazepam 2mg	Tablet	N/A	N/A	0.6	43
Lovastatin 40mg	Tablet	N/A	N/A	0.7	35
Metformin HCl 500mg	Tablet	1.2	12	1.8	8
Metformin HCl 1000mg	Tablet	0.6	41	1.0	19
Metoprolol Tartrate 50mg	Tablet	0.8	30	N/A	N/A
Metronidazole 500mg	Tablet	0.5	50	N/A	N/A
Mirtazapine 15mg	Tablet	N/A	N/A	0.8	28
Mirtazapine 30mg	Tablet	N/A	N/A	0.7	37
Mupirocin 2%	Ointment	N/A	N/A	1.2	15
Naproxen 500mg	Tablet	0.8	31	N/A	N/A
Omeprazole 20mg	Capsule	N/A	N/A	1.4	10

Enclosure II

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Paroxetine HCl 10mg	Tablet	N/A	N/A	0.6	38
Paroxetine HCl 20mg	Tablet	N/A	N/A	2.3	3
Paroxetine HCl 30mg	Tablet	N/A	N/A	0.8	22
Paroxetine HCl 40mg	Tablet	N/A	N/A	1.2	14
Penicillin V Potassium 500mg	Tablet	0.5	48	N/A	N/A
Potassium Chloride 20mEq	Tablet	0.8	34	0.8	25
Ranitidine HCl 150mg	Tablet	1.3	9	0.5	48
Ribavirin 200mg	Capsule	N/A	N/A	2.1	4
Sulfamethoxazole Trimethoprim 800-160mg	Tablet	1.0	25	N/A	N/A
Tizanidine HCl 4mg	Tablet	N/A	N/A	0.7	31
Tramadol HCl 50mg	Tablet	1.2	13	1.3	11
Trazodone HCl 50mg	Tablet	0.8	35	N/A	N/A
Trazodone HCl 100mg	Tablet	0.6	39	N/A	N/A

Source: GAO analysis of CMS Medicaid state drug utilization data.

Note: Our sample contained 77 multiple-source outpatient prescription drugs in Medicaid for the first quarter of 2006, which comprised 27 frequently used prescription drugs, 27 high expenditure prescription drugs, and 23 prescription drugs that overlapped both categories. N/A appears in the table for drugs that were not in the overlap category.

Enclosure III

CMS Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

DEC - 6 2006

Administrator
Washington, DC 20201

TO: John Dicken
Director, Health Care
Government Accountability Office

FROM: Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office (GAO) Draft Report: "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs" (GAO-07-239R)

Thank you for the opportunity for the Centers for Medicare & Medicaid Services (CMS) to comment on the proposed report on Federal Upper Limit (FUL) reimbursement and retail pharmacy acquisition cost. This report examines the potential effects on retail pharmacies of the provision of the Deficit Reduction Act of 2005 (DRA) that requires CMS to set the FUL at 250 percent of the lowest average manufacturer price (AMP) (computed without regard to customary prompt pay extended to wholesalers) in a FUL group.

Section 1927(e)(4) of the Social Security Act requires the Secretary to establish a Federal upper reimbursement limit for certain multiple source drugs. By regulation, this limit has been set as 150 percent of the least costly therapeutically equivalent drug as listed in published compendia of cost information for drugs for sale nationally.

It has been routinely reported that, over time, the FUL was increasingly less effective in assuring that the Medicaid program paid appropriately for multiple source drugs. This fact had been documented by studies of the Inspector General of the Department of Health and Human Service (HHS), by the bi-partisan Medicaid Commission, and in testimony before the House Energy and Commerce Committee. Over time, the reported prices used to set the FUL in published compendia have become less reliable as estimates of the true acquisition cost of drugs. As long as States must rely on prices that are not based on verifiable data, reimbursement is inflated, increasing the cost to Medicaid. In mandating the use of AMP, Congress required that the reimbursement system be based on reliable data and not on self-reported manufacturer's or distributor's data that is subject to bias. The DRA changes are intend to make transparent accurate pricing data to assure that the Federal government and state Medicaid programs are paying appropriately for multiple source drugs.

Enclosure III

This GAO study responds to concerns of the retail pharmacy industry that establishing a FUL reimbursement based on 250 percent of AMP will be insufficient to cover retail pharmacists' costs of purchasing drugs. If this were true, the actual AMP of a drug, as reported by manufacturers, multiplied by 2.5 would be less than a pharmacy's purchase price, meaning that the handling costs and profits in the distribution chain far exceed the actual cost of the drug product.

This GAO study purports to document that the AMP-based FULs are lower than average retail pharmacy acquisition cost for the 77 FUL drug groups reviewed. We find GAO's conclusion premature and unsupported by the report. This study cannot be thoroughly analyzed or replicated because the GAO will not release the data on which it is based. It admittedly uses incomplete and misleading information, as well as nondisclosed pricing data. We believe a more thorough analysis of pharmacy acquisition costs is necessary, based on verifiable and complete data, before any report is released.

GAO Findings

Using first quarter 2006 Medicaid data, 50 drugs that were identified as the most frequently used drugs, and 50 drugs that accounted for the highest Medicaid expenditures were selected for the study. With some drugs overlapping the two categories, the resulting sample contained 77 multiple source drugs groups.

The GAO determined that for 59 of the 77 multiple source drug groups analyzed in the study, the AMP-based FUL was lower than average retail pharmacy acquisition cost. On average, GAO estimated that the AMP-based FUL was 36 percent lower than average retail pharmacy acquisition cost. For high expenditure drugs, GAO estimated that the AMP-based FUL was 65 percent lower, and it was 15 percent lower for the frequently used drugs. For the drugs that overlapped both categories, the estimated AMP-based FUL was 28 percent lower than average retail pharmacy acquisition cost.

CMS Response

Based on the methodological flaws discussed below, we do not concur with the GAO findings that the AMP-based FUL would be lower than average retail pharmacy acquisition cost. The GAO study fails to credibly document this finding and we believe the release of the report would mislead the public.

The CMS has significant concerns with the validity of the estimate GAO used to approximate pharmacist acquisition costs. The CMS is unable to validate the findings of the GAO related to average retail pharmacy acquisition cost. The report does not provide source documents or evidence of how IMS Health arrived at the acquisition cost used in the comparison study other than to state that data on sales transactions were collected. Specifically, IMS cost and utilization data by national drug code (NDC) was not provided to CMS. This brings into question the overall validity of this self-reported data. Further, the GAO states in their report that "the average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual average acquisition cost,

Enclosure III

Page 3 – John Dicken

because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers." Thus, even were the GAO to supply this data, we cannot determine the accuracy of the ingredient cost actually incurred by the pharmacy. Therefore, CMS has no confidence that the estimates used in this analysis adequately measure pharmacy acquisition costs.

