Submitter : Dr. Jaydeep Khatri **Date:** 02/18/2007

Organization : Whole Health Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

We already have seen some impact on availability of drugs to our Coloradao medicaid recicpients. We have turned away some people from dipsensing drugs as the reimbursement from medicaid has fallen way below even the cost of the drug.

Submitter : **Dean Bryan** **Date: 02/18/2007**

Organization : **Bryan Drugs**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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

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

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

AMP should reflect prices paid by retail pharmacies. Including these elements is eounter 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 implcmentation of the AMP Regulation could create an avcnue for market manipulation. Thc risk of both price fluctuations and market manipulation, duc 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 ealculate 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 thc FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These cntities can only be captured if the 11-digit package size is used.

In conclusion, I support thc more extensivc commcnts that are being filed by North Carolina Association of Pharmacists regarding this proposed rcgulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

Dean Bryan, RPh

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Dr. Serge Drouin** **Date: 02/18/2007**

Organization : **Wal-Mart Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
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Subject: Medicaid Program: Prescription Drugs; AMP Regulation
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I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy is located in Mebane, NC. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

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Sincerely,
Serge Scott Drouin PharmD
Wal-Mart Pharmacy
Mebane, NC

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Dr. Dan Stovall** **Date: 02/18/2007**

Organization : **Target**

Category : **Pharmacist**

Issue Areas/Comments

Background

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Sincerely,
Dan Stovall, PharmD, RPh

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Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Brian Holloman** **Date: 02/18/2007**

Organization : **Thomas Drug Store & HME**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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Subject: Medicaid Program: Prescription Drugs; AMP Regulation
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Sincerely,

Brian Holloman, PharmD, RPh
Thomas Drug Store & HME

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Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : Dr. Gerard Herpel **Date:** 02/18/2007

Organization : Deep Creek Pharmacy McHenry, MD.

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

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

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.

Collection of Information Requirements

Collection of Information Requirements

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.

GENERAL

GENERAL

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

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

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 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, manufacturers 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.

Response to Comments

Response to Comments

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 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 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 consequencces for patient care and access.

Submitter : **Laura South** **Date: 02/18/2007**

Organization : **Tennessee Pharmacist Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment

CMS-2238-P-873-Attach-1.TXT

Submitter : Mr. Stephen Morton **Date:** 02/18/2007

Organization : Morton Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-874-Attach-1.DOC

Submitter : T. Paul Stauffer **Date:** 02/18/2007

Organization : Valley Pharmacy & Lower Valley Drug

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am an owner of Star Valley Drug Co which has 2 stores in rural Wyoming, one in Afton & one in Thayne. There is one other small pharmacy in our valley (Star Valley), & no other chains. The 3 pharmacies serve about 12,000 people.

Collection of Information Requirements

Collection of Information Requirements

Aecording the the GAO report the current definition of AMP on which our reimbursement would be calculated would result in a 36% below our acquistion cost reimbursement for generic Medicaid prescriptions. See comment below on what our response would be.

GENERAL

GENERAL

My comment is brief & too the point. Our two pharmacies (& I strongly suspect our only other competitor in this rural area) will not be able to sustain a 36% reimbursement less than our acquisition cost based on the current description of AMP. We will absolutely be forced to discontinue providing services for Medicaid which will mean at least a 75 mile drive one way, assuming there is a pharmacy in Jackson, WY that will accept Medicaid patients & if not a 100 mile drive one way, assuming there is a pharmacy in Idaho Falls, ID that will help them. I thought the idea discontinuing AWP & going to AMP as a basis for pricing was to base pharmacy reimbursement on something as close to our acquisition cost plus a dispensing fee as possible. I have no quarrel with that idea, but I cannot sell medications for less than they eost me & stay in business. I know that last year at least 8 pharmacies in Wyoming closed due to the impact of Medicare D. If we have to close our stores in Star Valley due to Medicaid it will be a considerable loss to the community both in services (we provide services for the local hospital also), & in employment & community support (one of my 2 other partners is also the mayor of Afton). AMP needs to be redefined to reflect our actual acquisition costs or else we need to go back to the old system which had a fix for the problem of AWP pricing being based on an unreasonable base price...the fix was MAC (maximum allowable cost) which, when applied usually gets the reimbursement to pharmacies on a more reasonable basis. But this would require Medicaid to pay more attention & include more drugs in MAC pricing which, obviously, they were unwilling to do which is why the system did not provide the savings to the government that they wanted. Thanks for the opportunity to comment. Sincerey, T. Paul Stauffer,RPh & owner.

Response to Comments

Response to Comments

Your own analysis says what I stated in "Provisions of the Proposed Regulations.

Submitter : **Date: 02/18/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

" See Attachment"

CMS-2238-P-876-Attach-1.DOC

Submitter : Ms. Christina Weisenberger **Date:** 02/18/2007

Organization : Mills Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I own a small pharmacy with just over $1 million in annual sales. 20% of that is medicaid. Including PBM rebates in the AMP is rediculous since retail pharmacy has no benefit from these rebates. On the contrary, it harms us. The pharmacies who directly benefit are the PBM owned mail order pharmacies. These PBM's then design benefits which provide incentives for the insured to use mail order. This is where you should be focusing the cost cutting. The cost of these rebates to PBMs are inflating the cost of drugs to the general public. It is against the law for Disc Jockeys to take kickbacks for playing songs on the radio, but its not against the law for drug companies to pay kickbacks be put on the PBM's preferred drug list. This severely compromises patient care placing your loved ones health in the hands of the highest bidder. What's wrong with this picture.
95% of my sales are prescription drugs, I cannot afford to lose money on 20% of the prescriptions I fill. I may have to stop accepting medicaid patients. A recent survey of my colleagues indicates that 86% of us feel this way. Please consider carefully the effect on the availability of service for the low income population. This also disincentivizes pharmacists from suggesting lower priced generics which will increase drug spending in the long run. I am a second generation independant pharmacist, and my son would like to be the third. Government involvement with Medicare D this past year has allowed plans to be designed to benefit mail order, with such low reimbursement terms for 90 day prescriptions which barely cover the cost of the drug. I have managed to keep my losses to a minimum by not signing these 90 day contracts. I have lost some customers to mail order because of it. Other pharmacies have signed all contracts at a great loss and have been put out of business by it. This is yet another attack on pharmacy. We don't have the deep pockets. As the president of my pharmacy I earned $60,000 last year. Find me a pharmaceutical company president can say the same. You are going after the little fish and ignoring the sharks.

Submitter : **Jeff Stillwagon** **Date: 02/18/2007**

Organization : **Clinic Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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Sincerely,

Jeff Stillwagon,RPh

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : Gary Sain **Date:** 02/18/2007

Organization : Bethlehem Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Gary L. Sain
cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : Mr. tommy spears **Date:** 02/18/2007

Organization : Mr. tommy spears

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

How in the world does the Federal Government expect private business
to REMAIN in business, and serve your beneficiaries, when you propose
to reimburse us an average of 36% LESS than we pay for the product we are 'selling'....much less be profitable. You should be ashamed for even suggesting this!

Tommy Spears, RPh.

Submitter : **Date: 02/18/2007**

Organization : **Phi Delta Chi**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed definition of average manufacturer's price (AMP) should be changed to reflect what it actually costs pharmacies to buy the drugs, otherwise pharmacies' reimbursements will not cover the costs to buy and distribute drugs to Medicaid patients, forcing many independent pharmacies to turn these patients away. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained.

Submitter : Dr. Steve Zaver **Date:** 02/18/2007

Organization : Town & Country Drugs and Home Medical

Category : Pharmacist

Issue Areas/Comments

Background

Background

To Center for Medicare and Medicaid Serives,

I am writing to submit these comments on Medicaid Program: Prescription Drugs; AMP Regulation CMS 2238-P RIN 0938-AO20. I am a pharmacist and owner of Town & Country Drugs and Home Medical, a community retail pharmacy located at 1051 S. Riverside Drive, Clarksville, TN 37040. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

Collection of Information Requirements

Collection of Information Requirements

The 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.

GENERAL

GENERAL

In summary, your consideration of these comments is essential:

1. Definition of "Retail Class of Trade" - Removal of PBM and Mail Order Pharmacies
2. Calculation of AMP - Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies
3. Removal of Medicaid Data
4. Manufacturer Data Reporting for Price Determination - Address Market Lag and Potential for Manipulation
5. Use of 11-Digit NDC versus 9-Digit NDC

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

Sincerely,

Steve Zaver, Pharm.D
1051 S. Riverside Drive
Clarksville, TN 37040

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

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

Regulatory Impact Analysis

Regulatory Impact Analysis

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy , where over 97% or the majority] of our business comes from prescription drugs. What the other sales in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

Response to Comments

Response to Comments

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

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

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

Submitter : Mr. magdi latif **Date:** 02/18/2007

Organization : Northshore Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Independent Pharmacy providing rural care to outer island population.
we are a small community pharmacy, that provides personal service to our clients/patients. Since we know most our customers by name and families we are able to provide them with comprehensive medication services.

Response to Comments

Response to Comments

Since we are on the outer Island, in a rural area. our cost of doing business is much higher. Wages, rent, taxes and other cost to do business goes up yearly and its at an accelerated pace in our area.
I have no idea what AMP is , but I can tell you that small pharmacies is the only way to give personalized care to patients. You are suggesting that we get reimbursed at the same level as a mail order pharmacy, that never sees it's patients, does not know anything about their lives, their families, their personal story that goes with every patient, with out that info it's impossible to give good patient care. Mail order and giant filling station pharmacies can get better contracts due to their volume. you are penalizing the small independent pharmacists, that most people turn to for free advice, and caring attitudes

Submitter : **Dr. Jannesah Marion** **Date: 02/18/2007**

Organization : **Dr. Jannesah Marion**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-884-Attach-1.DOC

CMS-2238-P-884-Attach-2.DOC

Submitter : Ms. jie Liu **Date:** 02/18/2007

Organization : Temple pharmacy school

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The congress has made a series of significant changes to pharmaceutical pricing, Medicare, Medicaid payments to pharmacies for prescription drugs. As a pharmacy intern, I already experienced the impact the new prescription plan, medicare the past few months.

I also concerned with lowering AMP on many prescription drugs because this may result in greater uniformity in manufacturer pricing and reduction in multitiered manufacturer pricing; however, this change will reduce already thin margin in the retail pharmacy supply chain. Current AMP calculated reflects only about 50% of actual acquisition price on generic drugs. If AMP calculated too low, the reimbursements for the prescription will be sharply below the pharmacy s cost, which will raise the question: where is the money to pay for the service of dispensing and preparing the medication for patient A serious financial consequence for the nation s community pharmacists. AMP need to be well defined and calculated accurately and reflect the real prices available to retail pharmacies. A clear cut definition of AMP is needed to reflect pharmacist s true drug acquisition costs. We, future pharmacists, studied hard and work hard to become who we are today. Our dream is to help the patient get well and improve their quality of live; in return, we also need congress to reconsider the change in AMP and think from our point of perspectives.

Submitter : **Ronald Watts** **Date: 02/18/2007**

Organization : **Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Ronald Watts

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Mrs. Janice Miner** **Date: 02/18/2007**

Organization : **Tom Olcese Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Subject: Medicaid Program: Prescription Drugs;AMP Regulation
CMS 2238P-RIN 0938-AO30

Collection of Information Requirements

Collection of Information Requirements

1.Definition of "Retail Class of Trade"Removal of PBMs and Mail Order Pharmacies.
2.Calulation of AMP Removal of Rebates Concessions to PBMs and Mail Order Pharmacies
3.Removal of Medicaid Data
4.Manufacturer Data Reporting for Price Determination-Address Market Lag and Potential for Manipulation
5.Use of 11-Digit NDC versus 9-Digit NDC

GENERAL

GENERAL

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

Submitter : **Robert Guy** **Date: 02/18/2007**

Organization : **Guy's Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Robert E. Guy, R.Ph.
Guy s Family Pharmacy

cc. Richard Burr http://burr.senate.gov/index.cfm?FuseAction=Contact.Home

Elizabeth Dole
http://dole.senate.gov/index.cfm?FuseAction=ContactInformation.ContactForm

Submitter : **Mrs. Rebekah Mooney** **Date: 02/18/2007**

Organization : **Campbell University School of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-889-Attach-1.DOC

Submitter : Miss. Van Le **Date:** 02/18/2007

Organization : APhA

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

My name is Van Le. I am currently a third year pharmacy student at Temple University. I am writing this letter to you in regard to Congress discussion about cutting Medicaid pharmacy reimbursement over the next 5 years. I was shocked when I was informed AMP is under consideration to replace AWP which may result in a reimbursement to pharmacies at or below acquisition cost. I, and many pharmacists, can not afford to see their pharmacy to be driven out of the Medicaid business. This will tremendously affect our salary in such a negative way. From the standpoint of a pharmacy student, pharmacy school is not easy. I have to spend total of four years to be professionally prepared for the field, not counting many years of undergraduate. I have borrowed a large amount of loan in order to maintain myself in school. I am not expecting to have an increase in the current standard salary of a pharmacist, but I am asking to be paid at the salary a professional pharmacist deserves. I hope you will take my opinion into consideration for this reimbursement discussion and change your mind not to replace AWP with AMP. Your decision can affect not only pharmacists, but the profession itself. Please remember: our profession is in your hand. And our profession is to do what best for the patients, your citizens. Therefore I believe we should be rewarded for the level of care we give out to our patients. I thank you greatly for your time and understanding. I hope my voice of opinion will be taken into account.

CMS-2238-P-890-Attach-1.DOC

Submitter : Mr. Carl Dean **Date:** 02/18/2007

Organization : Blue Bell Village Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Retail Pharmacist - 30 yrs. -Independent owner in Montgomery Co.,Pa.
Subject- Prescription Drugs: AMP regulation CMS 2238-P RIN 0938-AO20

Collection of Information Requirements

Collection of Information Requirements

Remove mail order Pharmacies & PBMs in the definition of "Retail Class of Trade" - the outfits do NOT dispense to the general public as retail Pharmacies do. See Pa.Pharm Assoc> extensive comments.
AMP should reflect prices paid by retail Pharmacies..Congress did not intend to include the above elements.
Also -please tremove Medicaid data which is heavily regulated.Also - we in independent Pharmacy believe CMS should use the 11-digit AMP value -Most common size packages dispnsed can only be captured this way!

GENERAL

GENERAL

I* support the more extensive comments being filed by the Penna Pharm. Association regarding this proposed regulation.

Submitter : **Mrs. Shauna Bradley** **Date: 02/18/2007**

Organization : **Cherokee Health Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-892-Attach-1.DOC

Submitter : Dr. Roger Riesberg **Date:** 02/18/2007

Organization : Shopko Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : **Ms. Jessica Miller** **Date: 02/18/2007**

Organization : **Ms. Jessica Miller**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am worried about the proposed changes in Medicaid prescription reimbursement rates. If the method of calculation is altered, many pharmacists will lose money by serving Medicaid beneficiaries and will choose to serve us no longer.

I am a Medicaid beneficiary myself, though I receive prescription drugs through Medicare Part D because I am a "dual eligible" (I receive Medicare as well as Medicaid). As a Medicaid patient, I know well the burden that comes from a limited choice of providers, pharmacies, and programs. I know what it is like to have limited financial means. People who receive drug coverage through Medicaid, as I once did, must not be told that they can only receive medications from larger chain pharmacies (such as CVS) or supermarket pharmacy counters. Only these larger companies will be able to absorb the financial losses associated with helping Medicaid beneficiaries; the smaller ones will face bankruptcy if they try to shoulder such burdens.

Patients' choice of pharmacies often centers around an understanding of the professionals involved and the quality of service received. Often the bigger pharmacies are busier and can give patients limited personal attention. Attention, however, is something Medicaid beneficiaries sorely need, dealing as we do with chronic health conditions and monetary woes. Whereas the local drugstore may have the time to dispense advice on the proper way to take a medication, a branch of a chain pharmacy has more people to see and less time to give them.

Many people on Medicaid also have transportation issue. I am disabled and will never be able to drive, and there is the issue of having enough money for public transportation. To be effectively told which pharmacy to go to will just complicate our daily struggles to get around and will add to already-existing psychological and financial issues.

I have filled my prescriptions at the same independent drugstore for years, both as a Medicaid patient (before Part D took effect in January 2006) and as a Part D beneficiary. The pharmacists there have always been both knowledgeable and compassionate. Always able and eager to answer my questions, they have never hesitated to put in extra effort in order to meet my needs. On the few occasions when I have had to go to a larger chain pharmacy for my medications, however, I have experienced a longer wait for my medications and less personalized service. I have received the impression that the people running the large chains want customers to "get in and get out", as if the store were an assembly line.

If codified, the new method of calculating pharmacy reimbursement rates will place an undue burden on Medicaid patients, as well as on the small-town pharmacists many of us choose to patronize. I am well aware that lawmakers have many legislative and financial concerns. However, there is no reason why many of the most vulnerable members of society should be forced to absorb much of the burden of legislative and fiscal change. Particularly for Medicaid patients such as myself, already overwhelmed with health, financial, and personal issues, small changes can be devastating. Such changes are bound to create gaping holes in the fabric of our lives, and many of us lack needles and thread.

It is bad enough that the services we receive are limited and underfunded and that the obstacles we face already seem unsurmountable. Please don't turn us into virtual pariahs, the ones whom nearly every pharmacy and provider must turn away. Don't break the solid bonds we have with our community pharmacists. Treat us, and treat the people with whom we conduct business, with dignity, respect, and compassion.

Please refrain from changing the method of calculation for the Medicaid pharmacy reimbursement rate.

Thank you.

Yours truly,
Jessica Miller

Submitter : **Dr. Stephanie Smith Cooney** **Date: 02/18/2007**

Organization : **Gatti Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

As a pharmacy owner, I am extremely concerned about the AMP-based FUL's. I have concern that this new reimbursement definition could cause me to no longer accept Medical Assistance contracts. There are several reasons why I am concerned. A summary of those reasons follows. I refer you to the trade organization that I belong to, NCPA, for further comments on this proposed rule. I support their position on my behalf.

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. Wayne Elwell **Date:** 02/18/2007

Organization : Stop & Shop Pharmacy (Independant)

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Grouping community pharmacies with mail order and hospital outpatient pharmacies will put our store at a definit disadvantage as we are not able to contract the prices they have access to.

We are just barely braking even after Medicare Part D, one more blow like an AMP calucated from mail-order and hospital outpatient pharmacies could be the end of our existencc. There was several independant pharmacies in our area when I first moved here and now there are but a few.

We are able to view the ACTUAL profit of each prescription dispensed in our system and even now we lose money on a few items. I don't even want to think about how many items will be dispensed at a price below acquisition cost if the newly proposed AMP goes through as it has been explained to me. I guess I will have to be out of stock on items to far below cost causing an unnecessary delay to my customers.

I would hope that those about to make decisions would consider the effect of grouping all types of pharmacies together as we don't all play with the same rules. Independant pharmacies remain an important part of distribution and provide much better service than mail order, but shouldn't have to use the same pricing formula as the giants that provide little if any service. I have lost several customers to mandatory mail order programs and have helped many of them when they come back in for me to identify the medication they were sent in the mail to see if the same as the ones I dispensed them. I usually ask them if they tried to get ahold of the mail order depot and they respond that they got a recorder or someone took a number and said the pharmacist would got back with them, Most of them never got a call.

The future of independant pharmacies depends on the decisions you make and we are hopcing that your considerations will include the different prices available to different kinds of stores.

Wayne Elwell RPH
Stop & Shop Pharmacy
1130 Washington Blvd
Ogden, UT 84404
801-399-4054

Submitter : Mrs. Mary Sauls **Date:** 02/18/2007

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 : Mr. Curt Evans **Date:** 02/18/2007

Organization : The Medicine Shoppe #1006

Category : Pharmacist

Issue Areas/Comments

Background

Background

as a pharmacist for 30 years, I am shaking my head at the proposed AMP pricing on generic drugs that the GAO itself has concluded would average 36% BELOW true acquistion cost for retail pharmacies

Collection of Information Requirements

Collection of Information Requirements

these provisions are not only unfair to retail phatmacies, they do not even make economic sense.....EVERY business deserves to make a fair and reasonable profit....that is the ESSENCE of being in business in the 1st place

GENERAL

GENERAL

AMP = a joke, is blantantly unfair to EVERY retail pharmacy across the country and hints to restraint of trade...imo, it is essentailly unconstitutional....

bottom line, EVERY retail pharmacy that serves a high percentange of medicaid patients WILL be forced out of business

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

GAO study

Regulatory Impact Analysis

Regulatory Impact Analysis

if AMP prices are lower than true acquisition cost for 59/77 generic drugs as the GAO report indicates, NO retail pharmacy will be able to afford to fill medicaid prescriptions anymore.....I, personally, would much rather lose the business vs losing $ on the business...I will be forced to turn my medicaid business away which approximates almost 70% of my business.....do you people honestly think I will fill 70% of my prescriptions below cost?

Response to Comments

Response to Comments

medicaid patients' rxs being refused by pharmacies all across the country will increase hospitalizations costs and increase medicaid expenses by geometric proportions.....how many medicaid patients will DIE because of this proposed AMP insanity?.....get real CMS....what's next?...coercing physicians to PAY CMS to even see medicaid patients?.....

Submitter : Dr. Vanessa O'Briant **Date:** 02/18/2007

Organization : Kinser Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please consider these comments as we feel they are absolutely VITAL to the survival of our profession. We are the most readily available health care professional...please do not take this away from our seniors and patients who need it most!!

Thank you!!!
Vanessa O'Briant
"See Attachment"

CMS-2238-P-899-Attach-1.PDF

Submitter : renae gaerke **Date:** 02/18/2007

Organization : renae gaerke

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-900-Attach-1.PDF

Submitter : Mr. Edward Millward RPh **Date:** 02/18/2007

Organization : Lowers Pharmacy Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

In order for our pharmacy or any other pharmacy to provide medication to the medicaid population we must be able to secure a reimbursement level that allows us a margin high enough to cover our cost of medication and expenses incured in the dispensing process. The Government Accounting Office's report on AMP pricing clearly demonstrates that the current AMP reimbursement rates will cause us an avcrage loss of 36% for each Medicaid prescription we dispense. And that is only considering the cost of the medication dispensed not the expenses incured in the dispensing process. In order for our pharmacy or any other community pharmacy to participate wc must be reimbured at a rate that allows us to have a reasonable profit to meet our expenses and provide a living wage to the employees of the pharmacy. Thc true danger in this calculation will be the ultimate withdrawal of most if not all community pharmacies from the Medicaid program. This will create a tremendous gap in the needed healthcare services to the population least ablc to find alternative resources for their medications. The Medicaid population will be forced to the hospitals and clinics for medication causng a collapse of their reserves. The current medication distribution system in this country has community pharmacies paying the highist cost for medication. Therefore, it is, at best, UNFAIR for AMP to be calculated on anything other than the cost of medication to the community pharmacy only. The PBM discounts, hospital discounts, mail order discounts and/or any other manufacturer discounts in which a community pharmacy can not participate in can not be used to calculate AMP. Again our pharmacy's future participation in the Medicaid program will depend on your prudent efforts to correct this reimbursement problem.

Submitter : Mr. Dan Hayes **Date:** 02/18/2007

Organization : Stedman Drug Center

Category : Pharmacist

Issue Areas/Comments

Background

Background

We are a community pharmacy located in a small rural town. We are the only pharmacy in this town. Who serves our community when we are gone.