The CMS has concerns that GAO failed to account for the differences in the definitions of AMP. The AMP data from first quarter 2006 used in this study is not a true reflection of the AMP data which will be submitted starting in January 2007. The DRA revises the definition of AMP, effective January 1, 2007, to exclude customary prompt pay discounts to wholesalers and requires drug manufacturers to include sales of authorized generics when they report their AMP. Since prompt pay discounts decrease AMPs, their exclusion would have the effect of increasing AMPs, and subsequently increasing the FULs. The absence of this factor in the analysis further calls into question the validity of GAO's findings.

The GAO also did not report on the effect that excluding outlier data would have on AMP-based FULs. The regulations, modified by the DRA, provide that FULs be set on drugs that are nationally available. We expect to address the elimination of outlier AMP data from use in calculating the FUL, as may be appropriate, before applying these new AMP-based FULs. Excluding outlier AMPs may significantly raise the FULs of many FUL groups and would further invalidate the GAO's findings.

The CMS has concerns that GAO's findings do not take into account the impact of existing state cost-containment mechanisms such as Maximum Allowable Cost (MAC) programs. While this report notes that States have MAC programs that further reduce the reimbursement used by States for multiple source drugs below the FULs, it fails to evaluate this effect on the GAO's overall comparison between acquisition costs and FULs. While we continue to disagree with the GAO's use of the average retail pharmacy acquisition cost, the report should at least compare the pharmacy acquisition cost to current State MACs instead of just the FUL.

The GAO study assumed that prescribing and filling practices will remain the same following the DRA change. In light of the DRA , we believe that assuming the same utilization of drugs within each of the 77 drug groups is incorrect. The GAO study provided no analysis of how States and pharmacies can mitigate the effect of the lower FULs by filling prescriptions with low cost generic equivalent drugs. We expect, with the implementation of the DRA provisions, that utilization will be driven to lower-priced generic versions of drugs, which will decrease costs in the overall. In addition, the GAO report fails to acknowledge that the FUL is not applied to brand name drugs when a physician certifies that these are medically necessary.

Prior Office of Inspector General reports have outlined the need for reform in Medicaid pharmacy reimbursement. The FUL amounts prior to DRA often exceeded pharmacy acquisition costs, and thus, increased cost to the States and the Federal Government. Using 250 percent of the lowest reported AMP rather than the current methodology of

Enclosure III

Page 4 – John Dicken

150 percent of the lowest price published in national compendia will reduce Medicaid expenditures for multiple source drugs and thus, result in billions of dollars of savings to States and the Federal Government.

Attachment

Enclosure IV

GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7119 or dickenj@gao.gov

Acknowledgments

In addition to the contact named above, Martha Kelly, Assistant Director; Rashmi Agarwal; Shamonda Braithwaite; Krister Friday; Yung Park; and Daniel Ries made key contributions to this report.

(290556)

GAO's Mission

The Government Accountability Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are $2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. Government Accountability Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Paul Anderson, Managing Director, AndersonP1@gao.gov (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, D.C. 20548

Submitter : Mr. Ante Brkic **Date:** 02/12/2007

Organization : Mr. Ante Brkic

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Date: 02/12/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Joe Cain **Date:** 02/12/2007

Organization : Independent Pharmacy Management

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Final Comments:

The rule, as currently written, would amount to gross negligence on the part of CMS if it ignores the OIG findings and input from all retail pharmacy organizations. By choosing to listen to the highly erroneous and self-serving input from PBM s, (which is readily apparent in the rule as submitted), CMS would be ignoring the one group (Independent Pharmacy) that truly makes the medicaid plan work on the patient level. For example: Most independent pharmacies deliver, chains and discount pharmacies do not. Many independent pharmacies are at the clinics near where patients live.

As a management consultant for indepent pharmacies in the southwest for the past fifteen (15) years, I can assure you this will put many small business and their employees out of business, and will most definitely cause the surviving pharmacies to no longer accept medicaid patients.

Submitter : **Mr. Edward J. Loeffler** **Date: 02/12/2007**

Organization : **Eckerd Drug Store**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

B.S. degree, St. John's Univ. 1975, community Pharmacist, currently working at Eckerd's Pharmacy in Glen Cove, NY.

GENERAL

GENERAL

The hits to community pharmacy's reimbursements for prescriptions, has already adversely affected the economic impact on community pharmacy, to the extent that any further reductions could jeopardise the delivery of medications to the most needy of patients. For too long, the burden of cost cutting has been on the backs of pharmacists.It's time for manufacturers to bear part of the burden. They continue to reap unprecedented profits, while pharmacies are closing their doors due to inadequate re-imbursement for professional services. Further cut-backs to the formula for prescription re-imbursement is not only grossly unfair, but economically disasterous.

Submitter : Mr. Joe Cain **Date:** 02/12/2007

Organization : RGV IPA

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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

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

Treatment of Manufacturer coupons with regard to Best Price pg. 55
Inclusion of Direct-to-Patient Sales with regard to AMP pg. 41

AMP Must Differ From Best Price

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

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

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper and grossly negligent. 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.

GENERAL

GENERAL

Final Comments:

The rule, as currently written, would amount to gross negligence on the part of CMS if it ignores the OIG findings and input from all retail pharmacy organizations. By choosing to listen to the highly erroneous and self-serving input from PBM s, (which is readily apparent in the rule as submitted), CMS would be ignoring the one group (Independent Pharmacy) that truly makes the medicaid plan work on the patient level. For example: Most independent pharmacies deliver, chains and discount pharmacies do not. Many independent pharmacies are at the clinics near where patients live.

As a management consultant for indepent pharmacies in the southwest for the past fifteen (15) years, I can assure you this will put many small business and their

employees out of business, and will most definitely cause the surviving pharmacies to no longer accept medicaid patients.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP. pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly.

Use of the 11-digit NDC to calculate AMP pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

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

The 11-digit NDC must be used when calculating the FUL.

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients. pg. 110

CMS discusses impact on pharmacy:
** On independents: potential significant impact on small, independent pharmacies. pg. 101

** On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 (a small fraction of pharmacy revenues). pg. 108

** We are unable to estimate quantitatively effects on small pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. pg. 110

Regulatory Impact Analysis

Regulatory Impact Analysis

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 stateset 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.