Collection of Information Requirements

Collection of Information Requirements

Cureent Deffinition of AMP is approximately 36% lower than pharmacies acquistion cost.

GENERAL

GENERAL

Dear Director Norwalk,

I operate a community pharmacy in a small, rural town in North Carolina. Approximately 40% of our patients are either Medicaid patients or Medicare patients. Should the current definition of AMP stand as it is, where AMP is 36% less than our cost to obtain generic drugs, our company will have to withdrawn from these programs. This will a severe negative impact on our patients who will lose access to their medicines from their local community pharmacy, plus also severly impact our business. We would be forced to lay off 10 of our employees also in order to try to remain in business. Last year we paid over $300,000.00 in taxes. That will not be case if we are no longer profitable or operating because of short-sighted government policies.

CMS possesses a deadly "weapon of mass destruction!" It exist in the form of its current disasterously low definition of AMP which will destroy the best pharmaceutical delivery system in the world. Please listen to pharmacy leaders and others who understand the delivery system and how your current policy will destroy it. There are many other ways to save the necessary money which will not destroy this vitally important element of the pharmacy care system.

Should you desire further information, or comments. Please don't hesitate to call. We are a real, vital part of our community. I wish to remain the same.

Sincerely,
Dan Hayes
Pharmacist-Owner
Stedman Drug Center
stedmandrug@aol.com

Response to Comments

Response to Comments

Impact to our business and others like it may be catastrophic and do irrepairable damage before the Washington beauracracy realizes what they have done and try to find a fix. The best fix, is not to do the damage in the first place.

Submitter : **Eldon Hodges** **Date: 02/18/2007**

Organization : **The Medicine Shop**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-2238-P-903-Attach-1.TXT

Submitter : Mr. Russell W Harcha **Date:** 02/18/2007

Organization : Wurster Drugs, Inc.

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

I can not dispense any prescription below cost. This will force me out of business immediately. Eleven employees will lose their jobs immediately.

Submitter : Mr. Robert Fulford **Date:** 02/18/2007

Organization : Tenessee Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-905-Attach-1.WPD

Submitter : Dr. M Walker **Date:** 02/18/2007

Organization : Olde Towne Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-906-Attach-1.TXT

Submitter : Mr. Robert Fulford **Date:** 02/18/2007

Organization : Tennessee Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-907-Attach-1.WPD

Submitter : rey moreNO **Date:** 02/18/2007

Organization : rey moreNO

Category : Pharmacist

Issue Areas/Comments

Background

Background

Community retail pharmacy as taken the lions portion of medicare d cuts.

Collection of Information Requirements

Collection of Information Requirements

proposed cuts in despensing fees for generic will only drive the program to more costly single sourse drugs. If retailers can make more money on a product-thats what happens
I for one will sell my store. If i can not help people and make a profit- its time to get out.

Response to Comments

Response to Comments

fcderal and state rules have madc pharmacy a more costly business to run. Yet, you authorize a despensing fee that does not cover the cost to comply with rules and make a profit. Each year you allow a cost of living incresc. The fees have actually been lowered.

Submitter : **Date: 02/18/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : Mr. Danny Chung **Date:** 02/18/2007

Organization : Kappa Psi

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

"see attachment"

CMS-2238-P-910-Attach-1.DOC

Submitter : Mr. JOHN GENTRY **Date:** 02/18/2007

Organization : SNEAD DISCOUNT PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

Submitter : **Mr. Randy Armbruster** **Date: 02/18/2007**

Organization : **Randy's Family Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-912-Attach-1.DOC

Submitter : **Mr. Hubert (Brett) Bryan Jr.** **Date: 02/19/2007**

Organization : **Bryan Pharmacy Inc.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I'm a independent pharmacy owner in Enterprise,AL. I graduated from Auburn Pharmacy School in 1994. I started my pharmacy career with a southern Pharmacy chain HARCO, which was later purchased by Rite-Aid. I worked at the same location for 9 years before opening my own pharmacy in September 2003. My pharmacy has grown at a conciderable rate since opening, mainly becausc we have adequate staff to serve our patrons. We do morc than just fill prescriptions, we listen, we consult patients, we give OTC medication advicc, we take vital signs, we hclp mothers with flavering their kids medicines, we give advice to physicians, we fill out prior autherations, we help fill out medicare part D forms; These are all things We do for our patients FREE OF CHARGE!!These are often not considered as a service but are. The profit we make from prescriptions pay for these free services. Pharmacies have to make a profit from medicine, if not from medicine we need to-be reimbursed for our services.

I'm afraid if this AMP goes thru as currently proposed I will be rcimbursed 38% below my acquisition cost, not including the almost $11.00 cost to dispence each prescription. Please consider your ramifications upon me and many other pharmacies.

Medicaid is a high percentage of my business. I will probally be forced out of business if AMP contines as currently proposed, as will many other independent pharmacies. All this will lead to a demenished level of care for your Medicaid patients. The pharmacies that are not forced to close will have to stop accepting Medicaid patients or serve them in a cheap manner. I hope it doesn't come to this.

How soon do we forget, how pharmacies handled the Medicare Part D fiasco in 2005. Us pharmacist that cared for our patients were forced to front our patients 2 to 3 monthes of medication without any payment. I was very proud how so many pharmacies performed during this tough time in pharmacy. Now here we are again, faced with a business threating ordeal.

Don't you think it's time to look for budget cuts from someone other than PHARMACIES. How about Brand Name Drug Manufactures or large PBM's. Both of which make money hand over fist.

Thanks for your time and consideration on this matter!

Submitter : Adrienne Sargent **Date:** 02/19/2007

Organization : E. Tennessee State University College of Pharmacy

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-914-Attach-1.DOC

Submitter : **Date: 02/19/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

While I understand that the government is looking for ways to save money, I feel as though the way in which this regulation attempts to accomplish it is totally wrong. For us, as independent pharmacies, the new regulations as proposed will make Medicaid services the equivalent of pro-bono work in the legal system. The profit for pharmacies will simply disappear, unlikely to be resurrected. After all, since ALL government is looking to try to save money, it is most UNLIKELY that state Medicaid officials will increase dispensing fees to offset this program. Most pharmacies have used the price differential between acquisition cost and reimbursed cost to maintain necessary profitability to allow them to stay affiliated with the Medicaid programs. If you remove this incentive without providing one to replace it, the consequences for pharmacies will be as catastrophic as if Hurricane Katrina had hit us individually.
Worse than that, though, is the quality of care for Medicaid clients will have to be drastically reduced. Fewer pharmacies will be able to stay in the Medicaid program, thus reducing the access to health care that these poor, mostly illiterate people need. With fewer pharmacies in the program, the ones that stay in the program will take on the added burden of additional customers, thus reducing their effectiveness in adequately spending time with their patients. OBRA violations will be a common site in these pharmacies, as pharmacists, who are already under the considerable stress of an aging population and management that desires faster and faster results, will be forced to reduce overall services. I have a hard time seeing how this will be good for the nation and its people overall.
I could bring forth a number of statistics that would bear light on the above summary conculsions. In doing so, the overall point would be lost. CMS and FDA need to understand that:
1. Any money saved will more than be offset by money lost in the overall economy when small and mid-sized pharmacies have to close their doors because of declining profits & customer base,
2. Many people will lose their jobs. With the competitive nature of business today, many of these people will have difficulty in even finding jobs at other places,
3. Many Medicaid patients will lose access to their pharmacists -- their valued professionals in the health-care system. The added burdens of dealing with new pharmacies (and pharmacists) will likely result in adverse events for these people ranging for underdosing critical medicine to increasing the likelihood of adverse drug, reactions through inability to closely monitor drug therapies.

CMS and FDA: the dollars saved in implementing these regulations as proposed pales in comparison to the potential adverse impact to hundreds of thousands of people (from pharmacists, technicians, clerks, and wholesalers, all the way down to the general public itself and especially those people insured in the Medicaid program) that have much more to lose than money. FDA's mandate, I believe, is to protect the public. How can FDA then say the adverse impacts on these people are justifiable, just to save money? And CMS's mandate is to provide the best quality health care for its Medicaid patients. Can't CMS see that this proposal would do just the opposite?
Unless FDA and CMS step in and either change the proposal to more favorable terms, or require the states to increase dispensing fees to respectable levels, the above scenario is likely to happen. It's my hope that this government of the people and by the people will reassess the situation and do something that will be FOR the people.
Thank you for the opportunity to comment on this issue.

Submitter : **Dr. Tara Pratt** **Date: 02/19/2007**

Organization : **Dr. Tara Pratt**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-916-Attach-1.RTF

Submitter : Dr. Wade Stanley **Date:** 02/19/2007

Organization : Dr. Wade Stanley

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-917-Attach-1.DOC

Submitter : Mr. Todd Sega **Date:** 02/19/2007

Organization : Mr. Todd Sega

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Today, people are forced to take on many roles in their professions, and everyone's lives become more hectic. However, even though pharmacies are becoming busier, the profit sources should not change. Before decisions are made, it is only right to first obtain feedback from the affected individuals. Since that step was not taken, the following is my opinion on the proposed legislation, and since I took the time to write this, I would appreciate it if my concerns were taken into consideration.

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. Kimberly Nealy **Date:** 02/19/2007

Organization : Campbell University School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-919-Attach-1.TXT

Submitter : **Mr. Gary Bowman** **Date: 02/19/2007**

Organization : **Best Care Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

GENERAL

GENERAL

February 18, 2007

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

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

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

Gary L. Bowman, RPh

cc. Members of Congress Rep. Butterfield

Submitter : Dr. Sylvia Miles **Date:** 02/19/2007

Organization : Williamstown Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 19, 2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

Sylvia M. Miles, Pharm.D., RPh
Williamstown Pharmacy, 426 Highland Ave., Williamstown, WV 26187

Submitter : Dr. John Holladay **Date:** 02/19/2007

Organization : Sumter Cut Rate Drugs

Category : Pharmacist

Issue Areas/Comments

Background

Background

CMS is proposing that reimbursements on generic medications be slashed as a part of the DRA of 2005. The use of Average Manufacturers Price(AMP) is proposed as a basis of payment. The current methodology uses the well known Average Wholesale Price (AWP).

Collection of Information Requirements

Collection of Information Requirements

The new reimbursement paradigm will be based on 250% of AMP for generic drugs and keep the AWP for branded medications.

GENERAL

GENERAL

The trend of slashing payments to pharmacies is sending a dire message to community pharmacies. Once the backbone of grass roots healthcare, we are now being placed in jeopardy by CMS cuts and ruthless PBM tactics. The proposed reimbursement cuts in generics will lower our payment to 35% lower than our ACQUISITION costs. In plain terms, we will lose money and potentially go out of business. This new plan by CMS will lead us to prompty switch every generic prescription to a branded product. This will drive up healthcare costs even more.

A potential solution is to ask the pharmaceutical manufacturers why a closed door pharmacy can buy products at a fraction of what a community pharmacy must pay. A significant reduction in our acquisition costs, which the manufacturers ALREADY GIVE mail order pharmacies, will allow us to absorb these AMP based cuts. Please make the market place a level playing field for all pharmacies...eliminate this discriminatory pricing and we will live with the budget cuts. Otherwise, we will be forced to switch patients to more expensive branded items. Please call me at 803-773-8432 if you want more input. Thanks, John Holladay, PhD

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

see below

Regulatory Impact Analysis

Regulatory Impact Analysis

see below`

Response to Comments

Response to Comments

see below

Submitter : **Mrs. Sharon Taylor** **Date: 02/19/2007**

Organization : **Alabama Independent Drugstore Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-923-Attach-1.DOC

Submitter : **Dr. Baeteena Black** **Date: 02/19/2007**

Organization : **Tennessee Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-924-Attach-1.DOC

Submitter : Dr. Eric Smith **Date:** 02/19/2007

Organization : Sterling Pharmacy Systems, LLC

Category : Long-term Care

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-925-Attach-1.DOC

Submitter : Dr. Andy Long **Date:** 02/19/2007

Organization : City Drug Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-926-Attach-1.RTF

Submitter : Dr. Scott Jenkins **Date:** 02/19/2007

Organization : City Drug Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-927-Attach-1.RTF

Submitter : Dr. Jeremy Long **Date:** 02/19/2007

Organization : City Drug Co.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-928-Attach-1.RTF

Submitter : Mr. Ron Lanton **Date:** 02/19/2007

Organization : H. D. Smith

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-929-Attach-1.DOC

Submitter : **Mark Trumm** **Date: 02/19/2007**

Organization : **Trumm Drug**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 19, 2007

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

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

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

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

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

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

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

Sincerely,

Mark Trumm RPh
Trumm Drug
600 Fillmore Street, PO Box 397
Alexandria, MN 56308

320-763-3111

Submitter : Mr. stephen rippetoe **Date:** 02/19/2007

Organization : howards pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am submitting these comments to CMS regarding the Dec. 20,2006 proposed regulation that would provide a regulatory definition of AMP as well as implement then new Medicaid FUL program for generic drugs. I am a pharmacist and owner of Howards Pharmacy at 3336 West Andrew Johnson Hwy, in Morristown, TN. We are a major provider to many Medicaid patients in our area.

Collection of Information Requirements

Collection of Information Requirements

The proposed definition of AMP would not reflect the prices that I can purchase generic drugs. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBM's and mail order pharmacies from the AMP determination recognizes that these are not community pharmacies,where ALL Tennessee Medicaid patients have their prescriptions filled. Both of these type of organizations do not dispense to the "general public" and should be excluded from the information used in calculating AMP to be used for determining and FUL.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

AMP should reflect prices paid by retail pharmacies. Rebates paid by manufacturers to mail order pharmacies and PBM's are not shared with community pharmacies and should be excluded from the calculation of AMP. The GAO report that retail pharmacies will be reimbursed, on average, 36% less than their costs to purchase the drugs included in the analysis. I can not stay in business if I have to dispense medications for less than i pay for them. The CMS claims that most all pharmacies sell goods other than prescription drug. This is not true. A Howards Pharmacy, 96% of my sales are prescription drug. This also the case at all independant pharmacies that I know of. Before owning this pharmacy, I work at several pharmacies and at all of them about 90 to 95% of their business came from prescriptions and not over the counter sales.

Regulatory Impact Analysis

Regulatory Impact Analysis

Medicaid pricing is heavily regulated by state and federal governments. Medicaid should be treated consistently with other federal payor programs, and slso be excluded from AMP in the proposed regulation. I also believe that CMS should use the 11-digit NDC number for all drugs. Some drugs are sold to mail order pharmacies in package sizes for 5,000 to 40,000 tablets or capsules.A typical retail pharmacy can not purchase these quantities or their inventory would be in the millions of dollars.

Submitter : Mr. Samuel Clay, Jr. **Date:** 02/19/2007

Organization : Cyrus Kirkpatrick Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-932-Attach-1.DOC

Submitter : **Dr. Allan Fettig** **Date: 02/19/2007**

Organization : **Trumm Drug Phamacies**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-933-Attach-1.DOC

Submitter : **Leonard Browder** **Date: 02/19/2007**

Organization : **Home Medical, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

If this legislation is enacted I will no longer be able to fill Medicaid Rx's as my cost for the drugs would far exceed my reimbursement. Since the government's own studies by the GAO confirm the last statement, how can the government expect pharmacies to continue to serve these patients?

Submitter : Dr. Jason Kizer **Date:** 02/19/2007

Organization : Kizer Pharmacy LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mr. Martin Jasion **Date:** 02/19/2007

Organization : Clearspring Rx

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AMP is not a true indication of the cost of any product..Like AWP it is a fake number created as a starting point in what a retailer would pay a wholesaler/manufacturer. The only fair way to arrive at a price would be to calculate an average reimbursement from ALL insurance companies, taking in account rebates from manufacturers or other incentives/discounts deducted..The end result would be a fair price for reimbursement.

Submitter : Dr. Kenneth Archer **Date:** 02/19/2007

Organization : Archers Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attatchmetn

CMS-2238-P-937-Attach-1.DOC

Submitter : **Mr. Richard Smith** **Date: 02/19/2007**

Organization : **Mr. Richard Smith**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

CMS regulations using AMP for Medicaid recipients

GENERAL

GENERAL

Pharmacists will not be able to keep their doors open with these low reimbursements. CMS needs to look at the cost of the medications; not hurt the professional trying to be accessible to their patients.

Regulatory Impact Analysis

Regulatory Impact Analysis

We have found that the cuts proposed by CMS will result in pharmacists being paid 36% less on average than their acquisition cost on every Medicaid generic drug prescription they fuill.

Many Pharmacists serve communities with limited access to health care providers, if pharmacists are forced to close their doors or drop out of the Medicaid program, patient access to the medications they need will be seriously threatened. According to a national survey; the average cost of dispensing a prescription is $10.50. not including the cost of the medication. With slow and low reimbursements; pharmacists are going to be forced out of the program

Submitter : Lisa Jokerst **Date:** 02/19/2007

Organization : Twin City Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The formular AMOP-based FULs will not cover pharmacy acquisition costs for multiple source generic medications. AMP must be defined to reflect the actual cost paid by retail pharmacys. You will see a decrease in the number of pharmacy's providing Medicaid services if the AMP-based FULs is inforced. This will lead to very unhappy Medicaid recipients if they have to travel far distances to get their prescriptions. Would you rather that happen? Or possibly the government may have to open their own pharmacy's just for Medicaid recipients - that in itself may be a greater expense than inforcing the AMP-based FULs. Consider the negative impact CMS-2238-P would be causing. Maybe this cost reduction should be a collaborative decision between a major Pharmacy Association and CMS so that it helps CMS and doesn't cause detrimental effects to the retail pharmacys (especially independents!)

Submitter : Mrs. Kathryn Reep **Date:** 02/19/2007

Organization : Florida Hospital Association

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-940-Attach-1.DOC

Submitter : **Heather Arnold** **Date: 02/19/2007**

Organization : **Heather Arnold**

Category : **Individual**

Issue Areas/Comments

Background

Background

Please do not let CMS cut reimbursement so low it harms patients. Pharmacists catch on average 3 mistakes a day and 1 of these would have potentail resulted in death of the patient. Losing money on prescriptions will not allow for pharmacists to be in business, infact not even being able to breakeven on prescriptions will greatly compromise patients care. Thus resulting in increase in health care costs such as emergency room visits, hospital costs and prescription cost. Pharmacists' wealth of knowledge and expertise should not be penalized. Instead other methods should be taken such as put the burden on the drug companies which make 65 cents out of every dollar of a prescription where pharmacies only make 3 cents. It just doesn't make sense to cut pharmacists reimbursement when they are not the real ones profiting off of prescriptions.
Thank You for your time
Sincerely,
Heather Arnold

GENERAL

GENERAL

Please do not let CMS cut reimbursement so low it harms patients. Pharmacists catch on average 3 mistakes a day and 1 of these would have potentail resulted in death of the patient. Losing money on prescriptions will not allow for pharmacists to be in business, infact not even being able to breakeven on prescriptions will greatly compromise patients care. Thus resulting in increase in health care costs such as emergency room visits, hospital costs and prescription cost. Pharmacists' wealth of knowledge and expertise should not be penalized. Instead other methods should be taken such as put the burden on the drug companies which make 65 cents out of every dollar of a prescription where pharmacies only make 3 cents. It just doesn't make sense to cut pharmacists reimbursement when they are not the real ones profiting off of prescriptions.
Thank You for your time
Sincerely,
Heather Arnold

Submitter : **Date: 02/19/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

We are a 25 bed Critical Access Hospital with an Emergency Department, Outpatient Oncology/Infusion Service, Outpatient Surgery, and periodic Outpatient Clinics with visiting physicians. The requirement to provide NDC information on billing submissions to Medicaid agencies would be very burdensome to us. This information would have to be added to each claim by hand by a biller for each drug administered. This is because our hospital computer system, Meditech, does not transfer the NDC number from the Pharmacy module to the Billing/Accounts Receivable (BAR) module. The BAR module does not even have a field for the NDC information. Meditech is a major computer company for small and medium sized hospitals, so this would affect many hospital throughout the nation. In addition, supplying NDC information is quite problematic for hospitals due to current supply shortages, which means having to change suppliers often. Each supplier has a unique NDC number for the same generic product. Maintaining such a file would be quite labor intensive.
In conclusion, I strongly feel that the impact of this regulation on workflow, staffing, and financial resources for our hospital is unrealistic and not justifiable given current fiscal and workforce constraints.
Thank you for the opportunity to comment.

Submitter : Mr. Dominic BARTONE **Date:** 02/19/2007

Organization : Hocks Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The AMP price calculation that is to be implemented in the very near future does not accurately reflect the true cost of pharmaceuticals to the Retail Pharmacy Community. Retail Pharmacy should be evaluated on the cost at which we can purchase pharmaceuticals. Retail pharmacy does not get special contracting pricing that is given to HMO's, Mail order Pharmacies, Nursing home Pharmacies and Closed Door Pharmacies. We do not get any manufacturer rebates such that are given to the previously mention entities. Grouping all pharmacy providers would be a very huge mistake if trying to determine real prescription drug costs for Retail Pharmacies.

Submitter : **Mr. Harry Taubman** **Date: 02/19/2007**

Organization : **Mr. Harry Taubman**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The Drug Store Pharmacy, Inc.

2940 Groveport Road

Columbus, Ohio 43207

614-491-3446

February 19, 2007

Acting Administrator Leslie Norwalk

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Att: CMS-2238-P

P.O. Box 8015

Baltimore, MD 21244-8015

Dear Ms. Norwalk,

As I see it, the Proposed Rule that is being considered has major flaws and ultimately will lead to keeping new generics off the market and significantly decrease service to Medicare and Medicaid recipients.

By setting the FUL based on the lowest AMP, it will force many manufactures not to risk putting new generics on the market, unless they could be assured that they could produce that drug at the lowest price of all the manufacturers all the time. Also, wholesalers would not purchase their products for fear that retailers would not be able to buy that product to dispense to Medicare, Medicaid or insurance customers since the retail reimbursement price has already been set from the AMP.

It also seems unfair to have profit margins in retail pharmacy set by other entities. In this case, manufactures are setting AMP based on their needs (i.e. manufacturing & distribution costs and desired profit). Wholesalers will set their wholesale cost to the pharmacy based on their needs (stocking & distribution costs & desired profit). And since all retail pharmacies get reimbursed based on FUL, their profit margins are set. This is against all free market principles and will undoubtedly cause many retail pharmacies to close. The retail pharmacies that remain open, will by necessity, have other niches of profit centers to offset the low reimbursement, mandated by the FUL, for prescriptions dispensed to Medicare, Medicaid and other third party customers.

Please review this Proposed Rule to make it equitable for all entities involved in the manufacturing, distribution and dispensing of generic drugs.

Respectfully,

Harry Taubman

Submitter : Mr. gbenga olajide **Date:** 02/19/2007

Organization : westside pharmacy & wellness ctr

Category : Pharmacist

Issue Areas/Comments

Background

Background

I'm a pharmacist that practice in community retail pharmacy setting. My practice is located in low income neighborhood.

Collection of Information Requirements

Collection of Information Requirements

My comment is on the proposed regulation that will use AMP instead of AWP to reimburse pharmacy services.

GENERAL

GENERAL

If this practice continues, many independently owned pharmacies might fold up resulting in higher unemployement and reduced income tax to be generated by the states. Also the patients will be at a loss since they will be unable to get a high quality of service from their neighborhood pharmacy

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

That AMP is not well defined and that other pharmacies that benefit from low priced drug purchases like mail order pharmacies are included in this calculation.

Regulatory Impact Analysis

Regulatory Impact Analysis

That the rctail pharmacies need to be compensated adequately, especially those of us in the low income neighborhood.That mail order pharmacies who are already bcncfitting from manufacturers rebates and other discount should not be included in calculating pharmacy reimbursement.

Response to Comments

Response to Comments

That the retail pharmacies are loosing money on every script filled today under the medicare prescription reimbursement. That the cost of supplies and labor are not being taken into consideration when paying pharmacist for services rendered. That too much emphasis are being placed on produets rather the pharmacists' time and knowledge.

Submitter : Mr. Mike Larkin **Date:** 02/19/2007

Organization : Kansas Pharmacists Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-946-Attach-1.PDF

Submitter : Mrs. Heather Rosati **Date:** 02/19/2007

Organization : Campbell University School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

Submitter : **Mr. Ron Lavigne** **Date: 02/19/2007**

Organization : **Osburn Drug Co.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist with 3 pharmacies all in rural towns in north Idaho. Over the last ten years the reimbursement rates for pharmacies has steadily declined. In Idaho there are five counties that have no pharmacies in them at all. This is a product of reimbursement rates being so low from insurance companies and now Medicare D that they can not afford to stay open. This leaves those residenst with no easy access to pharmacy care. One of the largest problems with Medicare D is that it is taking more than 2 weeks to get our funds from insurance carrierers. We have to pay our wholesalers every 2 weeks and most insurance companies with other plans pay every 2 wecks. Effectivley these pharmacies with limited cash flow are loaning the government money for upto 8 weeks in some cases because that is how long it can take to get paid. Small retail pharmacies play a vital role in rural health care. These pharmacies provide valuable health care to thier patients. In a small twon one of the first lines of medical care is the local pharmacist. A the present time the avereage pharmacy is running on a 17% gross profit margin. I do not know to many retail businesses that run on that small of a margin. In a place where you can fill a lot of prescriptions you may be able to pay the high costs of pharmacists wages and the high costs of compliying with pharmacy regulation but for small pharamacies this is just not possible. They can not fill enough prescriptions to make up the difference. Lowering the generic reimburesment rate will put many of these small rural pharmacies accross the country out of business. Please reconsider this AMP price schedule we are barley making ends meet now. Thank You

Submitter : Mr. R Jeffrey Hedges **Date:** 02/19/2007

Organization : R.J. Hedges

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I assist retail pharmacies with the HIPAA Privacy and Security Rules. With the changes in Medicare Part D, pharmacies are struggling to stay afloat. The AMP proposal will force many pharmacies in the country to go out of business. The reason, Medicare is setting reimbursement rates and the insurance industry follows suit. The government wants to regulate the prices of medications, but avoids the real issue. Drug manufactures, by law, can not sell directly to the pharmacies. Pharmacies do not have the ability to set their own prices. Medicare sets the standard. However, the middle guy is making all the money and this proposed regulation does not affect them. The drug wholesalers, Cardinal Health, AmeriSource Bergen, and McKesson, all in the top 10 profitable companies in the U.S., purchase drugs in large quantities and then distribute the drugs to the pharmacies. AMP sets the average, but which average. Currently, pharmacies are required to fill prescriptions at a loss in a lot of cases. Express Scripts forces pharmacies to fill all or none of the scripts. If the pharmacy fills a script at a $100.00 below their cost, how does anyone stay in business?

This proposed rule on face value seems to control prescription costs, but it doesn't. It kills the retail pharmacy. In addition, the pharmacy does not get reimbursed for patient care and counseling. Pharmacy patient care saves countless hospitalizations, adverse drug interactions and deaths. If AMP goes into law, pharmacies will fail and who will fill prescriptions? Wal-Mart because they sell at or below cost and make up the loss in the commercial retail market.

Ask your local pharmacy about AMP or your parents about Part D. It sounds good, but when you live with it, it is disastrous.

You can contact me at 814-446-4176 if you have any questions.

R. Jeffrey Hedges

Submitter : JAMES TALLENT **Date:** 02/19/2007

Organization : WIL-SAV DRUGS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

2-19-2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

James S. Tallent
121 Wilson Rd
Madisonville, TN 37354
Ph (423) 442-5265

Submitter : Mr. TRAVIS RICHEY **Date:** 02/19/2007

Organization : Henderson Drugs LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

i.e. "See Attachment"

CMS-2238-P-951-Attach-1.DOC

Submitter : **Mrs. Robert Lassen** **Date: 02/19/2007**

Organization : **National LTC Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Long Term Care Pharmacy Services Provider

Collection of Information Requirements

Collection of Information Requirements

Changc from AWP to AMP pricing

GENERAL

GENERAL

I do not feel the change from AWP to AMP pricing has been properly reviewed for impact to pharmacies as a whole and independent pharmacies specifically. When we are approaching the implementation date and CMS and the State Medicaid plans are the only ones who have the purposed cost, how are pharmacies to know if they can even fill the provide the medications at the new reimbursement rates? The impact of Medicare D (implementation by Med D plans) have been severe on the profession of pharmacy. Now you are asking us to put our heads on the block again. We need more information sooner not later regarding the impact of the change from AWP to AMP. The continual shrinkage of profits and increased operating cost will eliminate independent pharmacies.

Response to Comments

Response to Comments

Decrease in operating cash flow

Submitter : **Mr. Chadd Levine** **Date: 02/19/2007**

Organization : **Mr. Chadd Levine**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Pharmacy Student and employee of an independent pharmacy owner. 100% of the pharmacy's patient population is medicaid.

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacy student attending Temple University and I also work at 5th St Pharmacy.

1. Removc PBM and Mail Order from the Retail Class of Trade

(i) Creates consistency in the Regulation

(ii) Conforms definition with market reality

2. Implement a Trigger Mechanism

(i) Addresses severe price fluctuations

(ii) Reduces risk of Market Manipulation

(iii) Mitigates Risk of Pricing Lag

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

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

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

Sincerely,

Chadd B. Levine

Student Pharmacist

Regulatory Impact Analysis

Regulatory Impact Analysis

Submitter : Dr. John Cronin **Date:** 02/19/2007

Organization : CWL Pharmacies, Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-954-Attach-1.DOC

Submitter : **Ms. Josh Harrison** **Date: 02/19/2007**

Organization : **Ms. Josh Harrison**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

CMS-2238-P-955-Attach-1.WPD

Submitter : **Mrs. Diane McClaskey** **Date: 02/19/2007**

Organization : **CoxHealth**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Who is going to pay for this? Health-systems will have to turn around and increase fees to pay for the staff to perform this function. You need to wait to see the estimate that ASHP is compiling on how much this proposal will cost.

Submitter : **Mr. David Hudson** **Date: 02/19/2007**

Organization : **Sullivan's Discount Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-957-Attach-1.DOC

Submitter : Mrs. Janie Skertich **Date:** 02/19/2007

Organization : Gate City Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

cms proposed regulation/medicaid program amp regulation.AMP should reflect prices paid by retail pharmacies. Implementing AMP regulation would allow for market manipulation by manufacturers. Cms should use 11 digit NDC versus 9 digit NDC

Submitter : **Date: 02/19/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-959-Attach-1.RTF

Submitter : **Mr. Jon Plummer** **Date: 02/19/2007**

Organization : **Blountstown Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

02/19/2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

Jon Mark Plummer

Submitter : **Dr. Debbie Lange** **Date: 02/19/2007**

Organization : **speaking as an individual**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-961-Attach-1.DOC

Submitter : Dr. Rae Anne Haffey **Date:** 02/19/2007

Organization : Howell and Heggie Drug Company

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : Mr. Gene Brown **Date:** 02/19/2007

Organization : Brown's Discount Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : **Dr. Kam Nola** **Date: 02/19/2007**

Organization : **Tennessee Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-964-Attach-1.DOC

Submitter : Mr. Denny Rutherford **Date:** 02/19/2007

Organization : Shelton's Discount Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Atttachment

Submitter : **Ashley Dick** **Date: 02/19/2007**

Organization : **Tennessee Pharmacy Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-966-Attach-1.DOC

Submitter : **Mr. Ron Bullock** **Date: 02/19/2007**

Organization : **Sav-Rite Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Dr. Matthew Cull **Date:** 02/19/2007

Organization : Dr. Matthew Cull

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment

CMS-2238-P-968-Attach-1.DOC

Submitter : **Dr. Shannon Lowe** **Date: 02/19/2007**

Organization : **Clen's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

Submitter : Mrs. Emily Stansberry **Date:** 02/19/2007

Organization : Clen's Pharmacy

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Dr. ROBERT MCNEESE **Date:** 02/19/2007

Organization : CORLEY'S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-2238-P-971-Attach-1.TXT

Submitter : Mrs. April Overholt **Date:** 02/19/2007

Organization : Mrs. April Overholt

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mr. William Rose **Date:** 02/19/2007

Organization : Thomas Drug Store & HME

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 19, 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. Thomas Drug Store is located in Wilson, 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,
William C. Rose, Thomas Drug Store

Submitter : **Mr. Robert Jones** **Date: 02/19/2007**

Organization : **Wil-Sav Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

2-19-07

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

Robert D. Jones
1660 Niles Ferry Road
Madisonville, TN 37354
423-442-9727

Submitter : **Marshall Davis** **Date: 02/19/2007**

Organization : **Davis Drugs**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The Davis Drugs 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 five pharmacies in the state of Kentucky. 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:

GENERAL

GENERAL

? 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.

Submitter : BEVERLY MEEKS **Date:** 02/19/2007

Organization : DAVIS DRUGS

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Davis Drugs 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.

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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 : Mr. Ernie Shuler **Date:** 02/19/2007

Organization : The Medicine Shoppe #638

Category : Pharmacist

Issue Areas/Comments

Background

Background

Pharmacists in South Carolina have not had an incease in price for filling Mediciid prescriptions in about 10 years. All drugs and utilities have increased. Our bottom line is shrinking to almost nothing now.

Collection of Information Requirements

Collection of Information Requirements

Pharmacists can't accept a decrease of 36% to fill medicaid prescriptions.

Submitter : PAT ELY **Date:** 02/19/2007

Organization : REIDLAND PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The REIDLAND PHARMACY 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 ONE pharmacies in the state of Kentucky. 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.

Submitter : **Miss. Stephanie Bean** **Date: 02/19/2007**

Organization : **Clen's Pharmacy**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Dr. Frank Butler **Date:** 02/19/2007

Organization : Dr. Frank Butler

Category : Pharmacist

Issue Areas/Comments

Background

Background

See attachment

Collection of Information Requirements

Collection of Information Requirements

See attachment

GENERAL

GENERAL

See attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

See attachment

Response to Comments

Response to Comments

See attachment

CMS-2238-P-980-Attach-1.DOC

Submitter : DENTON WOOD **Date:** 02/19/2007

Organization : Smithland Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Smithland Drugs 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 -1- pharmacy in the state of Kentucky. We are a major 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 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.

Submitter : Ms. Jill June **Date:** 02/19/2007

Organization : Planned Parenthood of Greater Iowa

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Comments attached

CMS-2238-P-982-Attach-1.WPD

Submitter : Mr. Willie C. Rose **Date:** 02/19/2007

Organization : Thomas Drug Store

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"see Attachment"

CMS-2238-P-983-Attach-1.TXT

Submitter : **Mr. Steven Davisson** **Date: 02/19/2007**

Organization : **DanMar Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 19, 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 Salem, IN_____. 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 (INDIANA PHARMACY ASSOCIATION) have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

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

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

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, (INDIANA PHARMACY ASSOCIATION) proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on claw back from manufacturer reporting error.

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

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

In conclusion, I support the more extensive comments that are being filed by (INDIANA PHARMACY ASSOCIATION) regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Frank D. Habermel III RPh.
Steven J. Davisson RPh.

cc. Members of Congress (Baron Hill)

Submitter : JENNIFER HARRELL **Date:** 02/19/2007

Organization : CORLEY'S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-985-Attach-1.TXT

Submitter : Mrs. Sara Bone **Date:** 02/19/2007

Organization : Campbell University

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-986-Attach-1.DOC

Submitter : **Date: 02/19/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attached letter.

CMS-2238-P-987-Attach-1.DOC

Submitter : Mr. Charles West, BS, RPh **Date:** 02/19/2007

Organization : FSH Lacrescent Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Mail order pharmacies and PBM's receive "price concessions" from drug manufacturers which are not available to regular retail pharmacies like ours. Including the mail order and PBM pharmacies in the same class with retail pharmacies will artifically lower AMP prices thus causing the prices we obtain from our drug wholesalers to be lower the the acquisition cost paid by us for our medications. Our profit on Medicaid Part D prescriptions is already lower than most of the other pharmacy insurance programs pay us. If we are to loose money by not being fairly reimbursed, we will have not choice but to drop the Medicare Part D prescription thus cutting off a large number of people on this program residing in our community. This will cause a hardship as the closest chain pharmcy is about 10 mile away in Wisconsin.

CMS-2238-P-988-Attach-1.DOC

Submitter : Mr. Albert Dessertine **Date:** 02/19/2007

Organization : Envision Consulting Group, a Unit of IMS

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-989-Attach-1.DOC

Submitter : **Date: 02/19/2007**

Organization :

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

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

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained.

As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities.

Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

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

Submitter : **Mike Morgan** **Date: 02/19/2007**

Organization : **Morgan's Medicine**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Hello, my name is Mike Morgan, an independent pharmacy owner, in Burkesville, KY. I opened January 19th, 2006 with much anxiety but great anticipation of owning and operating my own pharmacy. I got in just as Medicare Part D was implemented which, from all accounts of pre-existing pharmacies, became the most trying year for the independent pharmacy.

PBM's have already whittled away at the independent pharmacy with take it or leave it contracts with no room for negotiation. Now, with the proposals on the table stemming from the Deficit Reduction Act of 2006, the future of Morgan's Medicine looks fairly bleak. According to the Government Accounting Office analysis, estimated AMP-based FULs were on average 36% lower than average retail pharmacy acquisition costs. So for every 100 dollars of medicaid claims billed, I will receive 64 dollars in reimbursement, not even factoring in the costs involved to dispense the prescriptions.

In short, if these proposals pass and are implemented, Morgan's Medicine would have to drop Kentucky Medicaid as a third party contract, and with Medicaid making up better than 20% of my current business and historically being one of the better third party reimbursers, would drop my prescription volume below the break even mark and force me to close the doors of Morgan's Medicine for good.

I see this scenario playing out across the state in many independents just like my own. Please reconsider the AMP proposal that is currently on the table and make it acceptable for the independent pharmacy considering the costs involved of dispensing a prescription. The small town independent plays a vital role in delivering health care and prescription advice to patients all across the state, and without our participation and our access by medicaid recipients, healthcare costs are bound to go up with increased hospitalizations due to the inability to recieve needed medications.

I am confident that this proposal will be revised and encourage all policy makers to reconsider the current proposal.

Thank you in advance for your consideration,

Mike Morgan
Morgan's Medicine

Submitter : **Mr. Karl Clearwaters** **Date: 02/19/2007**

Organization : **Herbst Pharmacies**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 19, 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

Herbst Pharmacy is located in Kokomo, In. We are a major provider of pharmacy services in the community and your consideration of these comments is essential. The proposed AMP regulations are problematic for continued participation in any future CMS programs.

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 our national pharmacy association, NCPA, regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Karl B. Clearwaters, R.Ph.

Submitter : Ms. Betty Cockrum **Date:** 02/19/2007

Organization : Planned Parenthood of Indiana

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-993-Attach-1.PDF

Submitter : Mr. BRIAN GERTH **Date:** 02/19/2007

Organization : IHS PHARMACY AND WELLNESS CENTER

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.

Collection of Information Requirements

Collection of Information Requirements

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: 02/19/2007**

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached.

CMS-2238-P-995-Attach-1.DOC

Submitter : **Date: 02/19/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-996-Attach-1.DOC

Submitter : Mr. Larry Webber **Date:** 02/19/2007

Organization : Mr. Larry Webber

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I strongly oppose implementation of this rule. The GAO has found that "Average Manufacturers Price-based Federal Upper Limits are, on average, 36% lower than average retail pharmacy acquisition costs." It is my contention that AMP is not appropriate as a baseline for reimbursement and must be defined to reflect pharmacy acquisition cost.

The formula for AMP-based FULs in the proposed rule will not cover our acquisition costs for multiple-source generic medications.

AMP must be defined to reflect the actual cost paid by our and other retail pharmacies.

If the proposed rule is implemented, it will be very difficult for our two community pharmacies, as well as thousands of others I'm sure, to continue to serve Medicaid recipients. This would create tremendous accessibility problems for those patients who are not able to travel any distances to receive pharmacy services.

I strongly urge that this proposed rule not be implemented at this time and that AMP be ehanged to reflect actual costs.

Submitter : Ms. Julie McNeal **Date:** 02/19/2007

Organization : Clen's Pharmacy II

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-998-Attach-1.DOC

Submitter : Mr. Michael Rohrer, R.Ph. **Date:** 02/19/2007

Organization : Mr. Michael Rohrer, R.Ph.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

In regards to CMS-2238-P please note that I own/operate two rural pharmacies in central Illinois. Implementation of the proposed reimbursement guidelines will cause the pharmacies to close, leaving hundreds of older and disabled members of our respective communities without local access to prescription medications. Please investigate alternate means to balance the budget rather than further reducing reimbursement to pharmacies.

Submitter : **Mr. Bill Brewster** **Date: 02/19/2007**

Organization : **Bradford Drug Store**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I own an independent Pharmacy in a rural area of Georgia and have served this area for 18 years. I am concerned that proposed cuts in Medicaid will adversely affect my business and my ability to remain as a provider for Medicaid recipients in my area. The current proposed basis for determining my cost for generic drugs, average manufacturer's price, would result in a reimbursement far below my acquisition cost and therefore a negative profit on each generic prescription I fill. I ask that this method of evaluating my generic drug cost be redefined in a manner that more closely reflects my true cost of goods. My wholesaler is greatly concerned about the future of retail pharmacy in general, independent and chain pharmacies, if this AMP valuation is used. They know my true cost.

Thank You,

Bill Brewster

Submitter : Mr. Travis Fleming **Date:** 02/19/2007

Organization : University of Tennessee College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1001-Attach-1.DOC

Submitter : **Mr. Thomas Smith** **Date: 02/19/2007**

Organization : **Geritom Medical Inc**

Categbry : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

February 19, 2007

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

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

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

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

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

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

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent and would result in FULs that are lower than a retail pharmacy s acquisition cost.

3. Removal of Medicaid Data

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

4. Manufacturer Data Reporting for Price Determination Address Market Lag

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

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

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

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

Sincerely,

Thomas D Smith

cc. Members of Congress
Senator Klobachar
Senator Coleman
Rep. Ramstead
Rep. Bachman

Submitter : **Ms. Eric Hamik** **Date: 02/19/2007**

Organization : **Registered Pharmacist**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I have worked in retail pharmacy for over 15 years. My patient include people from all areas of our communtity. I work in a town of 29,000 people.

GENERAL

GENERAL

I feel that this would be detrimentle to pharmacy. The only pharmacies that could operate with this kind of reimbursements would be the Wal-Marts of the country because they could make up for the loses in other areas.

Pharmacy has always made their fees from a margin of cost of goods not a professional fee. This fee has been built into the cost of medication when purchased. This has allowed us to be very accessible to the patients and has worked great. John Doe can call a pharmacy and get unheard of medical advice without ever paying a fee. As a matter of fact the majority of the patients we talk to have not been able to access their doctors or other health care provider and we were their only hope.

If you implement the AMP structure it will take away our only area to collect reimbursement for all of our services. Thc existing dispensing fees are set to coincide with our purchasing margins NOT TO BE OUR SOLE SOURCE OF INCOME!!!!

I feel that if you go ahead with the current AMP plan without a substantial fee increase that we will see a crisis situation for people trying to get their medications filled. If you remember the medicare fiasco in January of 2006, that would be just the tip of the iceberg compared to this. And by the way, Who was the ones there taking care of all the problems with that??? You guess it the community pharmacists :)

Thank you for listening,
Eric Hamik R.P.

Submitter : Dr. Robin M. Henry **Date:** 02/19/2007

Organization : Walgreens Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mira Signer **Date:** 02/19/2007

Organization : Planned Parenthood Advocates of Virginia

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-1005-Attach-1.DOC

Submitter : Mrs. Anna Long

Date: 02/19/2007

Organization : UT College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : **Mr. Christopher Decker** **Date: 02/19/2007**

Organization : **Pharmacy Society of Wisconsin**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

comments re CMS 2238-P

GENERAL

GENERAL

comment attached

CMS-2238-P-1007-Attach-1.PDF

Submitter : Mrs. Connie Woodburn **Date:** 02/19/2007

Organization : Cardinal Health

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-2238-P-1008-Attach-1.DOC

Submitter : **Ms. Julie Johnson** **Date: 02/19/2007**

Organization : **Minnesota Pharmacists Association**

Category : **Health Care Provider/Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1009-Attach-1.DOC

Submitter : Mr. J Leon Claywell **Date:** 02/19/2007

Organization : Kentucky Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : **Robert Salmon** **Date: 02/19/2007**

Organization : **Southern Discount Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1011-Attach-1.DOC

Submitter : **Dr. Katharine Hall** **Date: 02/19/2007**

Organization : **Regional Medical Center at Memphis**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Regional Medical Center at Memphis (The MED) is a 335 bed hospital located in Memphis, TN, 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. Our electronic billing system is not configured to substitute NDC numbers as identifiers for clinic administered drugs. The manual coding of NDC numbers would come at the expense of staff resources and would disrupt administrative operations. Assuming CMS' estimate of 15 seconds per claim is accurate, when you multiply this by 192,000 doses per year, you are adding 800 hours per year for this administrative activity. But... in my opinion, CMS dramatically underestimates the time required to manually code NDC numbers and the time required would be much greater than this.

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. If our hospital were to lose all 340B savings on clinic administered outpatient drugs it would affect us by $135,000 per year. If clinic administered outpatient drugs include Emergency Department and Ambulatory Surgery medications, our drug expense would increase by $420,000 per year.

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. To give you some idea of the amount, for the top 10 drugs dispensed by our retail pharmacy, the annual drug expense would increase by $395,000 if we were unable to use 340B pricing. In regard to nominal contracts, with Nexium? IV alone, we may increase expenditures by $20,000 per year.

The 340B program has helped safety net hospitals. Even with these savings available, our financial struggles are profound. The proposed regulations would be harmful to the MED.

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.

Submitter : **Ms. David Ridout** **Date: 02/19/2007**

Organization : **SaintMary's Family Pharmacy-Wege Center**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I manage an outpatient pharmacy for Saint Mary's Healthcare which services many specialties as well as indigent programs for the hospital and community, as well as services as a neighborhood pharmacy. We are a major provider of prescriptions for the downtown Grand Rapids MI area which include homeless, HIV and high psychiatric utilizers. We are very concerned about the proposed AMP calculation for the prescription benefit. 95% our our business in third party and of that 95%, 50% is in Medicare and Medicaid programs.

Collection of Information Requirements

Collection of Information Requirements

Having managed hospital, retail, and closed door pharmacies which include staff model HMO and hospice, I know there is considerable differences in manufacturer pricing. As a matter of fact, the differences are huge. When you factor in mail-order with their rebates from manufacturers based on market share contracts, there is no way we will be able to continue to serve our community if CMS utilizes their cost schedules in it's proposed AMP model. You will put every small pharmacy out of business. Please reconsider what you have proposed to do and ask those organizations which represent the authorities on drug pricing what model is best. You should not be allowed to make these decisions in a vacuum.