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 must be independently verifiable with a substantial level of transparency to have accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

Submitter : Mr. Emory Laffin **Date:** 02/12/2007

Organization : Mr. Emory Laffin

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist asking you to delay public release of AMP data until it accurately reflects retail aquisition cost. The current proposed AMP definition would pay retail pharmacies around 36% LESS than our actual aquisition cost. The problem with the proposed definition is that it includes rebates and discounts to PBM's and sales to mail order and nursing home pharmacies which ARE NOT AVAILABLE to retail pharmacies. CMS also needs to direct states to pay an adequate fee to cover the dispensing costs for retail pharmacy, which currently is about $10.50. Thank you for your consideration. Emory W.Laffin RPh

Submitter : **Mr. Charles Zimomra** **Date: 02/12/2007**

Organization : **Mr. Charles Zimomra**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

retail pharmacist

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. Derek Hicks **Date:** 02/12/2007

Organization : Medical Center Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Comment

CMS-2238-P-391-Attach-1.RTF

391

February 12, 2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

Derek V. Hicks, Pharm.D.
Medical Center Pharmacy

Submitter : Mr. Curt Bailey **Date:** 02/12/2007

Organization : One Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition, under CMS-2238-P Prescription Drugs, will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs, thus causing us to incur tremendous losses. As a small, independent pharmacy, such reimbursements could put us out of business in a very short time.

I ask that AMP be defined so that it reflects pharmacies' total ingredient cost, an action that would be fair to everyone. As it is currently defined, AMP is estimated to cover only HALF that market price paid by a pharmacy.

Should our pharmacy incur such losses, we will eventually be forced to turn away Medicaid patients.

Please reconsider issuing a clear definition of Average Manufacturers Price that is comparable to what we actually pay for drugs. This definition should be issued as soon as possible, before AMP takes effect.

Submitter : **Mr. bernard natt** **Date: 02/12/2007**

Organization : **shelbourn chemists inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

the pharmacist ahd always been the source of information for a person in teh community. As the number of medications increased as well as the possible drug interactions and adverse reactions increased the pharmacist has become a guardian to protect their customers from adverse reactions. The professional fee is small now and the fianancial survival of the pharmacy can only exist if there is a profit bewteen the the purchase price of a medication and the reimbursement from Medicaid. The current proposal would cause a net loss on most prescriptions which cannot be survived. Does Medicaid want to create a situation in which the Medicaid patient cannot get proper advise on their medications since many pharmacies will no longer be in the Medicaid program?
Bernard Natt
Suoervising Pharmacist

Submitter : Mr. Eric Graf **Date:** 02/12/2007

Organization : Ritzman Pharmacies, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-394-Attach-1.PDF

Corporate Office
8614 Hartman Road • Wadsworth, OH 44281
330•335•2318 • Fax 330•335•3222

February 9, 2007

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

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

The Ritzman Pharmacies Corporation is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. Our Corporation operates nine pharmacies in Ohio.

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

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

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

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

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

- **AMP was intended to help State Medicaid departments obtain rebates from pharmaceutical manufacturers so that the States could obtain best pricing. The modification of AMP to try to adopt this to retail pharmacies to reflect their cost of goods is a failed and misguided methodology.**

- **CMS could obtain retail pharmacies acquisition costs by requesting the information from the wholesalers which supply retail community pharmacies. It would be much easier and more accurate to cut out all the manipulations of numbers at the manufacturer level, whom we don't purchase from, and go directly to our purchase source to determine our costs.**

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next five years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended, because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. **A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system. Don't ignore the facts!**

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. **The Grant Thornton Study of over 23,000 pharmacies has just been completed and gives a national benchmark average at $10.50 cost to dispense per prescription and $12.10 cost to dispense per pharmacy. Don't ignore the data!**

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) and National Community Pharmacists Association (NCPA) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Eric L. Graf, M.S., R.Ph.
President & Chief Executive Officer

CC: Senator Sherrod Brown, Senator George Voinovich, Representative Ralph Regula, NACDS, NCPA, State Representative Bob Gibbs, State Senator Ron Amstutz

1328 Cedar Road
Akron, OH 44320
(330) 867-8700

11 Conservatory Drive
Barberton, OH 44203
(330) 745-9011

234 North Main Street
Bryan, OH 43506
(419) 636-3175

120 Bob Street
Wadsworth, OH 44281
(330) 336-2895

98 Arch Street, Ste. G10
Akron, OH 44304
(330) 376-1771

4045 S Cleveland-Mass Road
Norton, OH 44203
(330) 825-2400

187 West Cedar Street
Akron, OH 44307
(330) 434-9121

9486 Center Street
Seville, OH 44273
(330) 769-2895

23 So. Main Street, #902
Akron, OH 44308
(330) 928-2001

Community Office
3464 Hartman Road
Wadsworth, OH 44281
(330) 336-2112

Submitter : **Dr. Keith Vance** **Date: 02/12/2007**

Organization : **Lewisville Drug Company, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

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

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

2. Implement a Trigger Mechanism
(i) Addresses severe price fluctuations
(ii) Reduces risk of Market Manipulation
(iii) Mitigates Risk of Pricing Lag

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

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

Sincerely,

Keith A. Vance, Pharm.D.
Vice-President / Pharmacy Manager
Lewisville Drug Company, Inc.

cc. Members of Congress
Representative Virginia Foxx
Senator Richard Burr
Senator Elizabeth Dole

Submitter : **Dr. Christopher Tuetken** **Date: 02/12/2007**

Organization : **Phillip Pharmacies**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-396-Attach-1.DOC

396

February 12, 2007

Centers for Medicare and Medicaid Services

Attention CMS 2238-P Mail Stop C4-26-05

7500 Security Blvd

Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation

CMS 2238-P RIN 0938-AO20

The MCLD Corporation dba Phillip Pharmacies is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates nine pharmacies in Eastern Iowa. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

CMS has already delayed release of these data, and we urge that release of these data be delayed again.

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost

of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Christopher Tuetken

Doctor of Pharmacy

President/Owner

MCLD Corporation

Dba Phillip Pharmacies

Submitter :

Date: 02/12/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-397-Attach-1.DOC

347

Familymeds

Familymeds

Corporate Headquarters
312 Farmington Avenue, Farmington, CT 06032
Phone: 860-676-1222/Fax: 860-679-9337
www.familymeds.com

Ed Mercadante, R.Ph.
President & Chief Executive Officer

February 9, 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

Familymeds, Inc. is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates 84 pharmacies in 13 states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Edgardo Mercadante
President & CEO

Submitter : Mr. Craig Burridge **Date:** 02/12/2007

Organization : Pharmacists Society of the State of New York

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"

CMS-2238-P-398-Attach-1.DOC

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

February 21, 2007

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

The Pharmacists Society of the State of New York (PSSNY) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

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

§447.504 Determination of AMP

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

Defining Retail Pharmacy Class of Trade

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

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

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

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the

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

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

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

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

Excluding mail order and PBM pharmacies from the definition of the retail trade of pharmacy would offer numerous benefits to pricing data and regulatory oversight, including reduced recordkeeping requirements, reduced risk of price fluctuations, and limiting the need for additional regulatory burdens. Since there would be fewer transactions, fewer records will need to be maintained by manufacturers and reported to CMS, thus reducing the reporting requirements of manufacturers. Since mail order pharmacies are most likely to participate in discounts, rebates and other forms of price concessions, the nature of these complex contractual arrangements are more likely to lead to misstatements and errors in accounting and the need for re-statement of pricing information – particularly between quarters - creating pricing volatility and fluctuations in AMP values. Excluding mail order and PBM pharmacies from AMP calculations thus assists to provide greater certainty and reliability in pricing data. Vertical

integration between manufacturers and mail order pharmacies creates transactions that are not at arms length and thus afford opportunities for market manipulation. In the future, CMS would likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

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

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to reconsider the inclusion of mail order pharmacy rebates, chargebacks and other price concessions.

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

§447.510 Requirements for Manufacturers.

This section of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements.

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

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

Market Manipulation

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

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

'Claw-back'

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

Pricing Lag

[3] §447.510(d)(2)

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

Severe Price Shifts

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

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

Record Keeping

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

Additional Comments

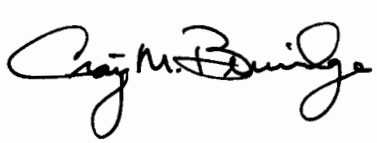
Use of the 11-Digit NDC Rather Than the 9-Digit NDC

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

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

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

Sincerely,



Craig M. Burridge, M.S., CAE
Executive Director

Cc: NYS Congressional Delegation

Submitter : **Mr. David Schomberg** **Date: 02/12/2007**

Organization : **Yadkin Valley Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located in Yadkinville, 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,
David W. Schomberg, Jr, R.Ph., MBA
Pharmacy Owner, Yadkin Valley Pharmacy

cc. Members of Congress Virginia Foxx

Submitter : **Paul Iverson** **Date: 02/12/2007**

Organization : **Iverson Corner Drug Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 11, 2007

Leslie Norwalk
Acting Administrator
CMS

Dear Administrator Norwalk,

I have received boatloads of e-mails from the national pharmacy organizations full of information about how the change to AMP, particularly on generic drugs is going to adversely affect my ability to practice pharmacy. I could reproduce that information again for you in this letter but I know you have already seen it. To me this is what it all boils down to. Does CMS value having pharmacies in rural America? If so you need to pay me enough to keep my business profitable. If you don t pharmacies will disappear from rural America and our citizens will suffer.

Saving dollars on a generic drug should not be the focus of your efforts. Your focus should be on how do we get a higher percentage of the medications used to be generics. In 2006 at our pharmacy the average brand name prescription was FIVE times higher then the average generic drug. Pharmacists can help you with that. Taking away all economic incentive to use generics is short sighted and foolish

Please consider the big picture when you make your ruling on how to determine cost of generic drugs. Make sure you set a price that is fair to all pharmacists.

Sincerely,

Paul S. Iverson BPharm
President

cc Congressman Colin Peterson
Senator Amy Klobuchar
Senator Norm Coleman

Submitter : Mr. Verne Mounts **Date:** 02/12/2007

Organization : Buehler Food Markets, Inc.

Category : Pharmacist

Issue Areas/Comments

Response to Comments

Response to Comments

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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 : Lisa Adams **Date:** 02/12/2007

Organization : North Carolina Association of Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attached

Submitter : **Dr. Frank Davison** **Date: 02/12/2007**

Organization : **Davison Drug & Stationery**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

In California, we need to make $12 per prescription to keep the doors open. In the last 2 years, we have seen our prescription volume increase by 9%, and our net profit decrease by 11%. We have 2 drugstores (my wife is also a pharmacist), and we each work 60-65 hours a week. Most of this extra work involves times necessary to serve poor medicaid patients. We will almost certainly have to close the doors if our margins slip any further. About 25% of our business is medicaid. Why is the government wanting to put pharmacies out of business?? We've made our books open countless times. Why does the government want to continually take it out on hard working pharmacies, when the whole country is aware of the ridiculous profits made by the PBM's and Drug Companies? How does this make sense? Is it because we can't fight? Is it because the government is afraid of addressing the major contributors (PBMs & Drug Companies)? Who do you think gives all of the free advice and health care to all of these people? We do. Colusa County is ready to lose at least 2 of only 3 pharmacies available to serve medicaid patients based on your decisions on AMP. Please make an effort to know the discrepancies in how different pharmacies pay for meds. Mail order and hospital pharmacies can NOT serve medicaid patients, but they buy drugs for much less. That is a FACT. PBM's have continued to impose Non-negotiable contracts on independent pharmacies because they know we can't fight individually. That is a FACT. Pharmacists are the only people that medicaid patients can walk up to any time of the day and get answers to their health problems. That is a FACT. We are on the edge of going out of business with increased minimum wage and shrinking margins. That is a FACT. Please use these FACTS when making your decision.

Submitter : **Ms. Trang Tran** **Date: 02/12/2007**

Organization : **Temple University, School of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-404-Attach-1.DOC

CMS-2238-P-404-Attach-2.DOC

#404

Philadelphia, February 12th, 2007

To whom it may concern,

I am a 3rd year pharmacy student at Temple University, school of Pharmacy. Having the opportunity to take the Practical Politics and Pharmacy course this semester, I get to learn about AMP. Although I am still in school, but I believe AMP will have a tremendous effect on my pharmacy career and the profession as a whole. With the Pharm D. degree, pharmacy students are well prepared with a lot of clinical skills. As a result, the role of a pharmacist today has become more and more important in managing the care for patients. Therefore, I believe pharmacists should be well recognized and appreciated and AMP is definitely not the solution.

I am writing this email with the hope that there will be changes made in regards to AMP. I as well as many other pharmacy students are studying very hard to fulfill the expectation of our patients and we should deserve no less benefit than other healthcare professions.

Thank you very much for your concern!