GENERAL

GENERAL

My comments are covered in the "Provisions of the Proposed Regulations.

Submitter : **Date: 02/19/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

As a practicing pharmacist in a retail independent pharmacy this new potential ruling CMS-2238-P is going to put me and the rest of my employees out of business. How can you expect a small business to dispense these medications at a loss and to continue to stay in business. Maybe the large chains can make up the difference in other store items or combined stores can help out losing stores, but one independent pharmacy can only help out itself and the patients we service. Please reject this proposal and come up with a fair proposal that we all can live with.
Thank you for this opportunity to speak.

Submitter : Dr. Ray Marcrom **Date:** 02/19/2007

Organization : Marcrom's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1015-Attach-1.DOC

Submitter : Nicky Otts **Date:** 02/19/2007

Organization : ReCept Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1016-Attach-1.DOC

Submitter : Mr. RICKY GUIDRY, RPH **Date:** 02/19/2007

Organization :. LOUISIANA INDEPENDENT PHARMACIES ASSOCIATION

Category : Pharmacist

Issue Areas/Comments

Background

Background

I own and operate a small independent pharmacy in a rural area in Louisiana and an very concerned about my existance with the AMP definition.

Collection of Information Requirements

Collection of Information Requirements

If the proposed regulations stand as they are presented, my pharmacy will probably go out of business.

GENERAL

GENERAL

If I am forced to be reimbursed at below the cost of a drug on one side of the equation, it would only be fair that I receive an adequate dispensing fee which would include a reasonable profit. I know that pharmacy is a complicated business and does not follow any other business known to man. In my store 90% of revenue is from prescription drugs and 10% is from gifts or over-the-counter medications. Of the 90% of revenue from prescription drugs, 85% is reimbursed by 3rd parties encluding Medicare Part D and Medicaid. Currently, we have no negotiating rights with any 3rd party payor. The contracts that we receive are take it or leave it contracts! This is why we are asking Congress to give us the power to come together as one to negotiate these reimbursement contracts. My biggest concern is when 50% of rural pharmacies are forced to close because of the inability to make reasonaly profit, Medicare and Medicaid people, usually one fixed incomes will be force to travel 30 to 60 miles round trip to get their prescriptions filled. With the cost of gasoline at about $2.15 a gallon, this will be a hardship and the poorist of the poor in this country. If the federal government can live with this, one could ask the question if they have a heart or a soul.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I find it very unfair to target cuts on the backs of pharmacies when drug manufacturers and pharmacy benefit managers(PBM's)have not been mentioned on being cut like we will if the currect rule stays the way it is/

Regulatory Impact Analysis

Regulatory Impact Analysis

It seems that everyone involved in this law and regulation are treating life saving chemical(medications) like it is some kind of commodity! This is not the case. These prescription drugs are not like corn or cotten. My point being that everyone who requires prescription drugs should pay the same price regardless is they buy it form a local pharmacy or a mail order pharmacy. We need to even the playing field when it comes to the cost of a drug. Quantity discounts in the different classes of pharmacy trade should not exist.

Response to Comments

Response to Comments

It seems to me that any regulatory agency dealing with health care in this country should look at the bottom purpose which is to deliver medications to the people who need them and to make sure that they understand side effects, interactions, missing doses and allergic reactions. This is the job that pharmacist do daily.

Submitter : Mrs. Christina Riddle **Date:** 02/19/2007

Organization : Marcrom's Pharmacy

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1018-Attach-1.DOC

Submitter : Mr. Michael Keogh **Date:** 02/19/2007

Organization : Independent Pharmaceutical Consultant

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1019-Attach-1.DOC

Submitter : Dr. Tom Marcrom **Date:** 02/19/2007

Organization : Marcrom's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1020-Attach-1.DOC

Submitter : **Mrs. Sheila Jones** **Date: 02/19/2007**

Organization : **Marcrom's Pharmacy**

Category : **Other Technician**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1021-Attach-1.DOC

Submitter : Dr. Kim Roberts **Date:** 02/19/2007

Organization : Marcrom's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1022-Attach-1.DOC

Submitter : Dr. Richard Randolph **Date:** 02/19/2007

Organization : Marcrom's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1023-Attach-1.DOC

Submitter : Mrs. Susan Helms **Date:** 02/19/2007

Organization : Marcrom's Pharmacy

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1024-Attach-1.DOC

#1024

February 19, 2007

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

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

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

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I work, where the majority of our business comes from prescription drugs. What the "other sales" in the pharmacy are should

not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Susan Helms
4457 Murfreesboro Highway
Manchester, TN 37355

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Lincoln Davis

Submitter : **Mr. Jack Hutson** **Date: 02/19/2007**

Organization : **Rhode Island Pharmacists Association**

Category : **Association**

Issue Areas/Comments

Background

Background

The Rhode Island Pharmacists Association 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

RIPA 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 RIPA 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.

CMS-2238-P-1025-Attach-1.DOC

#1025

Rhode Island Pharmacists Association

1643 Warwick Avenue, PMB 113, Warwick, RI 02889
737-2600 Fax: 737-0959

March 3, 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 Rhode Island Pharmacists Association 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

RIPA 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 RIPA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

§447.504 Determination of AMP

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

Defining Retail Pharmacy Class of Trade

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

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

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

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

fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

RIPA 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. RIPA 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

RIPA 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 RIPA asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers, and third party payors, and, thus, they are not available to the "general public." Since PBM and mail order pharmacies (i) now often are vertically integrated with manufacturers and others in the supply chain, (ii) have contractual arrangements in many states that are not transparent in the healthcare system, and (iii) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade, they are clearly distinguishable from the community retail pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to reconsider the inclusion of mail order pharmacy rebates, chargebacks and other price concessions.

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health

plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the 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.

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

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

Record Keeping

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

Additional Comments

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

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

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

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

Sincerely,

Jack Hutson
Executive Director

cc. Members of Congress in Rhode Island

Submitter : Dr. Melissa Stanley **Date:** 02/19/2007

Organization : Marcrom's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1026-Attach-1.DOC

#1026

February 19, 2007

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

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

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

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I work, where the majority of our business comes from prescription drugs. What the "other sales" in the pharmacy are should

not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Melissa Stanley
232 Dorey Ave.
McMinnville, TN 37110

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Lincoln Davis

CMS-2238-P-1027

Submitter : Dr. Christy Saunders **Date:** 02/19/2007

Organization : Thomas Drug Store

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1027-Attach-1.TXT

#1027

February 19, 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. Thomas Drug Store is located in Wilson, 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,
Christy P. Saunders, Thomas Drug Store

CMS-2238-P-1028

Submitter : Mrs. Karen Rose **Date:** 02/19/2007

Organization : Thomas Drug Store & HME

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1028-Attach-1.TXT

#1028

February 19, 2007
Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850
Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20

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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,
Karen Rose, RN, Thomas Drug Store & HME

Submitter : Mr. Patricio Gonzales **Date:** 02/19/2007

Organization : Planned Parenthood Assoc.Hidalgo Co. Tx Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

Background

Background

Planned Parenthood Association of Hidalgo County is a 501 c (3) health care provider for the 43 years. We are situated on the Texas Mexico border and serve two of the most poorest counties in the country Hidalgo and Starr Counties. Our poverty rates range from 41% to over 50% in Hidalgo and Starr Counties respectively as compared the national average of 13.3%. The total population between both counties is approximately 720,000 residents. We serve approximately 17,000 poor uninsured women and men annually in all of our 10 medical centers. The average income for these individuals is less than $14,000. They depend on the preventive care and birth control we provide them so that they can work and provide for their families. Our population is so dependent on the care and discounted pricing offered throughthe 340B program for the past 43 years. We are their only safety net provider, medical home base and source of referrals for primary care and medications.

Collection of Information Requirements

Collection of Information Requirements

The proposed rules issued at the end of December 2006 through the Deficit Reduction Act(DRA) does not extend the best price exception to all of our centers. Our clinics and clients depend on this discounted pricing for their birth control and other medications. These proposed changes will dramatically impair our sites to offer preventive health care. Without these discounted prices our centers would not be able to continue operations as a sfety net provider for poor and unisured individuals. My agency requests that these changes not be implemented without a correction to the DRA that will allow medical centers that provide preventive care to poor women and men. This techinical change to the DRA will not cost the governemnt any additonal charges or funding.

Submitter : Ms. Jonna Gardner **Date:** 02/19/2007

Organization : Thomas Drug Store & HME

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1030-Attach-1.TXT

#1030

February 19, 2007
Centers for Medicare and Medicaid Services
Attention CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd
Baltimore, Maryland 21244-1850
Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20

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(i) 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,
Jonna Gardner,Thomas Drug Store & HME

CMS-2238-P-1031

Submitter : Mrs. Stacey Boone **Date:** 02/19/2007

Organization : Thomas Drug Store

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1031-Attach-1.TXT

#1031

February 19, 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. Thomas Drug Store is located in Wilson, 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

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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,
Stacy Boone,Thomas Drug Store & HME

CMS-2238-P-1032

Submitter : Mr. R. David Yost **Date:** 02/19/2007

Organization : AmerisourceBergen Corporation

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1032-Attach-1.DOC

the involved parties. Furthermore, administrative fees – a term typically used to describe fees manufacturers pay to GPOs and PBMs to support the contracting functions those entities perform on behalf of numerous buyers or health plans – meet the definition of a *bona fide* service fee under a variety of circumstances consistent with CMS' preamble guidance published with the 2007 Physician Fee Schedule Rule. Therefore, we recommend that CMS clarify, either in § 447.504(i)(1) itself or by adding a new paragraph to the subsection, that all fees that manufacturers pay to customers or third parties meeting the definition of a *bona fide* service fee are to be excluded from the calculation of AMP.

Customary Prompt Pay Discounts

AmerisourceBergen applauds CMS' decision to include language in the Proposed Rule expressly instructing manufacturers to exclude Customary Prompt Pay Discounts ("CPPDs") given to wholesalers when determining AMP. We also support the definition CMS provided for the term "customary prompt pay discount" in an effort to clarify the types of price concessions that should not be included in the AMP calculation. We are particularly pleased that the agency did not incorporate any specific payment amounts or time terms in the definition. Although we anticipate that some manufacturers may ask CMS to further define the various aspects of CPPDs, we encourage CMS to maintain the proposed definition in the Final Rule because this approach allows manufacturers and wholesalers the necessary flexibility to negotiate payment terms, including CPPDs, based on their particular situations and the commercial conditions at the time of the particular transaction. We believe that this flexibility also will promote competition in the healthcare distribution business, which ultimately will lower distribution costs.

Also, in order to avoid potential confusion, AmerisourceBergen requests that CMS clarify that its requirement that cash discounts be deducted from the calculation of AMP and Best Price ***does not*** include CPPDs.

Retail Pharmacy Class of Trade

AmerisourceBergen agrees with CMS that in order to qualify as a member of the retail pharmacy class of trade, an entity must provide public access. For that reason, we disagree with including certain entities listed in 42 CFR § 447.504(e) as part of the retail pharmacy class of trade. Specifically, mail-order pharmacies, PBMs, and hospital pharmacies should be excluded from the definition of retail class of trade. In addition to these entities, AmerisourceBergen also believes that CMS should clarify that sales of drugs to physicians for administration in their offices should not be included in the retail pharmacy class of trade for the purpose of calculating AMP.

We object to the inclusion of PBMs in the retail pharmacy class of trade because PBMs contract with retail pharmacies to offer pharmacy services at prearranged prices to enrollees in the health plans the PBMs represent. They negotiate insurance payment terms, which is significantly different from arranging for the purchases of drugs that pharmacies make from their manufacturer and wholesaler vendors. PBMs do not affect the net prices manufacturers are paid by wholesalers and retail pharmacies for drugs dispensed to the general public. Therefore, under the controlling statutory definition of AMP, the contract terms between manufacturers and PBMs, and any related rebate payments provided to PBMs, should not be factored into the determination of AMP.

AmerisourceBergen supports CMS' decision to exclude sales to Long-Term Care facilities ("LTC") and urges CMS to exclude sales to other entities that do not satisfy the threshold public access criterion from manufacturers' AMP calculation, including sales to mail-order pharmacies. The reason CMS gave for excluding sales to LTC pharmacies from the calculation of AMP was that those pharmacies are closed operations that serve only the residents of specific LTC facilities, not pharmacies that are open to the general public. The same is true for mail-order pharmacies, the vast majority of which are affiliated with PBMs or with health plans that administer pharmacy benefits internally. These mail-order pharmacies are not open to the general public and the services provided are more limited than those provided by community pharmacies. Access to any particular mail-order pharmacy is limited to individuals enrolled in a health plan with a mail-order option that is sponsored by the organization that operates the pharmacy or that contracts with the PBM that operates the pharmacy. In other words, mail-order pharmacies are closed operations in the same way that LTC pharmacies are closed operations.

PBM Rebates

AmerisourceBergen objects to CMS' proposal for deducting PBM rebates from the AMP calculation. CMS' proposal for deducting PBM rebates when AMP is calculated is contrary to the statutory definition of AMP at Social Security Act § 1927(k)(1) (as amended by the DRA) and to the definition of AMP in the Rebate Agreement. Both definitions say AMP is "the average price *paid to* the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade (emphasis added)." Rebates *paid by* the manufacturer to a PBM that does not buy or take possession of drugs simply do not qualify. They are not part of the price paid to the manufacturer by the pharmacies in the PBM's retail pharmacy network because those pharmacies do not share in the PBM rebates. CMS does not have the statutory authority to reinterpret the definition of AMP to focus on the net revenues realized by manufacturers instead of the net costs incurred by retail pharmacies for the drugs they dispense.

Additionally, although PBMs only collect rebates on single source drugs,[2] CMS' position on the handling of these rebates will have a negative impact on State Medicaid budgets. The OIG found that some manufacturers do not currently view transactions with PBMs as sales and, therefore, do not net PBM rebates out when they calculate AMP.[3] It also observed that other manufacturers only include a portion of their PBM rebates in AMP.[4] As a result, the Proposed Rule's treatment of PBM rebates will lead to lower AMPs and lower rebate payments on some single-source products. We do not have access to the data needed to estimate the total revenue reduction, but we are confident the losses will be significant since the CBO recently reported State Medicaid programs received rebates in 2003 on single source drugs that averaged 31.4% of AMP.[5] Further, the CBO observed that the percentage of State Medicaid revenues tied to rebates on single source drugs has been trending upward.

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[2] *Prescription Drug Pricing in the Private Sector* at p 12; *Pharmacy Benefit Managers* at 50-55.

[3] *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of* 2005, OIG (A-06-06-00063) (May 30, 2006).

[4] *Id.*

[5] *Payment for Prescription Drugs under Medicaid* at Table 2.

Dispensing Fee

AmerisourceBergen applauds CMS' decision to recommend that State Medicaid programs "reexamine and reevaluate the reasonableness of the dispensing fees paid as part of a pharmacy claim"[6] if they elect to adopt AMP-driven pharmacy reimbursement formulas. We urge CMS to consider the results of a recently completed national survey of dispensing costs when it reviews proposed State Plan Amendments revising Medicaid pharmacy reimbursement formulas. Grant Thornton LLP obtained cost data from nearly half the retail pharmacy outlets in the United States for the 6-month period from March through August 2006 and determined that the mean cost of dispensing per prescription was $10.50 and the mean cost of dispensing per pharmacy was $12.10.[7] For the 65 million Medicaid prescriptions included in the sample, the mean cost per prescription was $10.51 and the mean cost per pharmacy was $12.81. Given these cost data, it will no longer be acceptable for States to skimp on payments for dispensing services to Medicaid recipients once they take steps to trim the margins on ingredient costs that have been subsidizing Medicaid dispensing for years.

We also recommend including a few additional elements in the list of services detailed in proposed 42 CFR § 447.502 that must be considered when a dispensing fee representative of fully loaded costs is developed. We are hesitant to rely on the "[p]harmacy costs include, but are not limited to" language currently used to preface the list because of the inadequacy of dispensing fees paid by State Medicaid programs over the years. The revised definition also needs to include the time pharmacists spend entering billing information into their computer systems and communicating by telephone, fax and email with State Medicaid agencies and PBMs about coverage and billing questions. As with other third party drug programs, the Medicaid program creates an additional cost due to accounts receivables, which can have a substantial impact on a community pharmacy. More importantly, the Proposed Rule must include as an element of pharmacy costs the important health, safety and counseling services community pharmacists routinely provide – typically based on an individualized understanding of the customers' medical needs and personal preferences – to ensure that each physician's prescription leads to the best drug regimen for the patient.

Innovator Multiple Source, Multiple Source, and Single Source Drugs

The Proposed Rule also does not define "covered outpatient drug" but rather lets stand without elaboration the definition of covered outpatient drug in the Medicaid Drug Rebate Statute at Social Security Act § 1927(k)(2). That statutory definition reaches beyond drugs approved by the FDA under NDAs, BLAs, antibiotic approvals or ANDAs to over-the-counter (OTC) products that have been prescribed by a physician. To capture the full breadth of the Medicaid drug benefit, we recommend including a definition of covered outpatient drug in the Final Rule that addresses both OTC and prescription drug products. The statutory definition of covered outpatient drug also incorporates grandfathered products and drugs still undergoing the DESI review process. The Proposed Rule's definitions of single source, innovator multiple source and multiple source drugs do not, however, reach all of the products that came to market

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[6] Medicaid Drug Rebate Program Release for State Medicaid Directors No. 144 (December 2006).

[7] *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies,* prepared for The Coalition for Community Pharmacy Action by Grant Thornton, LLP (January 2007), available at http://www.rxaction.org/publications/COD_Study.cfm. The cost of dispensing per pharmacy treats every pharmacy equally, regardless of prescription volume. It is higher than the cost of dispensing per prescription because high-volume, lower-cost stores are weighted more heavily in this statistic.

before 1962 and remain commercially available today. To avoid any ambiguities, AmerisourceBergen suggests CMS revise the definitions of multiple source, innovator multiple source and single source drugs to address these gaps.

Lagged Methodology

AmerisourceBergen also is concerned that the Proposed Rule does not set forth a methodology for dealing with lagged unit data or lagged discounts when monthly or quarterly AMPs are calculated. This lack of guidance is problematic because the Proposed Rule requires manufacturers to consider sales and associated price concessions extended to State Children's Health Insurance Programs ("SCHIPs") and State Pharmaceutical Assistance Programs ("SPAPs") when they determine AMP. This requirement is virtually impossible to achieve because manufacturers have no way of knowing how many units of drug were dispensed to enrollees in these programs or what their program rebate liabilities will be until they receive quarterly rebate invoices from the States. Unfortunately, our experience shows that these invoices rarely arrive prior to the stipulated deadline for filing quarterly AMP reports under the Proposed Rule. Depending on the plan, Part D rebate demands and PBM rebate demands also may arrive too late to be properly included in quarterly calculations.

Therefore, we believe that the best approach to address the inevitable delays in the receipt of data critical to AMP calculations is to include instructions for processing lagged data into the Final Rule. We strongly recommend using a 12-month rolling percentage methodology similar to that required in the ASP rule.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time also can distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, AmerisourceBergen encourages CMS to build a well-defined smoothing methodology for handling all price concessions – not just lagged concessions – and for handling lagged unit data that must be considered when AMP is determined. We believe that the methodology would operate much like the 12-month rolling percentage methodology specified for quantifying lagged discounts under the ASP rule. However, for AMP purposes, we suggest instructing manufacturers to look to the four (4) full calendar quarters before the reporting period to calculate the rolling 12-month percentage. That percentage could then be used to determine all three monthly AMPs and the quarterly AMP.

If CMS is not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates because chargebacks often relate back to sales from previous quarters. Because of the complexities involved, we request that CMS provide examples showing how the methodology should be applied in both the monthly and the quarterly context. Those examples also should take into account the proper treatment of the various types of bundled sales.

AMPs and FULs Set at 11-Digit NDC Level

AmerisourceBergen strongly disagrees with the Proposed Rule's instruction to calculate and set Federal Upper Limit ("FUL") reimbursement at the 9-digit NDC level for purposes of calculating AMP. We are concerned with the utilization of the 9-digit AMPs because this methodology would exclude tying FULs to the package sizes most frequently purchased by pharmacies.

In order to address this concern, and to ensure that the most accurate FUL reimbursement and AMP are calculated for a given product, we urge CMS to modify the Rule to require manufacturers to calculate and report AMPs at the 11-digit NDC level. The utilization of 11-digit level NDCs would permit FULs to be established based on the most commonly purchased package sizes, and this approach would be consistent with past FUL calculation practices.

AMPs and Outlier Methodology

We applaud CMS's recognition of the need to eliminate outlier AMPs from the determination of FUL. Eliminating the sale of product that is extremely short-dated or otherwise distressed avoids setting an artificially low FUL based upon prices that do not reflect true market conditions (comparable to CMS' decision to disregard AMPs for NDCs that have been terminated). To ensure that reimbursement is adequate to permit retail pharmacies to buy from reputable suppliers with sufficient supply to meet retail pharmacy demands, we would prefer to see FULs calculated using the weighted average AMP of the therapeutically equivalent products available in the market. However, if CMS decides it will not take that approach, we propose that the outlier test should incorporate market-share as a fundamental criteria in defining outliers. To that end, we support requiring manufacturers to report, along with monthly AMPs, data at the 11-digit level (as discussed above) on the volume of product sold during the period. CMS could then classify monthly AMPs associated with low market share as outliers that do not represent available prices.

Specifically, we recommend examining AMPs on a cumulative market share basis starting with the lowest reported AMP, then the next highest and so on, rejecting AMPs until a cumulative market share of 50% is reached. This approach will allow CMS to focus directly on whether a low-priced NDC is only available on a "limited basis"[8] (rather than the indirect price-based test CMS proposed). Doing so should "ensure that a drug is nationally available at the FUL price"[9] because it will disregard AMPs that, despite low price, were only able to capture less than half the market. If product, from one or more sources, is not available to at least 50 percent of the market, its price is not indicative of true market conditions and, being available in only limited quantity, it's not available for sale nationally. For example, if manufacturers reported monthly AMPs for five NDCs of a given drug/strength/dosage form of a multiple-source product of $0.30, $1.50, $4.50, $5, and $5.50 with corresponding sales volumes of 100 units, 400 units, 6000 units, 3500 units, and 500 units, the first two would be classified as outliers as they represent less than a 5% market share. The FUL would be set based on the $4.50 price because the 6,000 units added to the previous 500 units (100 + 400) would cross the 50% market share threshold. In other words, $4.50 is the lowest price for a product that is available

[8] 71 FR at 77188 (Dec. 22, 2006); see also proposed rule §447.514(c).
[9] *Id.*

for sale nationally. This contrasts with an FUL of $3.75 (250% x $1.50) under the price-based outlier methodology described in the proposed Rule – an FUL that would not be representative of prices for half the market (and would likely result in a local pharmacy losing money on most Medicaid sales).

Definition of Wholesaler

AmerisourceBergen is concerned that the Proposed Rule defines "wholesaler" in an overly expansive fashion, including within the reach of the definition not only traditional full-service wholesalers and specialty distributors but also pharmacy chains, pharmacies, and PBMs See 42 C.F.R. § 447.504(f). We request that this definition be revised so that it is consistent with the provisions of the Food Drug and Cosmetic Act incorporating the Prescription Drug Marketing Act (PDMA)[10] and with the definitions of "wholesale distributor,"[11] "wholesale distribution,"[12] and "distribute"[13] in the FDA regulations that govern prescription drug marketing. Although we believe these definitions are quite broad, they adequately and appropriately limit wholesalers to entities engaged in selling, offering to sell, delivering, or offering to deliver drugs to persons other than a consumer or patient.