Sincerely,

Trang Tran

Submitter : **Mr. Avrom Essen** **Date: 02/12/2007**

Organization : **Temple University School of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-405-Attach-1.DOC

Dear Sir or Madam,

This letter is in response to the Department of Health and Human Services Centers for Medicare and Medicaid Services 42 CFR Part 447 Medicaid Program; Prescription Drugs; Proposed Rule. As a pharmacy student with intentions on going into retail pharmacy, I have read this proposal with an open mind, trying to weigh both sides of the matter in an attempt to understand the consequences. Having both my father and uncle as community pharmacists, I have seen first hand the costs of doing business and the apparent double standards of pricing from manufacturers. We have already seen drastic cuts in pharmacy reimbursements at the expense of community pharmacy. While their overhead and expenses have not changed, the profits have continually been eroded by the state or federal government. With this proposal, Pharmacy continues to be the whipping boy. The natural competitiveness of the business usually precludes a cohesive response to a threat, but this attack should bring unity never before seen in our profession.

If this proposed rule becomes law, it can potentially drive many pharmacies, especially community pharmacies, out of business. Changes in Medicare reimbursement over the last year have forced many stores to cut back on staff or close down altogether. Fewer choices of pharmacies will lead to increased traffic in existing stores, guaranteeing less time spent with each patient. Some pharmacies no longer even accept Medicare because of their rule changes. Among the potential damage is increased workload, because more prescriptions will have to be filled at lower prices, thereby decreasing the time spent counseling a patient on his or her medications. Learning about Medication Therapy Management(MTM) in school, I realize how important it is to patients. It not only decreases medication errors, but is associated with better health outcomes, less time in the hospital and fewer doctor visits. The very people Medicare is purporting to help, the elderly and less fortunate, will suffer the most.

The proposed rule forecasts losses to pharmacies to be minimal, though in billions, due to the fact they believe that much revenue is generated by the "front end" merchandise. What they fail to realize is that many community pharmacies do not have vast, if any, items besides the drugs themselves. While a chain drug store may have their own "house brand" OTC products, community pharmacies often do not. Moreover, while the new law will offer rebates based on AMP, each individual

pharmacy may not have the same acquisition costs. With this in mind, the smaller pharmacies who do not buy in bulk will pay higher prices at best, or at worst be forced out of business, creating havoc for the patient.

In closing, pharmacists have received an extensive education and it would be a travesty to not have them use their knowledge to help patients to the best of their abilities. Physicians, nurses, dentists and other health professionals are compensated based upon their credentials. Once again, it seems that pharmacy is an easy target that will not fight back. I hope, that in this case, the professionals that have gone before me realize the ominous cloud that hangs over our profession. We need to be paid based on our service to the community and not be dictated to by those outside the profession, with little understanding of the daily operations and benefits we offer. Furthermore, our obligation to our patients health and safety, and ultimately, their quality of life, will be affected adversely by the proposed rule. I hope that you will reconsider your position on this matter, as I believe will negatively impact millions of people.

Sincerely,

Avrom Essen
Third Year Pharmacy Student

Submitter : Garrison Rosato **Date:** 02/12/2007

Organization : Temple University

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-406-Attach-1.DOC

To whom it may concern,

In regards to the Medicaid Average Manufacturers Price (AMP), I would like to voice my concerns about the negative impact this will have on community pharmacies and most importantly the patients. The reinbursment rates in this plan will be at or below pharmacies' drug-acquisition costs. AMP is not reflective of the price independent pharmacies pay for medicines. It includes prices charged to mail order vendors as well as discounts and rebates provided to other purchasers that are not available to community pharmacies. Dispensing fees must cover the costs to safely and effectively care for the patient, a service which will be greatly hindered if the reimbursment rate to pharmacies is replaced by AMP. These cuts will undoubtingly result in a lack of access to medications due to the community pharmacies being unable to stay open, especially in lower income neighborhoods. Cutting reimbursment on generics will also lead to an increase in more expensive brand name medications being dispensed, ending up costing Medicaid more in the longrun. Currently only 52% of Medicaid's prescriptions are generic. Encouraging the use of generics will much more effectively decrease the costs Medicaid without jeopardizing the safety of our patients. Initiating an AMP reinbursment plan will be devestating to the pharmacist-patient relationship and the health of our patients will suffer as a result.

Submitter : Vinay Yakkundi **Date:** 02/12/2007

Organization : Vinay Yakkundi

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a soon to be pharmacist, I am concerned about the new legislation
CMS-2238-P (part of the deficit reduction act), which does not address the issue of generic dispensing fees. There needs to be specific legislation setting a standard percentage of the cost of the medication or a flat fee for dispensing generic medications, which is higher than the current standard (currently state medicaid programs drastically underpay pharmacists dispensing fees, e.g. $4 per generic dispensed when it costs almost $10 to dispense the generic product). If this continues, why should community pharmacies accept state medicaid patients (we will just be losing money on each prescription, which makes zero business sense)?
This issue needs to be addressed now in order to help medicaid patients and pharmacists around the country!

Submitter : Mr. Angelo Spadell **Date:** 02/12/2007

Organization : na

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

In regards to the Medicaid Average Manufacturers Price (AMP), I would like to voice my concerns about the negative impact this will have on community pharmacies and most importantly the patients. The reinbursment rates in this plan will be at or below pharmacies' drug-acquisition costs. AMP is not reflective of the price independent pharmacies pay for medicines. It includes prices charged to mail order vendors as well as discounts and rebates provided to other purchasers that are not available to community pharmacies. Dispensing fees must cover the costs to safely and effectively care for the patient, a service which will be greatly hindered if the reimbursment rate to pharmacies is replaced by AMP. These cuts will undoubtingly result in a lack of access to medications due to the community pharmacies being unable to stay open, especially in lower income neighborhoods. Cutting reimbursment on generics will also lead to an increase in more expensive brand name medications being dispensed, ending up costing Medicaid more in the longrun. Currently only 52% of Medicaid s prescriptions are generic. Encouraging the use of generics will much more effectively decrease the costs Medicaid without jeopardizing the safety of our patients. Initiating an AMP reinbursment plan will be devestating to the pharmacist-patient relationship and the health of our patients will suffer as a result.

Submitter : Mr. Steve Geltch **Date:** 02/12/2007

Organization : CVS Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Tell CMS the following:

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Mr. Brad Tabaac** **Date: 02/12/2007**

Organization : **Friendly Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The proposed calculation of AMP for "Retail Class of Trade" that is scheduled to take effect on July 1, 2007 will be devastating to retail community pharmacy.