We do, however, agree that warehousing pharmacy chains and warehousing mass merchant and supermarket pharmacy operations should be treated as wholesalers for purposes of calculating AMP and Best Price. They function virtually identical to traditional wholesalers and specialty distributors: they buy drugs directly from manufacturers and/or other wholesalers; consolidate orders for products from a variety of sources; and distribute the drugs to pharmacies within their chain, which resell the drugs at retail to consumers who present a prescription. Also, warehousing chains, warehousing mass merchants and supermarkets are licensed as wholesalers under State laws implementing the requirements of the PDMA.

Although we agree that the above entities should be treated as wholesalers under the Rule, we object to identifying other entities including mail-order pharmacies operated by PBMs, as wholesalers. These entities are quite different from wholesalers because they have a limited product inventory, routinely sell drugs to consumers and patients and they rarely function as or are licensed as wholesalers under applicable State laws.

We are particularly troubled by the inclusion of PBMs in the definition of wholesaler. Although many PBMs operate mail-order pharmacies, they typically function merely as an ancillary to the PBM's primary business operation. As discussed above, we do not believe these types of entities should be classified as wholesalers.

As discussed above, we urge CMS to align that definition with the definitions of wholesale distributor, wholesale distribution, and distribute in the FDA regulations implementing the PDMA. We also suggest including a statement in the preamble to the Final Rule saying CMS has adopted those FDA definitions which are well-recognized throughout the industry.

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[10] P.L. 100-293.
[11] 21 CFR § 203.2(dd).
[12] 21 CFR § 203.2(cc).
[13] 21CFR § 203.2(h).

Postponing the Posting of AMPs

AmerisourceBergen urges CMS to consider delaying postings of AMPs because there are valid reasons for delay and in consideration that the delay likely will be for a reasonably short period of time. We believe a delay is appropriate in this instance because many critical issues related to ensuring the accurate calculation of AMP remain unresolved and are unlikely to be completely resolved and understood throughout the industry prior to the scheduled posting of AMPs. In the past, CMS wisely has delayed implementing programs because too many problems remained unresolved, and the agency took additional time to resolve those outstanding issues related to the program. We believe that approach may be useful in regard to the public posting of AMPs, and that the posting should be delayed until all the regulatory changes have been finalized and manufacturers have been given sufficient time to update their systems to satisfy the final reporting requirements.

Therefore, we urge CMS to delay website postings until the new AMP rule becomes effective, or at a minimum to preface any web-postings of AMP values with an introductory discussion explaining the current shortcomings of AMP as a measure of retail prices and pharmacy acquisition costs and highlighting the potential for changes in the calculation methodology underlying AMP over the next year.

Retail Survey Price

We had hoped CMS would address implementation issues related to DRA § 6001(e) in the Proposed Rule. We were looking forward to the opportunity to comment on how and from what sources data underlying RSP should be collected and how the data should be used to determine "a nationwide average of consumer purchase prices, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available)"[14] since the DRA defines RSP but provides little other substantive guidance on RSP-related issues. For example, because RSP is supposed to be representative of "consumer purchase prices" at retail, we wanted to talk about how CMS and its vendor would ensure only pharmacies within the retail class of trade are surveyed. We wanted to speak to how CMS would ensure valid results by structuring surveys to include an appropriate sample size and geographic distribution. We also wanted to discuss other steps that could be taken to ensure that RSP data is true to the statutory requirement to capture the out-the-door prices pharmacies charge consumers.

We note Medicaid Drug Rebate Program Release No. 144 for State Medicaid Directors dated December 15, 2006 – a week before the Proposed Rule was published in the *Federal Register* – advises States that CMS will begin disseminating a monthly national survey of retail prices beginning in January 2007. We take that promise to mean CMS is moving forward with plans to implement DRA § 6001(e). That said, we strongly urge CMS to engage stakeholders, as soon as possible and in a meaningful way, in the development of the procedures the RSP contractor will be tasked with using when it collects, aggregates, and disseminates RSP data. Including stakeholders in the regulatory processes relating to the implementation of DRA § 6001(e) likely will allow the development of RSP policies and procedures that anticipate issues associated with data availability and adequacy, reflect a more nuanced approach to data collection and analysis, and, in the end, result in the dissemination of RSP data that is – as the

[14] DRA § 6001(e) adding Social Security Act § 1927(f)(1)(A).

DRA mandates – representative of consumer purchase prices at retail for outpatient prescription drugs.

* * * * *

In closing AmerisourceBergen appreciates the opportunity to provide you its comments on this important Proposed Rule. We are available at your convenience to address any concerns related to these Comments, the proposed Rule, or the pharmaceutical supply chain.

Sincerely,

R. David Yost

R. David Yost

CMS-2238-P-1033

Submitter : Mr. Dennis Roberts **Date:** 02/19/2007

Organization : The Regional Medical Center at Memphis

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1033-Attach-1.TXT

#1033

2/19/07

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 Regional Medical Center at Memphis (The MED), 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 Med is a 335 bed hospital located in Memphis, TN, 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. In general, hospitals' electronic billing systems are not configured to substitute NDC numbers as identifiers for clinic administered drugs. The manual coding of NDC numbers comes at the expense of staff resources and disruption of administrative operations. CMS underestimates the time required to manually code these NDC numbers into the billing system.

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. If our hospital were to lose all 340B savings on clinic administered outpatient drugs it would affect us by $135,000 per year. If clinic administered outpatient drugs include Emergency Department and Ambulatory Surgery medications, our hospital would be affected by $420,000 per year.

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. For example, with Nexium® IV alone, we may increase expenditures by $20,000 per year.

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,
Dennis Roberts
Pharmacist
The Regional Medical Center at Memphis

{D0135904.DOC / 1}

Submitter : **Mr. jignesh patel** **Date: 02/19/2007**

Organization : **columbia pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a pharmacist and have been working in various community pharmacies for the past 12 years.

GENERAL

GENERAL

I believe that the idea of rembursing pharmacies based on AMP is not realistic as this doesnot reflect the actual cost to the pharmacies. This is going to be so very true for generic drugs. Also to go along with the cost of drugs there is no specifications on the reimbursement of dispensing fee which at the present is no were close to the actual cost of dispensing a prescription. The average gross profits for pharmacy after the Medicare Part D have gone down & if the AMP reimbursement is implemented I think that the community/independent pharmacies will really have a tough time being in business & the others will be paying their pharmacy overheads selling front end. I think controlling the cost of drugs could be much effective if the government controls the pricing of drugs from manufacturers, Since every year the cost of brand Drugs goes up by 15-30% on average. It would be interesting to see manufacturers cross examined for how they come up with pricing of brand drugs & how they justify the price increases then after, each year at the rate of 10-30%. I hope its not about how much influnce each sector has against the survival of an entire sector. I am a 37year old pharmacist, I started an independent pharmacy in NYC 6 years back & I think with all the changes that have been implemented in the name of cost cuts, have ultimately affected the quality of service that we render & for the time to come I think the law makers want us to run pharmacy business like a factory where the primary goal will be quantity rather then quality. I hope my comments are read & thought about. Thank you for the time.

Submitter : Mr. Krishnayya Bikkina **Date:** 02/19/2007

Organization : K&C Pharmacy D/B/A Nicks Drugs

Category : Pharmacist

Issue Areas/Comments

Background

Background

See Attachment

Collection of Information Requirements

Collection of Information Requirements

See Attachment

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1035-Attach-1.PDF

1035

K&C PHARMACY T/A NICK'S DRUGS

VIA ELECTRONIC SUBMISSION

February 19, 2007

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

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

As an owner of an independent pharmacy store in New Jersey serve a diverse Medicaid patient population for pharmacy care needs. I am very troubled by the CMS proposed regulation referenced above that seeks to define and establish an average manufacters' price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that my independent pharmacy can afford to continue provide Medicaid generic pharmacy prescription services to my Medicaid prescription patients without incurring unsustainable financial losses.

Below are my specific comments on and recommended changes to the proposed rule:

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

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 calculating the AMP.

"Retail pharmacy class of trade" definition should only 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.

K&C PHARMACY T/A NICK'S DRUGS

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

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

Treatment of Manufacturer coupons with regard to Best Price.

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

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

PBM price concessions reporting to CMS.

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.

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 rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

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-digit 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.

Impact on small pharmacies demonstrated by (General Accountability Office (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.

K&C PHARMACY T/A NICK'S DRUGS
800 Broad Street, Newark, NJ 07102 - 2776
Tel: 973 - 596 - 1800 Fax: 973 - 596 - 1849
e-mail: nicksdrugs@verizon.net

In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

- 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.*

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

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,

Krishnayya Bikkina

CMS-2238-P-1036

Submitter : James Dunaway **Date:** 02/19/2007

Organization : Dunaway's Imperial Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1036-Attach-1.DOC

#1036.

February 19, 2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

James E. Dunaway, R.Ph.

CMS-2238-P-1037

Submitter : ROBERT WHEATLEY **Date:** 02/19/2007

Organization : ONTARIO PHARMACY, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

THE ONTARIO PHARMACY CORPORATION IS WRITING TO PROVIDE OUR VIEWS ON CMS' DEFINITION OF AMP AS WELL AS IMPLEMENT THE NEW MEDICAID FEDERAL UPPER LIMIT PROGRAM FOR GENERIC DRUGS.

OUR CORPORATION OPERATES FIVE PHARMACIES IN 2 STATES, OREGON AND IDAHO. WE ARE A MAJOR PROVIDER OF PHARMACY SERVICES IN THE COMMUNITIES IN WHICH OUR STORES ARE LOCATED.

THE 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 BENIFICIARIES 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 SUPPORT THE MORE EXTENSIVE COMMENTS THAT ARE BEING FILED BY THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES REGARDING THIS PROPOSED REGULATION. WE APPRECIATE YOUR CONSIDERATION OF THESE COMMENTS AND ASK THAT YOU PLEASE CONTACT US WITH ANY QUESTIONS. THANK YOU.

SINCERELY,

ROBERT WHEATLEY, RPH
ONTARIO PHARMACY, INC.
925 SW 3 AV
ONTARIO, OREGON 97914
541-889-8087

Submitter : Mr. James Martin **Date:** 02/19/2007

Organization : Texas Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

CMS-2238-P-1039

Submitter : Mr. Wesley Wheeler **Date:** 02/19/2007

Organization : Valeant Pharmaceuticals International

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1039-Attach-1.PDF

1039

February 19, 2007

BY ELECTRONIC DELIVERY

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-2238-P (Medicaid Program; Prescription Drugs)

Dear Administrator Norwalk:

Valeant Pharmaceuticals International ("Valeant") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Proposed Rule regarding Medicaid price reporting (the "Proposed Rule").[1] Valeant is a global, science-based specialty pharmaceutical company that develops, manufactures and markets pharmaceutical products, primarily in the areas of neurology, infectious disease and dermatology.

Valeant is pleased that CMS has chosen to further clarify the rules surrounding the average manufacturer price ("AMP") and best price calculations, and we agree with many of CMS' proposals. We are disappointed, however, that CMS has not taken this opportunity to include in the Proposed Rule the statutory time limit on a State's ability to revise utilization amounts for which Medicaid rebates are claimed, and we are commenting to urge CMS to include such a provision in the Final Rule. We also are responding to CMS' request for comments regarding the feasibility of including rebates paid to Pharmaceutical Benefit Managers and other similar entities in the calculation of AMP. Valeant believes that such a requirement would present a significant operational burden and urges CMS to eliminate this requirement from the Final Rule. Last, Valeant requests that CMS provide additional clarity regarding the Customary Prompt Discount quarterly reporting requirement.

[1] 71 Fed. Reg. 77,173 (Dec. 22, 2006).

I. CMS Should Include in the Final Rule a Provision Limiting the Time Period In Which a State May Submit Utilization for a Rebate Payment.

The Medicaid rebate statute requires States to report to each manufacturer not later than 60 days after the end of each rebate period information on the covered outpatient drugs dispensed and paid during the period.[2] This is an explicit statutory deadline with no exceptions. In the 1995 Proposed Rule, which was never finalized, CMS took the position that this language does not relieve manufacturers from their obligation of paying rebates in situations in which the States fail to meet this deadline.[3] Under current CMS policy, therefore, there appears to be no limit on how long after a rebate period ends a State may submit revised utilization amounts and claim a rebate. CMS has never provided any rationale or statutory language as a basis for this interpretation of the Medicaid statute, and has never issued this policy through notice-and-comment rule-making such that it could be subject to stakeholder review and comment.

Valeant believes that this CMS policy is unsupportable given the explicit statutory language and lack of formal rule-making, and also bad policy, as it subjects manufacturers to potentially indefinite rebate liability for late claims submitted by State agencies. Valeant asks that CMS include in the Final Rule a provision that would limit manufacturer liability for Medicaid rebate payments to claims submitted by State agencies within 60 days of the end of the rebate period, in order to comply with the language of the Medicaid statute. In the alternative, Valeant urges CMS to at least implement the one year limitations period included in the 1995 Proposed Rule. Such a provision is equitable, would meet the needs of both the States and manufacturers, and comports with general business principles.

CMS itself recognized the need for a time limit on State submissions of rebate claims in the 1995 Medicaid price reporting proposed rule (the "1995 Proposed Rule").[4] The 1995 Proposed Rule included a deadline of one year from the end of a rebate period for States to bill manufacturers.[5] Although the 1995

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[2] Social Security Act ("SSA") § 1927(b)(2)(A).

[3] Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers; Proposed Rule, 60 Fed. Reg. 48,422, 48,460 (Sept. 19, 1995).

[4] *Id.*

[5] The 1995 Proposed Rule included the following proposed section 447.530(c)(3):

> (3) If a State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ends—
> (i) a manufacturer is not required to pay a rebate on those drugs; and
> (ii) a State may be considered out of compliance with section 1927 of the Act for failure to collect rebates.

Proposed Rule was never finalized, the need for this provision remains. As CMS explained at the time, imposing a deadline of one year from the time a State pays a claim is equitable "because it parallels the . . . timeframe for providers' and States' responsibilities"[6] under Medicaid, which permit pharmacies up to one year to submit claims to the States for drugs dispensed to Medicaid beneficiaries and up to one year for States to pay such claims.[7]

A one-year time limitation is fair to the States as well as the manufacturers. States would not have to forfeit rebates on Medicaid utilization where circumstances are such that they are unable to submit the utilization information to meet the 60-day deadline set forth in the Medicaid drug rebate statute, and Manufacturers would not have indefinite Medicaid rebate liability when a State fails to report its utilization data within the 60-day timeframe.

This limitation is also consistent with general business principles. As CMS explained in the preamble to the 1995 Proposed Rule, a rebate submission time period that is longer than one year translates into the manufacturer being responsible for rebates more than three years after the drug is dispensed. Specifically, providers are given one year to submit a claim, the State is given one year to pay the claim, and under this proposed provision, the State would have one year to claim the rebate. As CMS noted in the 1995 Proposed Rule, the Internal Revenue Service generally requires that records be maintained for only three years, subject to exceptions, and thus this proposed timeframe is consistent with general business principles.[8] Significantly, manufacturers may not be able to validate rebate claims for more than three years after a drug is dispensed. Although CMS finalized regulations in 2004 requiring manufacturers to maintain records relating to their rebate calculation for ten years,[9] manufacturers remain liable for late utilization claims for an indefinite period (including prior to the finalization of this 10-year record retention requirement), and it is conceivable that disputes involving utilization claims for which manufacturers have not maintained records may arise. As CMS stated in the preamble to the 1995 Proposed Rule, "[a]dding more disputes to the resolution process for data where no records may exist is not . . . a cost effective or efficient manner of operating the drug rebate program."[10]

See 1995 Proposed Rule, 60 Fed. Reg. at 48,486.

[6] 1995 Proposed Rule, 60 Fed. Reg. at 48,460.

[7] 42 C.F.R. § 447.45(d).

[8] 60 Fed. Reg. at 48,460.

[9] 69 Fed. Reg. 68,815 (Nov. 26, 2004).

[10] 60 Fed. Reg. at 48,460.

Finally, we note that a one year timeframe for the submission of Medicaid utilization data will encourage States to pursue potential lost revenue in a timely manner in the event it discovers that its initial utilization data submission is understated, thus ultimately benefiting the States and the federal government. Moreover, this one year time period is a sufficient amount of time to permit the States to properly determine their utilization data, and it serves the significant business interest of manufacturers by enabling them to close their financial books within a reasonable timeframe.

II. Inclusion of PBM and Similar Rebates In the Calculation of AMP Presents a Significant Burden to Manufacturers.

The Proposed Rule requests comments on the operational feasibility of incorporating rebates from Pharmacy Benefit Managers, as well as similar entities such as Medicare Part D Plans and State Pharmacy Assistance Programs, in the calculation of AMP.[11] Valeant believes that this obligation would present very real operational difficulties. Sales and chargeback data typically are stored in the same, or at least linked, information technology systems, and can be more readily imported into a manufacturer's government pricing calculations. Rebate data, by contrast, typically are housed in a separate system, such as an accounts payable system or stand-alone electronic spreadsheets, and therefore may not be systemically tied or linked to sales data. As a result, manual intervention usually is necessary to include rebate data in government pricing calculations. Such manual steps not only pose significant operational burden, but also increase the likelihood of error. For all of these reasons, Valeant urges CMS to eliminate this requirement from the AMP calculation.

III. CMS Should Clarify the Customary Prompt Payment Discount Data To Be Reported on a Quarterly Basis.

The Proposed Rule directs that manufacturers report each quarter the Customary Prompt Payment ("CPP") discounts "paid to all purchasers in the rebate period."[12] CPP discounts typically are not affirmatively "paid" by a manufacturer, as may be the case with discounts that take the form of rebates. Rather, entities that have been offered a CPP discount typically realize that discount by reducing the payment of the invoice at issue by the amount of CPP discount earned. For this reason, Valeant requests that CMS clarify that the CPP discounts to be reported as those taken or realized by purchasers, rather than those paid by the manufacturer.

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[11] 71 Fed. Reg. at 77,179 .

[12] *Id.* at 77,198 (proposed 42 C.F.R § 447.510(a)(3)).

The Proposed Rule also does not specify whether the CPP discounts to be reported are those offered by the manufacturer on sales that are invoiced in the reporting quarter or those taken or realized by the purchaser on invoices paid in the quarter. There is a time lag between the date that an invoice is issued and the date by which it must be paid in order for the CPP discount to be available, and therefore using one or the other data set will affect the CPP data reported for the quarter. As AMP is designed to measure the sales price in a quarter, inclusive of arrangements that subsequently adjust the price realized, Valeant believes the appropriate data to report are the CPP discounts offered on sales in the quarter, and requests that CMS adopt this approach in the Final Rule.

Finally, the Proposed Rule does not provide any guidance on the proper format for reporting customary prompt pay discount data. There are a number of different ways that such data may be submitted. Therefore, in addition to clarifying the issues discussed above, Valeant requests that CMS provide guidance regarding the format manufacturers should use to report customary prompt pay discount data to the agency.

Valeant appreciates the opportunity to comment on the Proposed Rule, and we look forward to working with CMS on these critical issues. Please do not hesitate to contact me if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Wesley P. Wheeler
President – North American Region
Valeant Pharmaceuticals International

Submitter : **Mr. Don Wall** **Date: 02/19/2007**

Organization : **Professional Pharmacy of Greer, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear sirs,

As owmer or co-owner of 5 independent pharmacies, I am very concerned about the Rx reimbursement being changed to AMP. It is calculated that this will result in reimbursment below cost for independent pharmacies. If this is the case, we will have no option other than to refuse to fill any Rx on which we lose money. While being concerned about the state of our deficit budget, I fell it is the fault of grandstanding politicians and resent being asked to lose money while performing my job.

Submitter : **Miss. Brooke Crawford** **Date: 02/19/2007**

Organization : **East Tenn. State University College of Pharmacy**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a student pharmacist at the East Tennessee State University College of Pharmacy and am interested in community retail pharmacy practice. I have worked at Ingles Pharmacy, a community grocery retail pharmacy located at 1200 W. Jackson Blvd., Jonesborough, TN, and I am familiar with the challenges in retail pharmacy practice.

Collection of Information Requirements

Collection of Information Requirements

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. What the other sales in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

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

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

I believe that CMS should use the 11-digit NDC AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date.

GENERAL

GENERAL

See Attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

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

Sincerely,

Brooke Crawford
1840 Presswood Rd. #17
Johnson City, TN 37604

Submitter : **Date: 02/19/2007**

Organization :

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1042-Attach-1.DOC

#1042

CEDARS-SINAI MEDICAL CENTER.
Department of Pharmacy Services
8700 Beverly Blvd., Room A-845
Los Angeles, CA 90048
Phone: (310) 423-5611
Fax: (310) 423-0412

February 19, 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 Cedars-Sinai Medical Center, 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. Cedars-Sinai is a 950 bed hospital located in Los Angeles, California, 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.

We recognize the need for a consistent approach to Medicaid rebate policies and for establishing a standard formula for pricing of pharmaceuticals, however, we are concerned that the regulations, as written, have unintended consequences that would inadvertently shift costs to hospitals. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create a significant burden for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Currently, our billing system is not setup to include the NDC numbers in the Chargemaster and be added onto the UB92. To obtain this capacity, our hospital will have to make significant changes to our billing system, at considerable expense in terms of staff resources and disruption of operations. Until the billing system can be modified, a manual process would have to be put in place if the NDC number is required. If the NDC number is only required for billing the Medicaid patients, it means that Finance would have to inform the pharmacy billing staff which claim and which drugs need to have the NDC numbers added. The pharmacy staff will then have to manually look up the NDC information and provided that to Finance to be added onto the UB92. This manual process can take up to 10

to 15 min of staff time per drug per Medicaid claim which is significantly greater than the 15 seconds estimated by CMS.

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. If this were to occur, our hospital would lose these savings. The impact that it would have on our hospital would be approximately $2.2 million based the cost savings achieved on 340b drugs during this fiscal year. Due to the administrative and financial burden mentioned above in order to provide the NDC number, it may no longer be feasible for us to participate in the 340B program which in turn will prevent us from providing medication services to meet all patient needs.

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 are extremely concerned with the increase in outpatient drug prices that would result if higher AMP figures were to be used for calculating 340B prices since our hospital is currently a disproportionate share hospital. We are also concerned with the additional financial burden that our hospital will incur due to the loss of nominal pricing contracts in the non-340B participating areas, i.e., the inpatient patient populations. It is possible that manufacturers will interpret the DRA act to eliminate nominal pricing to the entire health system. This act will essentially lead to the undue and improper increases in the costs of drugs to our healthcare facility and ultimately our patients. Due to the seriousness of this potential misinterpretation by the manufacturers, the Office of Affairs sent out a letter on January 30, 2007 to all the manufacturers to clarify the issue of AMP calculation and should not include the prompt pay discount.

We recognize the need to have a cohesive approach to the management of prescription drugs under the Medicaid program, however, we hope that you will give serious consideration to the issues addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Rita Shane, Pharm.D., FASHP
Director, Pharmacy Services
Cedars-Sinai Medical Center

CMS-2238-P-1043

Submitter : Mr. James Martin **Date:** 02/19/2007

Organization : Texas Pharmacy Association

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1043-Attach-1.DOC

#1043

March 3, 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 Texas Pharmacy Association 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

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

§447.504 Determination of AMP

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

artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

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

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

this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

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

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

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

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

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29." Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to

1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive.

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

§447.510 Requirements for Manufacturers.

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

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the

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

rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

[3] §447.510(d)(2)

would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

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

Record Keeping

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

Additional Comments

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

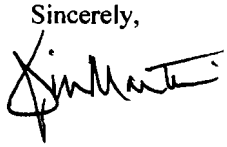
CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form

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

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

Sincerely,



Jim Martin, R.Ph.

cc. The Honorable John Cornyn
The Honorable Kay Bailey Hutchison
The Honorable Joe Barton
The Honorable Kevin Brady
The Honorable Michael C. Burgess
The Honorable John R. Carter
The Honorable Mike Conaway
The Honorable Henry Cuellar
The Honorable John Abney Culberson
The Honorable Lloyd Doggett
The Honorable Chet Edwards
The Honorable Louie Gohmert
The Honorable Charles A. Gonzalez
The Honorable Kay Granger
The Honorable Al Green
The Honorable Gene Green
The Honorable Ralph Hall
The Honorable Jeb Hensarling
The Honorable Ruben Hinojosa
The Honorable Sheila Jackson Lee
The Honorable Eddie Bernice Johnson
The Honorable Sam Johnson
The Honorable Nicholas Lampson
The Honorable Kenny Marchant
The Honorable Mike McCaul
The Honorable Randy Neugebauer
The Honorable Solomon Ortiz
The Honorable Ron Paul
The Honorable Ted Poe
The Honorable Silvestre Reyes

The Honorable Ciro D. Rodriguez
The Honorable Pete Sessions
The Honorable Lamar S. Smith
The Honorable William M. "Mac" Thornberry

Submitter : Mr. Francis Rodriguez **Date:** 02/19/2007

Organization : self

Category : Other Technician

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

1) With respect to manner in which Average Manufacturers Prices are determined: I suggest that the definition of retail pharmacy be such that entities that would have access to unique rebate or price reductions that would not be available to retail, community pharmacies, not be included in any survey for establishing average manufacturers prices (AMP); or, in the alternative, that such unique rebates or price reductions not be considered in the calculation of AMP. 2) With respect to Dispensing Fee: I suggest that it is appropriate for CMS to specify those costs that must be taken into account by each state in determining its dispensing fee. A recent study sponsored by the Coalition for Community Pharmacy of data gathered from 23,000 community pharmacies located nationwide indicates that, depending on the state, the dispensing cost range from $8.50 to $13.08 per prescription. That cost range is far above the dispensing fee schedule of the State of New Jersey, where I live. I suggest that a federally-funded cost-to-dispense study is in the public interest If the totality of changes proposed by these regulations result in reduced, timely access of the patient population to community, retail pharmacies because there are fewer of those pharmacies, the health-cost savings envisioned by these changes would be of only short-term value; long-term, costs would rise as those patients are forced towards costlier health-provider alternatives.

Submitter : Mr. Michael Murphy **Date:** 02/19/2007

Organization : Mississippi Discount Drugs

Category : Pharmacist

Issue Areas/Comments

Background

Background

I have been an independent pharmacy operator for over 25 years. We fill over 8,000 prescriptions per year. We service a small town in central Mississippi, where over 50% of the residents are either on Medicaid or have Medicare Part D. I feel my business is typical of other independent operations.

Collection of Information Requirements

Collection of Information Requirements

The proposed regulations of AMP. Average Manufactures Price is not based on my ability to purchase generics. It takes in to account the Medicaid contracts and PBM contracts. Most of these type entities get some type of rebate. It is my understanding you will apply the rebates to find AMP. I do not get rebates. I am afraid if you use the pricing these entities net, it will be below my cost. Your intentions are to help control cost. I understand the task. But your cost control method is unfair to independents like me. All of our cost are increasing and with AMP our retail price will decrease. Forcing many business out of business. Who will service these patients?

GENERAL

GENERAL

I am only asking for fair pay for a fair product. This new pricing will elminate any possibility of that. The rates of reimbursement now are below the value of the service now. We can help control cost, by controlling the drug therapy and many other services that will produce a healthy population.

Regulatory Impact Analysis

Regulatory Impact Analysis

I ask that you take hospitals, government agencies and governement programs out of your calculation. ONLY use retail operations to find what the drugs cost the true service providers of the public.

Response to Comments

Response to Comments

The use of AMP will certainly limit my ability to continue to provide the service level I have provided in the past. Since AMP is truely unknown, only a projected AMP is availiable, It is my worst nightmare that even with the high volume and past sucess I will be unalbe to make a profit. We are almost there now. AMP will be the demise of pharmacy in the retail market.

Submitter : Mr. Curtis Eirew **Date:** 02/19/2007

Organization : Sail Drug Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

The formula used on the "AMP"-based FULs will not cover the acquisition costs paid by retail pharmacies and will jeopardize the care of millions of patients by retail pharmacies who will no longer be able to offer their personal services like delivery etc. The community retail pharmacies are struggling now and with the proposed AMP - This will not only hurt the retail pharmacy, but most of all the patients who depend on them.

Submitter : **Dr. Mary Mundell** **Date: 02/19/2007**

Organization : **Susitna Professional Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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. Susitna Professional Pharmacy is my pharmacy and is located in rural Wasilla, Alaska. Nearly 70% of our services are for medicaid/medicare patients, thus 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

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

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

Sincerely,

Mary D. Mundell, RPh-owner
Susitna Professional Pharmacy
1751 E. Gardner Way Suite G
Wasilla, AK. 99654
907-373-7933 ph
907-373-7939 fax
susprof@mtaonline.net

Submitter : **john clay** **Date: 02/19/2007**

Organization : **ncpa**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

GAO was questioning the validity of old pricing structure based on AWP(average wholesale price) was giving rise to so called AMP(average manufacturers price) for use as FUL(federal upper limit) in hope of saving a lot of money for CMS

GENERAL

GENERAL

Unlike what president Bush stated in Feb 2006, Pharmacies are not 'overcharging the system'. They are barely making a razor-thin profit(in some cases as low as 5% to cover their professional expenses & financing the expensive medicines to stock on their shelves) & service american citizens.

AMP or any other pricing formulas should not dip below what pharmacies are paying their suppliers for the medicines!!

average manufacurers price has nothing to do with the price pharmacists are paying the suppliers.

If this AMP gets approved as our new basis for reimbursements on medicines...it will irreversibly destroy the network of little & big corner apothecaries & cripple even big outfits that fills community prescriptions in urban areas.

AMP is definitely not the way to measure cost of filling a prescription. Medicines cost way more than $4.00 (as advertised by WAL-MART which is only a gimicky ploy to lure uninsured cash paying customers). By the way an average cost of filling a prescription is $ 9.85 in USA !!

A sure way to close the fiscal gap is to go after manufacturers who play all kind of games in raising cost of brand name drugs & extending & manipulating patent laws.

Another way to be fair is to include several community health professionals(esp.pharmacists) to help reformulate pricing structures instead of other vested interest groups who are eager to see little retail-pharmacies disappear & they can have a field day with their monopoly on rx-supply !!

I know you legislatures are wonderful human beings & care for not just the citizens who voted you in but also for supposedly most respected professionals-PHARMACISTS !!

Submitter : **Date: 02/19/2007**

Organization : **San Juan Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

UphA PERSPECTIVE

The proposed rule does not address national and state pharmacy associations 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 concerns that are not accessible to traditional community pharmacy. All major mail order pharmacies in the U.S.A. are owned by PBM s. The alignment of the PBM, its customers and their mail order division permits them to leverage manufacturers for substantial rebates which are not available to retail pharmacies. If the final rule permits the inclusion of mail order pricing in the calculation of AMP then mail order pharmacies will have an unfair competitive advantage over retail pharmacy where 80% of consumers currently access these products. Consequently, AMP will bet set at a rate lower than what community pharmacy can purchase multi-source generics.

The proposal does not address dispensing fees and continues to let States determine the reasonable dispensing fee they are required to pay pharmacists. UphA is concerned that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. In Utah, the Medicaid dispensing fee is $3.90,while a recent study indicated that the average cost to dispense a medication in the state of Utah is $12.39. It is unlikely that the State of Utah would set the Medicaid dispensing fee high enough to cover the cut in drug cost reimbursement that will result from AMP based pricing.

One Utah pharmacy owner estimates that if the proposed AMP based reimbursement is implemented, this would result in a net loss of $117,000 in net profit in his two small independent pharmacies!

Submitter : **Bob Hager, Jr** **Date: 02/19/2007**

Organization : **Quality Discount Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 19, 2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

Robert Hager, Jr., RPh.
Quality Discount Drugs
4109 Eva Road
P.O. Box 98
Eva, Alabama 35621

Submitter : Mr. Patrick Hilger **Date:** 02/19/2007

Organization : Gregwire Drug Store

Category : Pharmacist

Issue Areas/Comments

Background

Background

Legislation passed changing the reimbursement of generic drugs under Kansas Medicaid. The move to a proposed AMP formula. This new formula would force thousands of patients to experience access issues and would cause many pharmacies to go out of business, furthering the problem of access to quality health care.

Collection of Information Requirements

Collection of Information Requirements

These provisions if implemented would require pharmacists like myself to sell prescriptions on average 36% below our actual acquisition costs.

GENERAL

GENERAL

It would be extremely detrimental to the patient, to the community pharmacy and to the delivery of health care to let this legislation continue and be implemented. This is absurd to expect pharmacists to dispense medication 36% below what it cost them. Please stop this before it has a chance to be implemented.

Submitter : Mr. Glenn Newsome **Date:** 02/19/2007

Organization : Mr. Glenn Newsome

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I live in a small community that depends greatly on the pharmacist in our local drugstore for advice and counsel regarding proper use of prescribed drugs. Our pharmacist normally recommends generic drugs to reduce cost to the customer. It is my understanding that proposed changes in the Medicaid program will discourage our local pharmacist from using generic drugs. I believe this will ultimately cost the consumer and our government more.

I do not have an answer for the current health care crisis in our country but I believe our government must do everything possible through law and regulation to encourage preventive care and healthy life styles and at the same time reduce the cost of medication.

I encourage you to carefully consider the long term impact of the rule change on small town local pharmacies that are struggling against the ever increasing "wal-mart" drug stores. It is my understanding that generic drugs cost less to produce and distribute. Any regulation that will reduce the use of generic drugs in not in the best interest of our country.

Thank you for the opportunity to share my comments.

Submitter : Dr. David Fong **Date:** 02/19/2007

Organization : United Pharmacists Network, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

My name is David Fong and I currently serve as the Vice President of Development for the United Pharmacists Network,Inc. (UPNI). We represent the interests of 700 independent community pharmacies throughout the Riverside/San Bernardino,Los Angeles,Orange and San Diego Counties. I also serve as the Chief of Operations for Cathay Medical Industries, which is owned by my parents. Cathay Medical Industries operates two independent community pharmacies in Los Angeles and I currently practice in one of the pharmacies on Saturdays. I am a graduate of the USC School of Pharmacy and have been in practice as an independent community pharmacist for over 24 years.

Collection of Information Requirements

Collection of Information Requirements

This proposed rule would implement the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs undre the Medicaid Program. Teh DRA would amend section 1927(e) to revise the formula CMS uses to set the Federal Upper Limits (FULs) for multiple source drugs in the Medicaid Program.

GENERAL

GENERAL

It is our feeling that the Pharmacy Community was not included at the table when the DRA was being developed. In addition, a study by the Government Accounting Office (GAO-07-239R) which looked at what would happen to 77 drugs if AMP-based FULs were implemented. The study found that for the entire sample of 77 multiple source outpatient drugs, AMP-based FUL's were, on the average, 36% lower than the average retail pharmacy acquisition cost.
In particular, the estimated AMP-based FUL were, on average 65% lower than average retail pharmacy acquistion cost for the 27 high expenditure drugs and 15% lower for the 27 frequently used drugs in the sample.
The results of the GAO study was based on 250% of AMP. There is no assurance that states and/or pharmacies will be reimbursed at 250% of AMP.
In addition. one may find an increase in the utilization of higher cost brand medications. General wisdom encourages the use of generic drugs because they are cheaper then brand drugs and they save the system money. The DRA actually encourages the use of brand medications and higher costs for State Medicaid Programs.

Regulatory Impact Analysis

Regulatory Impact Analysis

Currently, the Medicaid program will reimburse independent community pharmcies for prescriptions for Medicaid beneficiaries at a discount off of Average Wholesale Price (AWP) plus a dispensing fee. Payments for most generic or multi-source drugs are subject to aggregate federal upper limits (FULs) that are usually 150% of the Wholesaler Acquistion Cost or WAC of the lowest published price for equivalent drugs.
The Deficit Reduction Act would change the way in which State Medicaid Programs would pay independent community pharmacies for prescriptions for their beneficiaries from AWP to Average Manufacturer Price (AMP) . The DRA would then set the FUL at 250% of AMP for multiple source drugs.
AMP was created thru OBRA'90 as a benchmark for rebate payments by manufacturers to State Medicaid Programs. The fundamental problem in creating, using and monitoring the use of AMP is that each manufacturer defines AMP differently. CMS has not provided clear guidelines on how to calculate AMP nor has it resolved price determination problems.
For example: Sales to mail order pharmacies and nursing homes when calcuating AMP, because mail order and nursing homes pay lower prices than retail pharmacies, because they are different classes of trade,i.e. one is a closed door pharmacy that does not see any walk in patients and the other is open to the public. Although they are both retail pharmacies, because they are in different classes of trade, the pharmaceutical manufacturers provide different pricing strategies for the products that they purchase. Includng mail order and nursing home pharmacies in the calculation would lower the AMP below the price a traditional retail pharmacy pays.
Another example would be that rebates paid to health plans and pharmacy benefits managers when calculating AMP would also result in a lower value for AMP. This is because PBMs are not distributors of drugs to retail pharmacies. PBMs do not purchase, warehouse nor do they deliver pharmaceuticals to retail pharmacies. PBMs mainly provide pharmacy network management services. The only instance where they would purchase drugs would be if they owned a closed door pharmacy/mail order house, which would process prescriptions and mail the medications to their patients. However, this type of activity is different from the activities of the PBM where price concessions and rebates are based on placement on their formulary and movement of market share for particular products. Independent community pharmacies do not share in these types of rebates, discounts or any other price concessions that PBMs negotiate.
Other issues regarding AMP include:

1. AMP was created as a way to determine the amount of rebates that pharmaceutical manufacturers would pay to stay on State Medicaid Programs. As such, there is an incentive to report the lowest number possible.
2. The 11-digit National Drug Code (NDC) for the drug should be used to calcuate AMP as it will offer the most accurate number according to package size.
3. Clarification of the AMP reporting period to a time frame that

is available in the private sector.

4. Direct the States to utilize monthly Retail Survey Price date. These payment amounts represent the weighted average reimbursement received by independent community pharmacies for each drug, reflecting a blend of cash and third party payments.
5. Rebates paid by the manufacturer for state sponsored assistance programs should not be included in the calculation of AMP as these rebates do not affect the price paid by independent community phamacies nor are the rebates shared with the pharmacy
6. Coupons redeemed by a pharmacy on behalf of the consumer should not be included in the calculation of AMP because manufacturer coupons are essentially cash discounts and in no way affect the price paid by the independent community pharmacy for the drug product.

Submitter : Ms. Tom Smallwood **Date:** 02/19/2007

Organization : Buena Vista Drug, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

If proposed AMP rules go into effect I will probably have NO CHOICE but to stop serving Medicaid patients because I will be LOSING MONEY on every prescription that I dispense on this program.

CMS-2238-P-1055

Submitter : Mr. Christopher Howes **Date:** 02/19/2007

Organization : Colorado Retail Council

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1055-Attach-1.DOC

#1055

CRC

Colorado Retail Council / 1580 Lincoln Street, Suite 1125 / Denver, CO 80202
www.coloradoretail.org / Phone (303) 297-0657

February 19, 2007

Leslie Norwalk, Esq.
Acting Administrator
The Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201
(via email)

RE: Proposed Rule To Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program; (Docket No. CMS--2238-- P)

Dear Administrator Norwalk:

The Colorado Retail Council appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). We are quite concerned about the impact of the proposed rule on our chain pharmacies. We represent over 500 pharmacies here in Colorado and employ more than 75,000 Coloradans and worry that the proposed rule may do real damage to our operations.

The Colorado Retail Council works with the Food Marketing Institute (FMI), and fully supports the comments filed by FMI and incorporates FMI's comments herein. In addition, we specifically wish to call your attention to the following issues.

As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Although we understand the challenge the dual use of AMP presents to CMS, we believe that several aspects of the proposed rule would unduly reduce AMP, thereby jeopardizing our member companies' ability to continue to serve Medicaid beneficiaries.

In this regard, we urge CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Supermarket pharmacy profit margins are in the range of approximately 2 to 3 percent of total revenues. Recent studies suggest that the Federal Upper Limits (FULs) based on AMP may result in ingredient

cost reimbursement that is below pharmacy acquisition cost.[1] In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. To the extent that FULs are below pharmacy acquisition costs for generic drugs, many companies may find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts in the states in which we operate that are far below the costs we incur to dispense prescription drugs to Medicaid patients.

Accordingly, although we do not believe that this situation can be fully addressed through the regulatory process and we are joining with FMI and others to seek a change in the underlying law, we believe that CMS should take the steps discussed below to mitigate the problem in the interim.

First, CMS should revise the proposed AMP regulation so that it will align more closely with the underlying statute and provide a more realistic and accurate benchmark for pharmaceutical reimbursement to pharmacies. Specifically, the statute defines AMP as "the average price paid to the manufacturer for the drug in the United States by wholesales for drugs distributed to the retail pharmacy class of trade." Accordingly, only those sales that are to entities that are truly within the "retail class of trade" should be included in the calculation. PBM's, mail order pharmacies and other non-retail entities should be removed. Similarly, purchases by entities other than wholesalers should also be excluded. Likewise, the FUL should be based on the weighted average AMP of therapeutic alternatives, not the lowest cost alternative.

Second, CMS should delay publication of the AMP information to ensure that the consequences of publishing the data are fully understood. Publication of the AMP data will result in an immediate impact on the pricing of generic drugs that will create a floor on the price discounts that generic manufacturers are willing to offer, thereby reducing the level of competition between generic manufacturers with potentially significant negative effects on neighborhood pharmacists and the Medicaid program alike.

Third, state dispensing fees must be reviewed in light of the changes imposed by the federal drug reimbursement scheme. Accordingly, CMS should ensure that all pharmacy costs are included in the federal dispensing fee definition and require states to update their Medicaid dispensing fees to ensure appropriate utilization of generic drugs.

We respectfully request that you address our concerns on the record. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to contact me at 303-355-1066 or at chris@chrishowes.com.

Sincerely,

Christopher D. Howes
President

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[1] Government Accountability Office "Medicaid Outpatient Prescription Drugs: Estimated 2007 Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs", Letter to Rep. Joe Barton (R-TX) (December 22, 2006).

CMS-2238-P-1056

Submitter : **Ms. Bobbi Jo Long** **Date: 02/19/2007**

Organization : **Zeigler Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare and Medicaid Services
Attn: 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 Long Rx Corporation is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definiton of AMP as well as implement the new Medicaid FUL program for generic drugs.

Our Corp. operates a pharmacy in Ohio. We are a major provider of pharmacy services in the community we are 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 medicaitons. I ask that CMS please do the following:

*Delay Public Release of AMP Data: The Centers for Medicare and Medicaid Services should not make AMP data public until a final regulatory definiton 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 thes data be delayed again.
*Define AMP to Reflect Retail Pharmacy Purchasing Cost: 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 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 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 lossed 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 NACDS reguarding this proposed regulation. We appreciate your consideration of these comments. Thank you.

Sincerely,
Bobbi

Submitter : Mr. Kelcey Diemert **Date:** 02/19/2007

Organization : WESTERN DRUG

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I'm afraid that the Proposed Rule will make it impossible for us to continue to provide pharmacy services to our Medicaid patients. We are in rural Montana and have a high Medicaid population. This Rule will force many Montana pharmacies to stop serving Medicaid patients, causing a serious hardship for that population. Thank you for considering the potential impact on rural pharmacies and our patients.

Kelcey Diemert, RPh

Submitter : Mr. Kelcey and Nancy Diemert **Date:** 02/19/2007

Organization : Chinook Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Proposed Rule by CMS will cut our reimbursement for Medicaid prescriptions to a level which is below our cost of dispensing. We will be forced to stop filling prescriptions for this population, leaving many Medicaid patients without pharmacy services. Rural pharmacies provide a valuable service to Medicaid beneficiaries.
We are the only pharmacy available in Blaine County. If we cannot fill these prescriptions, many people will have to travel 50 to 100 miles round-trip to get their medications.

CMS-2238-P-1059

Submitter : Becky Claiborne **Date:** 02/19/2007

Organization : Four Way Prescription Shop

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

By passing the AMP Rule, you will be ending the life of the Independent Pharmacies thru out the state of Tennessee. I have had the privilege of working in 4 of these pharmacies in our area in the past 18 years. Yes I did have to find work at another independent when my first employer was put out of business by TennCare. I have seen the poor hard working Independent Pharmacies struggle thru all the changes in Tennessee's health care. WE MADE IT.....BUT will not be able to endure if this passed. We love our customers and hate to see them have to go elsewhere, as well as ourselves. IT IS NOT FAIR, chain stores have all the breaks due to size. I beg you to please help us. Blessings to you all and please pray for our troops.

Submitter : **Dr. clive fuller** **Date: 02/19/2007**

Organization : **Bascom Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

AMP, average manufacturers price as a basis for medication cost

GENERAL

GENERAL

To :Leslie Norwalk, Acting Administrator

From :Clive Fuller, PharmD;

I am writing this letter in opposition to CMS using the Average Manufacturers Price (AMP) as the basis for reimbursement for Medicaid and Medicare patients for the following reasons.

1. The formula for AMP based Federal Upper Limit (FULs) in the proposal will not cover pharmacy acquisition cost for multiple source generic medication.

2. Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement

3. To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy.

4. The true cost will only be reflected by the following

a. Excluding all rebates and price concessions made by Manufacturers which are not available to retail pharmacies.
b. Excluding all Mail Order facilities and PBM pricing from AMP calculation. Mail order and PBM are extended special pricing from manufacturers, and they are not publicly accessible as is a community retail pharmacy.
c. Reporting AMP at the 11-digit NDC level to ensure accuracy.

Submitter : Mr. Douglas Heidbreder **Date:** 02/19/2007

Organization : Addison Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

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

I am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer s price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Addison, Michigan. Addison Pharmacy is a major provider of pharmacy services in the community and your consideration of these comments is essential to ensure that we can continue to meet the needs of our area.

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

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

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

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

3. Removal of Medicaid Data

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

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

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

GENERAL

GENERAL

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

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

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

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

Sincerely,

Douglas Heidbreder
Addison Pharmacy

Copy: Members of Congress

Submitter : Mr. Hunter Baird **Date:** 02/19/2007

Organization : Medical Arts Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

CMS-2238-P-1063

Submitter : Mr. Jimmy Nuckolls **Date:** 02/19/2007

Organization : Hudson Drug Store

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

Submitter : Dr. Marc Summerfield **Date:** 02/19/2007

Organization : University of MD Medical Center

Category : Hospital

Issue Areas/Comments

Background

Background

I am writing for a major urban DSH Hospital in Baltimore Maryland.