GENERAL

GENERAL

Calculation of AMP for Retail Pharmacy Class of Trade sould only include independent pharmacies, independent chains, traditional chains, mass merchants & supermarket phamacies, excluding rebates. It should not include mail-order pharmacies. Based on national survey conducted by the Grant Thornaton Accounting firm, it costs $10.50 to dispense a single prescription. PA medicaid offers a $4 professional fee while the Medicaid HMO's offer only $1.50 -to-$2.00. CMS must employ a complete definition on cost to dispense which must include valuable pharmacist time doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax, e-mail with state Medicaid agencies and PBM's entering billing information and other real costs such as rent, utilities, salries, morgate payments, etc. For many years, the retail community pharmacy has been the back bone to the public assistance program, creating the vast network of pharmacy providers ensuring adequate access to medications to those in need. If AMP becomes the basis of reinbursment to community Pharmacies, the Pharmacies will lose money on most of the prescriptions resulting in most pharmacies dropping out of the medicaid programs.

The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications.

Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement. Yhe use of Wholesaler Acquisition Cost (WAC) would be a better use and is readily available now by pricing services.

To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid be retail pharmacy. This can be accomplished by:

1. Excluding all rebates and price concessions made by manufacturers which are not available to retail pharmacy.
2. Exclude all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended pricing not available to retail, independent or chain.
3. Reporting AMP at the 11- digit NDC level to ensure accuracy.

Please, do not prevent us from providing pharmacy services to our patients.

Thank you,

Brad Tabaac, R.Ph.
Friendly Pharmacy
2258 N. Front Street
Phila., PA 19133
215-425-5230

Submitter : Bob Comorosky **Date:** 02/12/2007

Organization : CVS/pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Dr. David Marley** **Date: 02/12/2007**

Organization : **Marley Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located at 5030 Peters Creek Parkway, Winston-Salem, NC 27127. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

David Marley, PharmD.

cc. Rep. Virginia Foxx
Sen. Richard Burr
Sen. Elizabeth Dole

Submitter : Mr. Ronald Higginbotham **Date:** 02/12/2007

Organization : CVS/pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Mr. Samuel Rotunna **Date:** 02/12/2007

Organization : CVS/pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Submitter : Mr. Tom Flora **Date:** 02/12/2007

Organization : CVS Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : Dr. Mark Riley **Date:** 02/12/2007

Organization : Arkansas Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-416-Attach-1.PDF

Arkansas Pharmacists Association

417 South Victory • Little Rock, Arkansas 72201 • (501) 372-5250 • Fax (501) 372-0546

February 12, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Norwalk,

Thank you in advance for considering my comments on the proposed AMP rules to be implemented in the near future. In light of the recent GAO report on the relationship of AMP with actual acquisition costs to community retail pharmacies, I would like to offer the following suggestions and then support my views.

1. Exclude all best price rebates and price concessions made by manufacturers that are not available to community pharmacies when they purchase drugs.

2. Exclude all mail order facilities and PBM pricing from AMP calculation. These entities are extended special pricing that is not accessible to community pharmacies, and thus are treated as a different class of trade.

3. Report AMP at the 11-digit NDC level to ensure accuracy.

First, excluding all rebates and price concessions which are not available to retail pharmacies is necessary because including these factors guarantees that retail pharmacies will be reimbursed significantly below cost. As I am sure you are aware, the recent GAO study found that retail pharmacies will be reimbursed at an average of 36 percent below their actual costs on generic drugs at the maximum allowed under AMP-based FULS of AMP plus 250 percent. To make matters worse, the President's 2008 Budget reduces the maximum allowed to AMP plus 150 percent, which will result in average generic reimbursement being close to 50 percent below pharmacies' actual acquisition cost.

As it currently stands, AMP is now to be the basis for two very different and totally unrelated purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. When AMP was created, it was never intended to serve as a baseline for reimbursement. AMP's only purpose when it was created was to reduce state expenditures on prescription drugs through rebates paid by the pharmaceutical manufacturers directly to the state. AMP has no relation to the price that pharmacies pay for their medications. If AMP is to be used in calculating community pharmacy reimbursement, then it MUST accurately reflect true retail pricing. To accurately reflect retail pricing, CMS should exclude all rebate and price concessions

included in "BEST PRICE" that are not appropriate to be included in calculation of AMP because they only serve to reduce the total cost to the states, which is totally independent of what the drug cost the pharmacies. Summarily, AMP should exclude any special pricing that is not extended to the retail pharmacy class of trade.

Second, mail order sales should not be included in the calculation of AMP because it is treated by the pharmaceutical manufacturers as a different class of trade. In addition, the PBM-owned mail order model is one that is under a great deal of intense scrutiny in the public, legislative, and judiciary arenas at this time. With the PBMs administrators of the plans and owing their own mail order houses, there is a distinct advantage in self-dealing, which makes for an unlevel playing field in the distribution of the prescription drugs to the retail class of trade. No other entity in government programs are allowed to "self-deal" like PBMs. In fact, it is illegal in other federal programs for physicians and other healthcare providers to self deal in this manner. Transparency in the PBM industry must be forthcoming before inclusion of their acquisition cost model can even be considered due to the potential devastating effect the inequity could have on retail pharmacies and Medicaid recipients. Until this debate is settled, it is imperative that PBM mail order pricing should not be included in the calculation of AMP for retail pharmacies.

Third, reporting of AMP at the 11-digit NDC level will ensure accuracy and limit the "games" being played with creative NDC numbers, which may occur with nine-digit NDC reporting. Additionally,nine-digit NDC reporting could also require smaller pharmacies to purchase larger package sizes, thus needlessly increasing inventory costs when the quantities having to be purchased are not justified by patient demand. In short, pharmacies buy the most efficient way possible based on price and inventory requirements now.

Please consider my final comments:

1) National cost of dispensing surveys show that, on average, pharmacies in the United States incur a $10.50 cost of dispensing for every prescription that is filled. While CMS has acknowledged that the states may need to adjust dispensing fees for pharmacies, expecting a dispensing fee adjustment of $10.50 as well as compensating for over $7.00 lost on the AMP calculation (36% below our acquisition cost on and average generic prescription cost of approximately $21.00) is not realistic.
2) AMP-based Federal Upper Limits (FULS) in the proposed rule will not cover pharmacy ascquistion costs for multiple-source generic medications.
3) AMP must be defined to reflect the <u>actual</u> cost paid by retail pharmacy.

I close by restating my original suggestions.

1) Exclude all rebates and price concessions made by manufacturers that are not made available to retail pharmacies.

2) Exclude all mail order facilities and PBM pricing from AMP calculations.

These entities are extended special pricing that is not accessible to community pharmacies, and thus are treated as a different class of trade.

3) Report AMP at the 11-digit NDC level to ensure accuracy.