Collection of Information Requirements

Collection of Information Requirements

The requirement to submit NDC numbers for physician administered drugs in our outpatient treatment areas is onerous.

GENERAL

GENERAL

See attachment

CMS-2238-P-1064-Attach-1.DOC

#1064

University Of Maryland Medical Center
Pharmacy Services
29 South Greene Street, Room 400
(410) 328-5650 FAX: (410) 328-8984

February 19, 2007

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

To Whom It May Concern:

On behalf of the University of Maryland Medical Center (UMMC), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 as published in the Federal Register on December 22, 2006. UMMC is a 700-bed Disproportional Share Hospital (DSH) under the Medicare program located in Baltimore, Maryland. UMMC also qualifies and is enrolled as a covered entity under the federal 340b drug discount program. Our primary concerns about the proposed regulations are as follows.

The proposed regulations would create enormous administrative, financial, and computerized systems burdens for our hospital by requiring the reporting of NDC information on drugs administered in our hospital outpatient locations. At present, NDC numbers are neither captured in our billing system charge master, nor transmitted/interfaced from our pharmacy dispensing system. This regulation would require us to negotiate software modifications necessary to accommodate this change with our billing software vendor. It would also require both billing and dispensing vendors to establish a new interface of data. HCPCS J-Codes are presently provided through UMMC's hospital billing system, and we are hard pressed to understand why the switch to NDC numbers is being suggested.

The pharmacy dispensing and billing system are not "brand" based, but, in fact, based on generic medications designations. At any time there could be multiple manufacturers of the same drug and strength in inventory and placed in any of the scores of outpatient treatment areas. This inventory is not managed as part of a perpetual inventory system. Once dispensed to the treatment area as floor stock or in unit-based cabinets, it is impossible to tell which manufacturer's drug is dispensed to which patient. Furthermore, in some cases, we actually repackage medications in pre-filled unit doses. In this case the manufacturer's barcode is not currently replicated and included on the new hospital packaging.

Because there are no currently available automated technology systems in place, or even designed as yet, to accommodate these regulations, the only alternative would be to regress to a contrived manual paperwork system. This would require the health care professionals treating the patient to manually record the drug's NDC being administered. Besides transcription errors and additional audits

to make sure the drug dispensed corresponds to the NDC manually entered, UMMC will also face a cadre of process issues on how to collect, reconcile, and record these manual transcriptions. This would have to occur at the same time the hospital is currently implementing CPMOE or Computerized Physician Medication Order Entry in the hospital to eliminate paper processing and more safely and accurately communicate the patient medication order.

Finally, from an administrative viewpoint, not all unit-dose medications are bar coded from the manufacturer. The FDA has in fact loosened the requirement for single or unit-dose bar coding. Therefore, any automated solution in the future would require the hospital to barcode these drugs with manufacturer-specific bar codes before deploying these to the outpatient treatment areas. UMMC is considering the future implementation of bedside scanning of medications, but this potential implementation is not currently budgeted or projected for the next 3-5 years.

We respectfully request that the concerns raised in this letter be given serious consideration as the proposed regulations are revisited during this open comment period.

Sincerely,

Marc Summerfield
Director of Pharmacy Services
University of Maryland Medical Center

Submitter : **Mrs. Karol Heidbreder** **Date: 02/19/2007**

Organization : **Addison Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

My husband and I own Addison Pharmacy in Addison, Michigan. The proposed legislation in its current form would have a tremendously damaging effect on our business and the customers we serve.
It's crucial that the definition of AMP include and reflect prices that retail pharmacies like ours have access to. It must not include rebates and discounts that PBM's and mail order pharmacies receive because these are NOT available to us.
Pharmacies like ours throughout the U.S. have been financially hammered by the Medicare D program over the past year. To ask us to bear the brunt of Medicaid cuts and reimburse us at levels of 36% below our acquisition cost would effectively put us out of business.
Dispensing fees have not kept up with inflation over the past 30 years. Fairness dictates that professionals like us be properly reimbursed for the important services we provide. The current proposed AMP would not result in proper reimubursement and must be changed.
Sincerely,

Karol Heidbreder
Addison Pharmacy

CMS-2238-P-1066

Submitter : Mr. JAMES MARMAR **Date:** 02/19/2007

Organization : WOODSTOCK PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

see the attached document

GENERAL

GENERAL

My letter is in the form of an attachment

CMS-2238-P-1066-Attach-1.DOC

CMS-2238-P-1066-Attach-2.PDF

CMS-2238-P-1066-Attach-3.DOC

#1066#1

MODEL COMMENTS FOR "INVOLVED" MEMBERS

go to : http://www.cms.hhs.gov/eRulemaking/

choose Submit electronic comments on CMS regulations with an open comment period

choose CMS-2238-P

March 3, 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 ..... 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 [STATE PHARMACY ASSOCIATION] regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Pharmacist name

cc. Members of Congress (individualize)

 1066-2

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

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

#1067.

March 3, 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 Wichita, Kansas. 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 Kansas Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

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

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

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

Submitter : Mr. Elliot Lekawa **Date:** 02/19/2007

Organization : Mr. Elliot Lekawa

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1067-Attach-1.DOC

#1067.

March 3, 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 Wichita, Kansas. 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 Kansas Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

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

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

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Elliot Lekawa

CMS-2238-P-1068

Submitter : **Date: 02/19/2007**

Organization :

Category : **Other Practitioner**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1068-Attach-1.DOC

#1068

March 3, 2007

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

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

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

Dana R Fasanella, CPhT
Doctor of Pharmacy Candidate
Campbell University School of Pharmacy

Submitter : Mr. Chip Cather **Date:** 02/19/2007

Organization : Brewster Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1069-Attach-1.DOC

CMS-2238-P-1069-Attach-2.DOC

1069

BREWSTER FAMILY PHARMACY
360 N. Wabash
Brewster, Oh 44613
Phone: 330-767-3436
Fax: 330-767-3090

March 3, 2007

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

To Whom It May Concern:

I am writing to provide my comments regarding the proposed rule CMS-2238-P.

Firstly, I would like to comment in regards to the determination of average manufacturer price section 447.504 locate on page 77177 of the proposed rule. It states average manufacturer price (AMP) is the price paid by a wholesaler to a manufacturer for a drug that is distributed to retail pharmacy class of trade. I was wondering why a reimbursement paid to a retail pharmacy is determined by what a third party, wholesaler, pays for a drug and not what a pharmacy pays? Just like with everything that is bought and sold in the United States every middleman increases the price of a product in order to make a profit. Therefore, wholesalers increase the price they paid for a drug in order to make a profit from the distribution. From a retail pharmacy perspective we should be reimbursed based on what we would pay for a drug and not what someone else paid for the drug. Even though there is a 250% increase in AMP this still does not offset the calculation fairly for everyone. Ultimately you are creating a bias for larger retail pharmacies. As a small independent pharmacy we do not have access to purchase directly from a manufacturer like other larger retail pharmacies. So if a pharmacy is capable of purchasing directly from a manufacturer then their reimbursement would be AMP x 250%. However, for smaller independent pharmacies we buy from a wholesaler, who adds a percentage on the cost of a drug so they can make money, which in turns leaves our reimbursement at AMP x 250% minus a percentage the wholesaler adds to drug cost. This may not be the case for every single drug, but for those that it does affect you leave small businesses at a direct disadvantage. The rule should be written to allow all pharmacy businesses equal reimbursement. To me the only way to offer equal reimbursement is to base reimbursement on average wholesaler price or average price per unit a pharmacy pays for a prescription drug.

Regarding the section, definition of retail pharmacy class of trade and determination of AMP on page 77178 of proposed rule I would like to make the following comments. I would like to agree with the statement presented that mail order pharmacies should also be excluded from AMP calculations. Mail order pharmacies are given different buying abilities in regards to the price they pay for drugs that independent and chain pharmacies are not given thereby placing them in a similar group as long term care pharmacies. For mail order pharmacies to be included in AMP calculations then the definition should only include drugs that all parties receive equal manufacturer concessions. With the stated argument that removal of mail order pharmacy, long term care pharmacy and PBM prices would not be consistent with past policy and could increase drug manufacturer rebate liabilities, who interest is this looking out for? Would it not be possible for manufacturers to alter the way rebates are offered so as not to increase their liability? If this rule is looked at reducing the cost on government agencies for drugs shouldn't the cost sharing be divided out proportionately across all players in the drug distribution system and not just on retail pharmacies. Retail pharmacies have had to deal with changes in past policies and it would not hurt for other parties to deal with changes too. Also I would like to comment on the use of general public in the definition of retail pharmacy class of trade. How can those patients

mandated to only use mail order pharmacies be considered general public? In my opinion they are no different then those patients in a nursing that all receive their medications from the same pharmacy. Retail pharmacy class of trade should only include those pharmacies that have an equal opportunity to serve the same patient population which in my opinion is only independent or chain pharmacies.

Also in the section titled, definition of retail pharmacy class of trade and determination of AMP on page 77178 of proposed rule I would like to comment on the inclusion of PBM rebates in AMP calculations. The real question is why should rebates a PBM receive affect what a pharmacy is reimbursed? A PBM does not literally buy drugs from a wholesaler or manufacturer so there is no reason that a PBM rebates should affect AMP calculations. No one except the PBM knows what happens to those rebates and I am sure they are not going to tell anyone especially since it is not mandated. I will tell you for sure that those rebates do not come to the pharmacies that actually buy the drugs so there is no way they affect what a pharmacy pays for drugs and therefore should not affect AMP. It is just outright preposterous for anyone to suggest this especially anyone that has any business experience. Lets me try and put it this way, say you are an employee of a business who reimburses you per gallon of gas used for work. You buy gas at $2.35 a gallon which is the cheapest you can buy. Your employer gets a rebate of 5 cents per gallon of gas used from a certain gas company. Since your employer gets the rebate it is determined you, the employee, should only be reimbursed say $2.29 a gallon. Do you think that you, the employee, is going think this is fair and a reasonable business practice? I would be willing to bet you wouldn't. So why is a rule going to be proposed to cheat businesses out of money that someone else is getting paid. Rebates paid to PBMs should in no way be included in AMP calculations. These comments also apply in regards to the rebates paid to PDPs being included in AMP calculations. To me and I am sure other people, this rule looks to allow insurers collect more money while only being required to pay out less, essentially putting more money into their hands. In other words someone is willing to take money from one person, pharmacies, and let others, PBMs and PDPs, collect more money without being required to share in the burden of cutting costs to healthcare expenditures. Only price concessions or rebates made directly to a pharmacy should affect the reimbursement paid to such pharmacy. By including these rebates in AMP it is artificially deflating the price a pharmacy pays for drugs.

In section 447.514 titled, Upper Limits for Multiple Source Drugs, I would like to comment on the decision not to use a drugs 11 digit NDC to calculate AMP. I would agree with the comments made that using 11 digit NDCs would allow for greater transparency and would not make calculating AMP more difficult. This would allow for proper reimbursement based on the package size a pharmacy is using allowing a pharmacy to cover the cost of a drug. Also this would prevent over reimbursement that could occur using only a 9 digit NDC. By not using the 11 digit NDC to calculate AMP this will ultimately provide a price advantage to larger pharmacies which in turn will lead to the creation of a monopoly market for large pharmacies. Smaller independent pharmacies will not be able to compete with larger pharmacies who buy drugs at larger quantities at a lower price per tablet. Creating a pricing structure that provides an advantage to larger pharmacies and an inability for other pharmacies to compete is going against laws that prevent the creation of monopolies. Here is actually pricing information in regards to Lisinopril 10mg as our pharmacy could purchase. A 100 tablet bottle of Lisinopril 10mg would cost $4.81 which is 4.81 cents per tablet. While a 1000 tablet bottle of Lisinopril 10mg would cost $34.88 or 3.49 cents per tablet. With larger pharmacies more than likely purchasing a 1000 tablet bottle this offers them a 1.32 cents advantage per tablet than pharmacies purchasing a 100 tablet bottle. With the average prescription being for 30 tablets, a month supply, this is roughly a 40 cent advantage per prescription for a larger pharmacy. Say a large pharmacy does 500 prescriptions a day this would equal close to $200 a day of increased profit for a larger pharmacy as compared to a smaller pharmacy that would purchase a 100 tablet bottle. However, by using an 11 digit NDC this would level the playing field for pharmacies allowing for proper reimbursement for their cost of goods while eliminating over reimbursement on per tablet basis.

As for as the following statement that was made in the proposed rule in the same section 447.514, "Furthermore, we expect that because the AMP is marked up 250 percent, the resultant reimbursement should be sufficient to reimburse the pharmacy for the drug regardless of the package size the pharmacy purchased and that to the extent it does have an impact, it would encourage pharmacies to but the most economical package size", I would like to make some comments. It is possible that with AMP marked up 250 percent that it may reimburse a pharmacy for the drug, but as the GAO (Government Accountability Office) report has shown AMP reimbursement would be on average 36% less than a pharmacy's acquisition cost for a drug. However, we will assume by chance that AMP reimbursement does cover the cost of a drug. Using the cost figures for Lisinopril 10mg that were presented above, if reimbursement covers the cost for a 100 tablet bottle this reiterates my comments on providing an advantage to larger pharmacies by only using a 9 digit NDC for AMP calculations. As far as encouraging pharmacies to purchase the most economical package size, the rule is only considering the economical standpoint or reimbursement and not the economical standpoint of a pharmacy's overhead cost. Once again let us take into consideration the cost figures for Lisinopril 10mg as stated above. If a smaller pharmacy only dispenses a limited quantity of Lisinopril 10mg and thereby purchases only 100 count bottles in order to prevent a large overhead and their money being tied up in product that might take months to actually dispense. They could be punished for this if AMP only uses a 9 digit NDC for AMP calculations. So now this pharmacy would have to purchase a 1000 tablet bottle of Lisinopril 10mg, the more economical package size according to the rule, so as to cover the cost of the drug which will tie up roughly $30 more in product that the pharmacy now can not use to pay their bills, payroll or rent. Take into consideration that a pharmacy needs to carry hundreds to thousand of drugs on their shelf in order to properly run a pharmacy and serve their patients. Purchasing larger package sizes, in order to purchase the more economical package size, so that a pharmacy can make money on a drug will result large overhead and the inability of a pharmacy to pay their bills with more money tied up in product. I am sure anyone with business knowledge will understand what happens to business with larger overhead and a lack of money to pay bills, it is called going out of business.

I have alluded to the potential impact on small independent pharmacies through my previous and I would like to further comment on the impact this rule will have on small pharmacies. Throughout the proposed rule document there are many comments on the impact to pharmacies. "We believe that these legislatively mandated section 6001 savings will potentially have a "significant impact" on small, independent pharmacies." "However, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries." "We estimate that 18,000 small retail pharmacies would be affected by this regulation." These comments should demonstrate some HUGE red flags regarding the potential impact this rule will have to pharmacies and patients served by these pharmacies. We all have seen how the Medicare Part D affected pharmacies and patients. We should learn something from the past and not jump into things without being able to quantitatively define the impact a rule will have on pharmacies and patients. This rule has the potential to significantly impact 18,000 small retail pharmacies that may be forced out of business due to low reimbursement. Let us say that these 18,000 pharmacies employ at least 4 employees that equals at least 72,000 employees that may not have a job after this rule is in effect. Everyone is concerned about improving unemployment, but a rule is proposed that could put 72,000 or more people without a job. All because we did not take the time to quantitatively define the impact on pharmacies. Also let us not forget about the patient these pharmacies serve. Assume these 18,000 pharmacies serve smaller towns with on average 2,000 people. That is 36 million patients that could be forced to find another pharmacy to provide them service and those pharmacies might be farther away or more difficult to access. Who is looking out for the patients? Yes pharmacies look to make a profit like any other business, but we are mainly there for the sole purpose of providing quality medical care to patients. Proposing a rule without fully understanding the impact it will have on pharmacies and patients is like paying Russian roulette. You are pulling the trigger not knowing what will happen and will deal with the consequences later. Well one consequence is suicide and after that there is not much one can do. So delay to implementation of rule until it can be determined what the true quantitative impact the rule with have an all parties involved.

There are two sentences, in the section on Effects on Retail Pharmacies on page 77192 of the proposed rule, that greatly irritate me. It is blatantly stated that pharmacies will incur revenue losses on prescription medications with this rule and no one cares. There should never be a rule proposed or passed that will force any business to take a loss on product period. A rule like this forces people out business and prevents people entering a business. It prevents the viability of a business and prevents people from making a living. However, to prevent these losses it is assumed that the business can sell other goods to offset the loss in revenue. I quote, "First, almost all of these stores sell goods other than prescriptions drugs, and overall sales average more than twice as much as prescription drugs sales." First, almost all stores sell other goods other than prescriptions drugs? So the stores that do not sell other goods they are just out of luck I guess. We are in a business to primarily sell prescription goods and not sell everything under sun. We should not be forced to take a loss on our primary business and forced to sell other goods. How does that look to patients when your pharmacist pitches to you about that new item you should not live without "As seen on TV" in order to make up for the loss they are taking on the prescription you just picked up? Also pharmacist look to improve a patients health not make it worse by selling them other goods, like cigarettes, to make up for the loss on prescription medications. I would begin to think patients would not respect their pharmacist as a medical professional if we are forced into this type of business. So how dare a rule look to diminish our profession that we work so hard to achieve. As far as the sale of other goods accounting for more than twice as much as prescription drugs, I do not think this is the case for all pharmacies. Those sales figures might be correct if you are looking at total sales of a store in which the pharmacy is located in a grocery store. Some pharmacies are actually just a pharmacy and are not selling you groceries or a plasma screen TV at the same time. Speaking on the sales of our pharmacy, prescription sales accounted for 90% of our total sales for the 2006 year. Now there is now way that our sales of other goods would offset the revenue loss that would occur using AMP. Our pharmacy is in the business of providing quality care with a focus on health care needs and not selling everything under the sun.

Secondly, in the next sentence it is stated that pharmacies can mitigate the proposed rule by changing purchasing practices. Sure pharmacies can changes their purchasing practices, but it would just force small pharmacies to assume more overhead and further place a strain on cash flow. I do not see how assuming more overhead will mitigate this proposed rule. I have demonstrated how this rule will produce more overhead for smaller pharmacies in previous statements. Also, can it truly be stated that pharmacies can mitigate the proposed rule by changing purchasing practices when no one really knows the impact it will have on a pharmacy? How can you present a possible solution to a problem if you do not even know what the problem will be or how big it will be? There are many players in the whole health care system that play a role in providing a prescription medication. It should not be the entire responsibility of pharmacies to mitigate the cost of decreasing expenditures on prescription medications. Manufacturers are not being forced to mitigate any costs or burdens. Anything that was deemed to effect manufacturers negatively in this proposed rule was abandoned, including the use of an 11 digit NDC and anything that would alter a manufacturer's rebates. All parties involved in the production to dispensing of a prescription medication should share proportionately in the cost sharing involved in reducing medical expenditures.

In section 447.504 Determination of AMP, I think there needs to be more clarification of the following statement; Manufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail pharmacy class of trade. There are many types of coupons and many different requirements for the redemption of these coupons so it should more clearly defined. Pharmacies receive coupons from patients that require electronic redemption from the pharmacy that will reduce a patient's copay by the defined amount. Will these coupons be included in the determination of AMP? Also pharmacies receive coupons that require the pharmacy to reduce a patient's copay by a defined amount, but then to mail the coupons in for redemption. Will these coupons be used in the determination of AMP? I feel that both of these coupon examples should not be used in the determination of AMP. These coupons do not alter the actual cost of a medication they are just reducing a patient's copay so as to allow a patient to receive a medication they can not afford or may not tolerate. I feel that the inclusion of manufacturer's coupons should be more clearly defined or removed all together.

I hope you will take these comments into consideration and make necessary changes to the proposed rule. This rule will drastically affect the pharmacy profession. It will force pharmacies to close, employees to look for other jobs and diminish quality care to patients. This rule was supposedly proposed in order to cut costs, but only to shift that cost to others, mainly pharmacies. More time should be taken to actually define the effects the rule will have on small retail pharmacies, which are at the greatest risk.

Thank you

Sincerely,

Chip Cather
RPh, PharmD, manager
Brewster Family Pharmacy
360 N Wabash
Brewster, OH 44613

Submitter : **Mr. Thomas Hawkins** **Date: 02/19/2007**

Organization : **Boone Drug & Healthcare**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

February 18, 2007

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

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

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

Thomas E. Hawkins, RPh

cc. Members of Congress (Virginia Foxx)

Submitter : Mr. Patrick Dorian **Date:** 02/19/2007

Organization : Mr. Patrick Dorian

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 : Ms. Amy George **Date:** 02/19/2007

Organization : Ms. Amy George

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I feel that CMS should not be reformed. A pharmacy should not be reimbursed less than what it paid for medication. That is not right nor fair. Doing so would surely put smaller pharmacies out of business. As a pharmacy student I can not see how decreasing reimbursment would benefit me or the thousands of other soon to be pharmacists. Why should pharmacies have to find ways to make money and by raising patients and punishing other patient that do not have government insurance. Another way to get medicaid and medicare undercontrol needs to be formulated.

Submitter : **Dr. Joseph Collins** **Date: 02/19/2007**

Organization : **Woodys Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

CMS-medicare/medicaid service is considering lowering reimbursement for prescription drugs to 36% below a pharmacy's actual acquisition cost. We cannot stay in business with reimbursements that low. Service to Medicare and Medicaid recipients will suffer. Pharmacy already has some of the lowest profit margins in retail businesses in America.

I oppose the up coming CMS rule change for AMP pricing that will result in reimbursement rates 36% below acquisition costs and urge higher reimbursement rates for pharmacies.

Sincerely

Joseph J Collins
PharmD

Woodys Pharmacy
408 south Broad Street
New Tazewell, TN 37825

Submitter : **Miss. Merritt Phelps** **Date: 02/19/2007**

Organization : **Miss. Merritt Phelps**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

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

Submitter : **Dr. Heather Christensen** **Date: 02/19/2007**

Organization : **Meijer Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer s price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Greenville, MI. Meijer Pharmacy is a major provider of pharmacy services in the community and your consideration of these comments is essential.

Collection of Information Requirements

Collection of Information Requirements

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

GENERAL

GENERAL

I appreciate your consideration of these comments and support the more extensive comments that are being filed by the Michigan Pharmacists Association regarding this proposed regulation. Please feel free to contact me with any questions.

Sincerely,
Heather Christensen, PharmD

Submitter : **Connie Connolly** **Date: 02/19/2007**

Organization : **Connie Connolly**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 19, 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 Maquoketa Iowa. 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 Iowa Pharmacy Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Connie J. Connolly RPh

cc. Senators Grassley and Harkins, Representative (Braley)

Submitter : Dr. Tripp York **Date:** 02/19/2007

Organization : Dr. Tripp York

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1077-Attach-1.DOC

#1077

February 19, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of Walgreens, a community retail pharmacy located at 826 North Main Street, Shelbyville, TN, 37160. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Tripp York
156 Maupin Circle
Shelbyville, TN
37160

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Bart Gordon

Submitter : Dr. Greta Goldshtein **Date:** 02/19/2007

Organization : Roxbury Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As community pharmacists, we are continously struggling to provide quality patient care in an environment of ever-shrinking reimbursements. Plans are often not even covering the cost of the medication dispensed, let alone the cost of the vial, label, man-power, rent, and other overhead costs! Never mind any return on our investment into our business! Patients are being forced into impersonal mail-order situations, but they continue to rely on the neighborhood pharmacist for the quality patient information they have always obtained from us. AND we are asked to provide this valuable service free of charge.