Thank you for the opportunity to comment on this critical issue. I respectfully am available to discuss this in the future in any forum you may wish.

Respectfully,

Mark S. Riley, Pharm.D.
Executive Vice President

Submitter : **Mr. James Fisher** **Date: 02/12/2007**

Organization : **Whitley Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

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

James N. Fisher, RPh

cc. Rep. Heath Shuler

Submitter : **Linda Baker** **Date: 02/12/2007**

Organization : **United Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-418-Attach-1.DOC

Submitter : **Dr. Steve Burney** **Date: 02/12/2007**

Organization : **Medicap Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

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

Steve Burney, Pharm.D.
Medicap Pharmacy
80 Shuford Rd
Columbus, NC 28722
828-894-6112

cc. Representative Heath Shuler

Submitter : **Date: 02/12/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this =3D 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 markct pricc paid by community pharmacy. Currently, each =3D manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Dr. James Beardsley** **Date: 02/12/2007**

Organization : **Wake Forest University Baptist Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. Although I work in a hospital and do not own a retain pharmacy, I feel that the following comments are important for the health of our citizens.

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,

James R. Beardsley, PharmD, BCPS
Assistant Director of Pharmacy
Wake Forest University Baptist Medical Center
Winston-Salem, NC 27157

cc. Howard Coble

Submitter : Dr. Jeff Shinoda **Date:** 02/12/2007

Organization : Jeffrey K. Shinoda, Pharm.D., Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-422-Attach-1.DOC

Submitter : Mr. jerel kerby **Date:** 02/12/2007

Organization : Med Care Pharmacy

Category : Other Health Care Provider

Issue Areas/Comments

Background

Background

Pharmacies have suffered enough cuts!!!!!! medicare low payments and slow payments from the insurance companies to us.....
Please do not take another cut out of us... we are already behind and falling furhter behind..... we need help...not more cuts...
i hope and pray someone reads this and cares!

Submitter : Ms. Sally Smith **Date:** 02/12/2007

Organization : National Indian Health Board

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-424-Attach-1.PDF

Submitter : Mr. Vivek Bhatt **Date:** 02/12/2007

Organization : Drug Mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

THERE WILL BE AN UPROAR IN EVERY COMMUNITY IF PATIENTS ARE TURNED AWAY FROM THE MEDICAID PROGRAM...IT WILL LEAD TO HIGH HEALTHCARE COSTS AND THE FIRING OF THE LEGISLATIVE MEMBERS WHO VOTED FOR IT. PHARMACIES WILL NOT FILL PRESCRIPTIONS BECAUSE WHY SHOULD THEY TAKE A LOSS...IF YOU ARE READING THIS...HOW WOULD YOU FEEL IF YOU HAD TO WORK FOR NOTHING FOR HOURS AND HOURS???? BE FAIR, BE REASONABLE. A CALL FOR A NEW DEFINITION FOR AMP. HOW ABOUT ARP (AVERAGE RETAIL PRICE)????

CMS-2238-P-426

Submitter : Ms. Valerie Davidson **Date:** 02/12/2007

Organization : CMS Tribal Technical Advisory Group

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-426-Attach-1.PDF

Submitter : **Dr. Harold King** **Date: 02/12/2007**

Organization : **Medicap Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. (My pharmacy is located at 2231 South College Rd in Wilmington, NC. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

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

2. Implement a Trigger Mechanism
(i) Addresses severe price fluctuations
(ii) Reduces risk of Market Manipulation
(iii) Mitigates Risk of Pricing Lag

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

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

Sincerely,

Harold (Hal) B. King III, R.Ph.,CDM

Submitter : Sean Sly **Date:** 02/12/2007

Organization : Discount-Drug Mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

**See Attachment

CMS-2238-P-428-Attach-1.DOC

Submitter : Mr. Thomas Saltsman **Date:** 02/12/2007

Organization : Mr. Thomas Saltsman

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Response to Comments

Response to Comments

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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. Alex Reinmann **Date:** 02/12/2007

Organization : Mr. Alex Reinmann

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

Passing this CMS payment reform will cause small chain and independent stores to file bankruptcy. If a pharmacy buys $100 of drugs you would only pay them a maximum of $65??? How is that ethical? That will cause any type of pharmacy to go under.

Submitter : Ms. Tricia Yerardi **Date:** 02/12/2007

Organization : Ms. Tricia Yerardi

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Miss. Jennifer Fehl** **Date: 02/12/2007**

Organization : **UF pharmacy student : CPhT**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Dear Leslie,

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Submitter : **Brenna Simcoe** **Date: 02/12/2007**

Organization : **Brenna Simcoe**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Brenna Simcoe
5th Year Pharmacy Student
Ohio Northern University
Raabe College of Pharmacy

Submitter : **MIchelle Geiser** **Date: 02/12/2007**

Organization : **MIchelle Geiser**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Michelle Geiser
5th Year Pharmacy Student
Ohio Northern University
Raabe College of Pharmacy

Submitter : **Katelyn Haugh** **Date: 02/12/2007**

Organization : **Katelyn Haugh**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away. A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

Katelyn Haugh
5th Year Pharmacy Student
Ohio Northern University
Raabe College of Pharmacy

Submitter : Dr. Benjamin Smith **Date:** 02/12/2007

Organization : Mission Hospitals

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. Although my primary practice site is in the primary care environment in Asheville, NC I have had a very large amount of exposure to community pharmacy practice and felt compelled to comment on this issue as the outcome has the potential to be detrimental to the health of individuals throughout western North Carolina.

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Ben Smith, PharmD

cc. Representative Heath Shuler
Senator Elizabeth Dole
Senator Richard Burr

Submitter : **Mr. Greg Marks** **Date: 02/12/2007**

Organization : **Medical Center Pharmacy**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

February 12, 2007

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

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

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

Greg Marks

Submitter : Dr. David Garrison **Date:** 02/13/2007

Organization : Rite Aid Corp, MD Pharmacists Assoc

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

To reduce reimbursement at the retail pharmacy level for generic drugs while exempting brand name drugs is unworkable and smacks of the usual corruption rife in this administration. This might be an appropriate subject for an inspector general investigation

Submitter : Dr. Aaron Hirst **Date:** 02/13/2007

Organization : Independent pharmacist

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Wheras the cost to fill a prescription in our pharmacy is $10 per prescription and a large percentage of our patients are being provided state assistance, if the new price structure for medicaid reimbursement is accepted as is, we may have to refuse to accept state assisted insurance, then cut back on staff due to the decrease in business. This may funnel medicaid insured patients to the big chain pharmacies which will continue to accept the reimbursement. This will set up a lower standard of care for medicaid patients than the rest of the population. I do not want to see that happen. I care about the medicaid patients we serve and do not want to see their care hindered. They will have to travel further for care, wait in lines much longer for care and the consultation will become more abbreviated than it already is at the big chain level. It may even take pharmacy 'out of reach' for some folks of which we provide free delivery. These folks may be home bound and unable to pick up their prescription and the chains won't deliver to them, we do.

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

Organization : Discount Drug Mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-441-Attach-1.TXT

Submitter : Mrs. Jennifer Rudell **Date:** 02/13/2007

Organization : CVS Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

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

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

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

Organization :

Category : **Physician**

Issue Areas/Comments

Background

Background

The proposed method that AMP is to be calculated is unfair to retail pharmacies because the cost basis will be calculated from cost of PPO, HMO, Outpatient Hospital clinics---all of whom receive bid prices from drug companies. To be fair the cost should be derived from the cost paid by retail pharmacies. If this process is not used, acess to medications will be greatly reduced. Many retail outlets will go out of business.

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

Organization : Toronto Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Hello, I am writing out of concern about the new prescription drug pricing that is to take effect 7-1-07 for some generic medicaid prescriptions. This new regulation would be devasting to all of community pharmacy but especially independent community pharmacy of which I am a part of. My pharmacy is a 98 percent prescription store. There is not "front end" to speak of. I try to provide very personal attention to my clients. The new pricing would certainly put me out of business. In additon it is just not "right". Reimbursed below cost of the product?? Doesn't make sense. And that is just cost of the medicine. No other costs of doing business are even taken into account. I am sure there are thousands of other independent pharmacies in the same position I am in and other community pharmacies as well.

I would also like to state that I(and other independents) aren't enjoying outrageous profits from the state medicaid plans as they are now and "ripping off the government" as has been reported. This is just simply not the case. We have to accept pricing that is already dictated to us. We do NOT do the pricing. The pricing is alredy at "bare minimum" again with no provisions for any other cost of doing business. Just the cost of the medicine is taken into account. I doubt if any other business has to contend with this.

These new regulations just do not make sense to implement and would certainly put a lot of businesses out of business. A lot of people being served by us would then also suffer as where would they go, and where/who would answer their questions and take care of a lot of their problems/concerns as we do?

Thank you for your care and attention to this matter,

Roger Lewis

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

Organization :

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-446-Attach-1.DOC

Submitter : Mr. Mark Marenberg **Date:** 02/13/2007

Organization : NACDS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Village Square Corporation is writing to provide our views on CMS December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates three pharmacies in Ohio. Prior to the implementation of Medicare Part D, we operated one additional pharmacy. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

? Delay New Generic Rates that Would Significantly Underpay Pharmacies: The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy s acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

? Require that States Increase Pharmacy Dispensing Fees: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy s cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

Sincerely,

Mark Marenberg, R.Ph.
President

Submitter : **Mrs. Beverly Lingerfeldt** **Date: 02/13/2007**

Organization : **Kerr Drug and NCAP**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 13, 2007

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

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

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

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

2. Implement a Trigger Mecbanism
(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,

Beverly H. Lingerfeldt, RPh

Submitter : Dr. Alania Pendarvis **Date:** 02/13/2007

Organization : Garden Park Medical Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mrs. Liz Wells **Date:** 02/13/2007

Organization : APCI

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-450-Attach-1.PDF

Submitter : Mr. Jerry de Bruin **Date:** 02/13/2007

Organization : Rite Aid Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-451-Attach-1.PDF

CMS-2238-P-451-Attach-2.PDF

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

Organization : J&A Drugs Inc./Krimko Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

If Pharmacists will be re-imbursed 36% below than what they are being paid now, it is DEFINITELY going to impact drastically the small retail pharmacy, who are serving the old , poor and sick people in their neighborhood. SMALL RETAIL PHARMACY WILL BE FORCED TO CLOSE THEIR DOORS. We are already having a very difficult time in paying our bills.If the small retail pharmacies are forced to close, lot of our patients will suffer as only the CVS,s and Rite Aids will be the only ones left. I hope the authorities are more realistic and dont kill the small neighborhood pharmacies. WHY CANT THE MANUFACTURERS BE FORCED TO SELL THEIR DRUGS AT THE SAME PRICE THEY SELL TO VETERAN ADMIN. HOSPITALS AND CANADA ETC? The axe has always been falling on the Pharmacist. I hope some one will listen. Thanks

Submitter : Mr. Ronald Lewullis **Date:** 02/13/2007

Organization : Lehigh Valley Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The calculation of AMP for "Retail Class of Trade" should only include independent pharmacies, traditional chain pharmacies, mass merchants and supermarket pharmacies. Including mail-order pricing in the calculation is totally unfair. None of the groups of pharmacies noted above can purchase products at the prices that mail-order can.
This inclusion will undoubtedly force the closing of many community pharmacies throughout the country. It must be corrected to fairly account for the cost of drugs in the actual "Retail Class of Trade."

Response to Comments

Response to Comments

This regulation as it stands with the inclusion of mail-order pharmacy in the "Retail Class of Trade" is totally unfair and it will force the closing of many community pharmacies. We, in pharmacy, want a fair and transparent system to reimburse us under Medicaid but no business can be expected to operate at a loss!

Submitter : Dr. Keith Vance **Date:** 02/13/2007

Organization : Lewisville Drug Company, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : Dr. Brent Chan **Date:** 02/13/2007

Organization : American Pharmacist Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

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

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Sirs,
I am very concerned about the proposed prescription drug reimbursement changes for Medicare and Medicaid. The most obvious way to decrease cost in this area is to do a better job of enforcing who gets coverage by the CMS programs. There are numerous reports of individuals abusing the system and costing the taxpayers money. When people come in with Medicaid cards and keys to Mercedes, there is a problem with the system. As a person who has worked in a retail pharmacy for almost seven years, I can not tell you how many people get prescriptions filled for drugs they don't need and won't take--drugs worth thousands of dollars (such as, for example, 3000 OxyContin)--they simply say "fill all my stuff"--because its free or nearly free. I have also be made aware that illegal immigrants can get coverage under these programs whether that is "officially" possible or not. I don't want to have to turn away patients because my pharmacy can't accept the proposed low-balled price provided by the government programs. I suppose that to circumvent that issue pharmacies would be forced to take those individuals, and obviously I don't think that would be a good idea either. Please don't cheapen our profession by enforcing this AMP ruling.

Submitter : Mr. Kyle Hutchings **Date:** 02/13/2007

Organization : University of Toledo

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.