We deserve to have the cost of our operations covered by the insurance companies that we work with, PLUS a professional fee. Instead, we face ever-shrinking reimbursements, under one guise or another.

This is one more attempt to cut the reimbursement to the pharmacist, further jeopardizing our ability to provide patient care.

Submitter : Mark Kinney **Date:** 02/19/2007

Organization : Independent Pharmacy Cooperative

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

February 19, 2007

VIA ELECTRONIC SUBMISSION

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

CMS file code: CMS 2238 P

Federal Register
Publication Date: December 22, 2006

Re: Prescription Drugs

Dear Acting Administrator Norwalk:

Thank you for the opportunity to comment on the proposed regulations governing the definition of retail class of trade and determination of AMP. The Independent Pharmacy Cooperative (IPC) represents the interests of pharmacist owners, managers, and employees of more than 3200 independent community pharmacies across the country.

The Reason for Ensuring that AMP be an Accurate Reflection of Retail Pharmacy Acquisition Cost

The Average Manufacturers Price (AMP) and the resulting Federal Upper Limit (FUL) impacts not only government Medicaid programs, but now has the far reaching effect of substantially impacting the entire private marketplace as well. Therefore it is essential that the FUL represents an accurate determination of pharmacy s actual acquisition cost. Former CMS administrator McClellan already backed away from posting incorrect AMP data, stating, "They just aren't the right numbers to use&We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement.

GENERAL

GENERAL

See Attachment

CMS-2238-P-1079-Attach-1.DOC

1. Rationale Against CMS Redefining Average Manufacturer Price to Lowest Manufacturer Price

In light of a recent Government Accountability Office (GAO) report (*GAO-07-239 Medicaid Federal Upper Limits, December 22, 2006, hereinafter "GAO report")*, it appears that CMS' initial determination at a proper FUL, based on its newly proposed definition of AMP, falls significantly short of an accurate mark. In that report, dated December 22, 2006 the GAO issued a strong rebuttal to CMS's contention that retail pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure.

The GAO report found that on average, FUL, defined as a ceiling of 250% of the proposed lowest AMP for the drug, was still on average 36% below the acquisition cost to pharmacies. CMS notes that rebates were not included in the GAO analysis. However, where independent pharmacies do receive rebates, the amount would not off set this significant short fall.

Most importantly, the issue of generic drug availability makes the CMS defined Lowest Manufacturers Price unworkable. As smaller generic manufacturers seek to capture market share (many from outside the United States, i.e., India) they would be willing to enter the market with a discounted price of 20-30% in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity**. These small generic manufacturers, (and the larger manufacturers as well) do not have the capacity to provide more than just a percentage of the Medicaid population's utilization. This effectively would require many pharmacies to acquire the product at a cost that is significantly higher than the LMP. To mitigate this outcome is the reason the statute defines manufacturer's price as the average. We would ask CMS to apply the plain meaning of the statute and utilize Average Manufacturer Price in their calculation.

It is also foreseeable that this process will stimulate more frequent generic conversions. The multiplicity of dosage shapes and sizes used for a single patient may contribute to a higher potential for medication misadventures, reduced patient confidence and compliance.

2. Retail Pharmacy Class of Trade Definition

IPC requests that CMS change its proposed definition of "retail pharmacy class of trade", proposed 42 CFR Sec. 447.504(e) at p. 130 as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, and traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy. This definition currently encompasses over 55,000 retail pharmacy locations.

In passing the DRA, Congress also gave CMS the authority to create a workable definition of AMP.

IPC requests that CMS adjust its proposed definition of AMP, 44 CFR Sec. 447.504 (a) as follows:

(a) AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the federal Food, Drug, and Cosmetic Act) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include retail pharmacy sales only (chain and independent); volume discounts related to retail pharmacies; AMPs for authorized generics; charge-backs to the extent paid to retail pharmacies; contingent free goods; and only adjustments that reduce the actual price paid by retail pharmacy.

IPC recommends that the following elements, which retail community pharmacy does not receive, be excluded from the calculation of AMP:

- Discounts, rebates and price concessions to PBMs/Mail Order
- State supplemental, state only and SPAP prices
- FFS/depot
- Non-contingent free goods
- Price adjustments that do not affect the actual price paid by retail pharmacy

3. The Rational Against Inclusion of PBM Price Concessions and Mail Order Rebates in the Definition of "Retail Class of Trade"

The Omnibus Reconciliation Act of 1990 through amended Section 1927 of the Social Security Act (the Act), created the Medicaid Drug Rebate Program. The rebate legislation became effective on January 1, 1991. **CMS has indicated that the program affords state Medicaid programs the opportunity to pay for drugs at discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers.** The rebate agreement attaches to sole-source drugs (new, under patent with no generic equivalents); and innovator multiple-source drugs (drugs that have new-drug FDA approval for which generic equivalents exist). **The rebate also includes non-innovator multiple-source generic drugs at 11%.** The purpose of the rebate for both brand name and generic medications is, and has been since its inception in 1991, to ensure that the government is buying in the marketplace like other large private purchasers. The proposed rule would result in the government "double dipping" by realizing the cost benefit on the front-end reimbursement to pharmacies and the back-end manufacturer rebate.

The PBM/mail order pharmacy business model today is so closely interrelated that the ability to distinguish between price concessions, discounts, rebates and fees of the two entities would likely be impossible.

Mail order pharmacies are frequently owned and/or operated in the HMO and "closed model" systems that are not available to the general public.

In addition, due to the transient nature of the Medicaid population, the mail order pharmacy model has not been found to drive savings and therefore has not been adopted by almost the entirety of state Medicaid programs. Since mail order pharmacies do not service this population, they should not be included in the definition of "retail class of trade".

IPC would recommend that PBM/Mail Order price concessions, discounts, rebates and fees not be included in the "retail class of trade" definition.

4. CMS is Setting an Unrealistic Threshold for Outlier Prices in the FUL Calculation

CMS proposes to set the FUL based on the lowest AMP, as long as that AMP is not more than 70 percent below the second lowest AMP for that drug.

It is particularly harmful to set an exclusion of outliers at an AMP that is so much less (70%) than the next lowest AMP. A reasonable outlier exclusion would be no more than 20%.

5. According to the CBO, CMS's Costs Savings Assume that States will Increase Dispensing Fees. If the States do not do so, then Pharmacy Reimbursements will be so Inadequate that Most Pharmacies will not be able to Participate in the Medicaid Program.

From *Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932 Deficit Reduction Act of 2005 Conference agreement, as amended and passed by the Senate on December 21, 2005*:

Based on administrative data on AMPs and prescription drug spending by Medicaid, CBO estimates that those provisions would reduce Medicaid spending by $3.6 billion over the 2006-2010 period and $11.8 billion over the 2006-2015 period. **Those savings reflect CBO's expectation that states will raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid.** The estimate also accounts for lower rebates from drug manufacturers resulting from increased use of cheaper generic drugs.

CBO does not reveal to what degree it "expects" states to raise dispensing fees when it calculates its numbers. A study recently completed by one of the four largest world-wide accounting firms, Grant Thornton, has found that the average cost to dispense in the nation was $10.50. As the current average dispensing fee among the states is only $4.50, states will be highly challenged to provide an adequate reimbursement to pharmacies, consistent with the documented cost.

6. Definition of "Dispensing Fee" needs to be Inclusive of the True Costs to Pharmacists/Pharmacies to Dispense Medicaid Drugs.

An adequate Dispensing Fee definition includes the true costs of: 1) valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling: communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and 2) other real costs such as rent, utilities and mortgage payments. Perhaps most importantly, pharmacies provide important health, safety and counseling services 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 outcome for the patient.

IPC accordingly recommends that the dispensing fee definition section of the final rule be written as follows:

42 CFR Sec. 447.502 Definitions.

Dispensing fee means the fee which:

Includes pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to any reasonable costs associated with:

Staffing costs: (a) salaries for pharmacists and technicians, and compensation to other employees such as managers and cashiers; (b) Licensure/continuing education for pharmacists and technicians.

Store operations and overhead: (a) rent or mortgage; (b) Cleaning, repairs, and security; (c) Utilities; (d) Computer systems, software ,and maintenance; (e) Marketing and advertising; (f) Accounting, legal and professional fees; (g) Insurance, taxes, and licenses; (h) Interest paid on pharmacy-related debt; (i) Depreciation; (j) Complying with federal and state regulations; and (k) Corporate overhead.

Preparing and dispensing prescriptions: (a) prescription dispensing materials (packages, labels, pill counters, etc.); (b) compounding the Rx when necessary; (c) special packaging (unit dose, blister packs, bingo cards) and special supplies (syringes, inhalers).

Assuring appropriate use of medication: (a) drug use review; (b) consumer/patient counseling; (c) consulting with prescribers, (d) disease management, and (e) education/training.

Adjustment for medical inflation.

A reasonable profit margin to ensure business viability.

7. IPC Supports the use of NDC 11-Digit Codes for Reimbursement Purposes

CMS states that the National Drug Code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For the purpose of this subpart, it would mean the 11-digit code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code) (p. 19). Identifying package size for reimbursement purposes should lead to a more accurate measurement of acquisition costs – i.e. the cost to pharmacy to purchase the medications.

Pharmacies already maximize product buying decisions. For example, an independent pharmacy would like to buy drugs in 1000-count package sizes in order to take advantage of the economies of scale that exist with the larger package size. However, that medication may be used infrequently. A pharmacist that bought the 1000-count size for such a medication might have to destroy significant amounts of unsold medications. In these situations, switching to an 11-digit NDC would fairly reflect the efficient purchasing of pharmacies.

8. IPC Advocates "Smoothing" of AMP Data

There are frequent, sudden changes in drug prices that are not accurately captured by the currently contemplated reporting period. Indeed, prices change on a daily basis, reflecting market place availability and the number of manufacturers supplying the product in question.

Under monthly pricing, 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. Invoicing to community pharmacy, however, continues to change daily.

Since frequent changes in drug prices and corresponding changes in AMP could negatively impact community pharmacists. Purchase prices could turn out to be significantly higher than reimbursements that are received after purchase and filling of the prescription. To lessen this unfair outcome, "smoothing" of AMP data is necessary because failure to average out AMP pricing could result in significant fluctuations from month to month. IPC recommends that CMS develop a "smoothing" process for AMP.

Respectfully,

Mark Kinney, R.Ph.
Vice President of Government Affairs
Independent Pharmacy Cooperative

Submitter : Mr. George Warren **Date:** 02/19/2007

Organization : Bay Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

First Medicare Part D and now AMP as a boggus cost base for Medicaid payment. How much worst can it get!

I am a second generation pharmacist practicing in Florida. My father and I own and operate four pharmacies. Medicare Part D just forced me to close one of them and I fear the other three are not far behind.

Gross margins have dropped over 10% since January 2006 and will continue to drop should AMP regulations become reality.

Community pharmacists,like myself, perform many valued services to our client base. Patients forced into mail order programs still count on me to help them when medications are delayed in the mail. I could say no and make them wait without meds, however, compassion and responsiblility are two of the biggest problems with today's managed care models.

Seven of my employees will loose their jobs on March 31st; I am sick over this. I am telling the world that Medicare Part D closed this pharmacy. Our government representatives need to understand the impact that their vote has.

Say NO to the use of AMP as the cost basis for Medicaid!

There are much better ways to produce cost savings in health care.

Could you maintain a business that looses money every transaction? The GAO report on AMP estimates that pharmacies will loose money on every transaction that uses AMP as a base for reimbursement.

You have created a monster here. Time to regroup and throughout AMP!

Submitter : Dr. Chester [Chet] Yee **Date:** 02/19/2007

Organization : Menlo Park Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am an independent pharmacy owner, and note that the formula for AMP
will impact my processing prescriptions at the below y cost levels that AMP will impose. The average dispensing fee per prescription for
my pharmacy is around $11.00, because of the services that I provide my patients. To fill prescriptions for my patients, I need a fair and
accurate cost of goods and an adequate dispensing fee. For many years I have allow the lower reimbursement I received for medicare/medicaid patients up to now.
If the new AMP is imprelemented
I will lose money on every medicare/medicaid prescription I fill.
The formula for AMP-based Federal Upper Limits [FULs] in the proposed
rule will not cover my pharmacy's actual acquisition costs for generics. To be appropriate, the AMP must be defined to reflect the actual cost paid by my retail
pharmacy. this could be accomplished by
excluding all rebates and price concession made by manufacturers which are NOT avilable to retail pharmacies such as mine.
And also excluding all mail order facilities and PBM pricing from AMP
calculation. Mail order facilities and PBMx are extended special prices from drug manufacturers, which are not available to independently owned pharmacies.

Submitter : Spencer Smith **Date:** 02/19/2007

Organization : Spencer Smith

Category : Pharmacist

Issue Areas/Comments

Background

Background

I've been a registered Pharmacist since 1992. I've run a pharmacy in a small town since 1994. I've had ownership in it since 1998. We opened a second pharmacy in 1995. It is yet to become profitable. I would like to purchase or open a couple more stores. As expected all this will be put on hold to the effects of this are seen.

Collection of Information Requirements

Collection of Information Requirements

This is concerning the provisions of the AMP pricing calculation.

GENERAL

GENERAL

It doesn't take a rocket scientist to figure this out. We're at the bottom of the chain to provide medicine to patients. We're operating on less than 5% profit. We read in the paper that all the PBM's are having record profits. They get rebates from manufactures. So do the states. They operate with profits in the 20% range. Why not cut the money from the PBM's who are making the most money in this situation? Why not get rid of them entirely? Why pay their CEO millions when that money could go to heathcare? It makes too much "cents" and the PBM's have the "cents" to keep the money going into their pockets and out of ours!

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I don't fill that all the information has properly been collected and released from and to the people that this will impact the most.

Regulatory Impact Analysis

Regulatory Impact Analysis

Once again CMS is cutting reimbursement from the wrong people and providers.

Response to Comments

Response to Comments

I believe that many independent pharmacies will be forced to close. The ones likely to be closed are in the rural areas where I am. There will be many people who can't get there medicine w/o driving 20mins. Many people can't do this easily and will not take medicines that they need. This will then lead to more doctor visits and hospital stays. What pharmacies stay in business will have to operate with less help. This leads to more unemployment. This will also lead to more medical errors. This will all cost more than the money they save by reducing our reimbursement below our costs.

Submitter : Mrs. Mary Montenery **Date:** 02/19/2007

Organization : The Medicine Shoppe 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. I understand the the payment I would receive for the drugs I buy would be far below what I actually pay for the drugs. If this becomes a reality, then it will not be possible for me to continue to fill prescriptions for Medicaid patients. Many of my patients are covered by Medicaid. Most of them are physically or mentally impaired or limited in some way. I have a full-time courier who delivers prescriptions to patients' homes free-of-charge. Most of these patients are on Medicaid. They are the most needy and most dependent of my customer base. The services I provide are not available from chain drug-stores or mail-order pharmacies. Small independent pharmacies, such as mine, draw customers by providing superior services at little or no additional charge to the patient. Our pharmacies will, of course, close if we cannot make at least a small profit. It will then fall upon the tax payors to provide these services at a much higher cost.

A proper definition of AMP is the first step towards fixing this problem. I ask that the AMP be defined so that it reflects what we actually pay for the drugs we sell. To do otherwise seems to be a conscious attempt to destroy our businesses. We work hard for very small profit margins and we deserve fair treatment.

Submitter : Mr. Scott Watts **Date:** 02/19/2007

Organization : Mr. Scott Watts

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit my comments to the Centers for Medicare and Medicaid Services (CMS) recarding 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 Juneau Alaska. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Remove PBM and Mail order from retail class of trade

2. Implement a trigger mechanism

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

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

Sincerely,

Scott Watts R.Ph.

Submitter : Mr. GLENN STOKEM **Date:** 02/19/2007

Organization : GLENN'S PHARMACY, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I own a independent pharmacy in a rural area of upstate New York. The formula for AMP will not cover my acquisition costs. AMP should not serve as a basis for reimbursement. AMP should exclude all manufacturer rebates not available to retail pharmacy and exclude mail order and PBM pricing as this pricing is not available to retail pharmacies. NY State has no intention of increasing prescription dispensing fees. The federal government should be encouraging generic drug dispensing not making it financially impossible to do. If this regulation goes into effect on July 1st we will have no choice but to pull out of the medicaid program. This will be a great hardship to the medicaid clients in our area will now have a 30 to 40 mile trip to the next nearest pharmacy. Washington should not be making it harder for people to get basic health care. This is a cold hearted regulation that will hurt many people in rural areas. Dropping out of the medicaid program is not a decision I am considering lightly. No business can remain viable by selling items below cost. This includes retail pharmacies. I feel that pharmacies should be encouraged to dispense generic drugs, not penalized for it. I realistic reimbursement level for generic drugs that encourages the dispensing of generic drugs will ultimately save the medicaid program money.

Submitter : John Skovmand **Date:** 02/19/2007

Organization : John Skovmand

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1086-Attach-1.DOC

#1086

To: Leslie Norwalk
Acting Administrator, CMS

AMP (Average Manufacturer Price) is intended to approximate the drug product cost component for Medicaid prescriptions dispensed. The proposed formula for calculating AMP is flawed because it includes discount pricing to mail order dispensaries and doctors, which is immaterial and irrelevant as neither of these classes of trade dispense medications under Medicaid. All Medicaid prescriptions are dispensed by community pharmacies, which do not have access to the special pricing given to these classes of trade. Additionally, rebates that are paid to pharmacy benefit managers are not available to community pharmacies. These discounts should be removed from the calculation of AMP.

RSP (Retail Survey Price), as currently proposed by CMS includes pricing from mail order and nursing home pharmacies which artificially and unjustly skew the price downward as noted above.

It is unreasonable to believe that the individual states will make up the difference between actual product cost and the artificially low reimbursement proposed by CMS by increasing the dispensing fee.

AMP attacks generic drug dispensing, the most cost effective way to treat many patients. If dispensing generics causes pharmacies to loose money, they will turn to more expensive name brand drugs, which will drive the Medicaid budget higher.

If pharmacies cannot cover their cost of doing business, they will stop filling Medicaid prescriptions. Where will those Medicaid patients go? They will go to hospitals and emergency rooms, which are much more costly alternatives, driving the Medicaid budget higher still.

My pharmacy's business is 20% Medicaid. If we loose 20% of our business because of unreasonably low reimbursement, some of my employees will be out of a job and onto welfare and Medicaid.

Pharmacies are already bearing the brunt of the Part-D burden through lower reimbursement rates. It is unreasonable to balance the Medicaid budget on the backs of pharmacies.

I urge CMS to redefine AMP and RSP, as described above, to more accurately approximate the cost of products dispensed to Medicaid patients, to provide a fair and just reimbursement to pharmacies for the care they provide to Medicaid patients.

Sincerely,
John Skovmand, Pharmacist
Seeber's United Drug
110 W. Harvard Blvd, #H

Santa Paula, CA 93060

Submitter : **Mrs. Peggy Harmon** **Date: 02/19/2007**

Organization : **McLeskey-Todd Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

February 19, 2007

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

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

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

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

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

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

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

Sincerely,
Peggy Harmon

Pharmacist name

cc. Members of Congress Gresham Barrett, Bob Inglis, Sen. Jim DeMint

Submitter : Mr. Lane Call **Date:** 02/19/2007

Organization : Individulal Practicing Pharmacist

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

ATTN Leslie Norwalk

Having owned a independent pharmacy for 40 years and at the end of that time saw then dim future for independent pharmacy. I was working harder to service may customers and receiving less because the Bigs (Mail order, hospital outpatient, and outpatient clinics) could receive better price on their inventory. They made an un-level playing field just because they had consolidated there money and could throw weight to manufactures and receive a lower price. Government is promoting unfair competition.

Lane Call, Pharmacist
Layton, Utah

Submitter : Dr. Kristi Miller **Date:** 02/19/2007

Organization : TPA

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Please 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. JOHN BLACK **Date:** 02/19/2007

Organization : Mr. JOHN BLACK

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. Babulal Bhorania** **Date: 02/19/2007**

Organization : **K & S Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1091-Attach-1.DOC

1091

CMS File Code: CMS-2238-P
Rule Title: Medicaid Program; Prescription Drugs
Federal Register Publication Date: December 22, 2006

Dear Leslie Norwalk,

I am deeply concerned with the new act that is being proposed and would like to submit my strong opposition to it as a private Pharmacy owner. If this law is put into place it will be impossible for private Pharmacies, like my own, to survive. This law will cause us to lose money and force patients to turn to retail chains. Many patients who come to K & S Pharmacy are registered in the Medicaid drug program and therefore will impact my Pharmacy very negatively. I strongly urge the board not to support and implement this proposition. Thank you for your time.
Sincerely,
Babulal Bhorania

Submitter : Dr. RANDY ELLISON **Date:** 02/19/2007

Organization : VALU-RITE PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

--I am a community pharmacist and owner with 36 years of experience in retail pharmacist.I have owned my own business(s) since 1980.I consider myself fairly well-informed on pharmacy matters and belong to several professional organizations.

I am commenting on this AMP issue because I think it is one of the most mis-guided "projects" that my profession has had to face in my 36 years of experience.The current plan will not work for many reasons.I am sure that by now,you have been informed of most of those reasons by our professsional organizations.Please investigate the facts as they are being told to you by these organizations.First of all,AMP was never intended to be used a method of calculating payment to anyone.It does not "figure in " all the variables that occur in the pharmacy market place....i.e.,it doesn't include mail-order pharmacy prices in retail pharmacy class of trade,or include PBM rebates,discounts,etc.for drugs,treatment of manufacturer coupons,or several other pricing issues.

At this date,we don't have all the figures in for how badly retail pharmacy did in 2006 due to Medicare plan D and the continuing regression of reimbursement from PBMs,so I think it is too soon to be formulating any new "hits" on the retail pharmacy sector.

Please look at the recent GAO findings on how this ruling would effect retail pharmacy....it would be devastating!!There needs to be a fair and comprehensive study(and I think some are being done right now!) on what the actual "cost of dispensing" a prescription is.Take those findings and work with that to formulate a method that is fair for this profession that has served the general population so well.

Thanks for the opportunity to speak and please call on me to discuss this matter further....

Randy Ellison
rellison@optilink.us
Valu-Rite Pharmacy
Dalton,Ga.
ph.706-217-2700

GENERAL

GENERAL

--Please see the background section...that has my comments in it!!

Submitter : Karen Gallus **Date:** 02/19/2007

Organization : Karen Gallus

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 19, 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 submiting these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacist at Unity Community Pharmacist in Fridley, MN. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

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

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

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

Sincerely,

Karen Gallus Pharm.D.

Submitter : **Dr. christian riffert** **Date: 02/19/2007**

Organization : **The Beaverton Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

A general summary is provided in this section on the debate about including nursing homes and mail order pharmacies in the calculation of AMP. Much of this debate is based on the "pharmacy industry believing that these pharmacies pay less for their drugs than do retail pharmacies, and thus inclusion of such prices would lower AMP below the price paid by such retail pharmacies." I commend your thoughtfulness regarding this subject and wish to further elaborate why this is. First, there is not a level playing field, pharmacies must operate independantly and are prevented BY LAW from organizing and negotiating for better rates. Also, many mail order pharmacies are, or have been owned by the very drug companies that report there AMPs to CMS. For example, MerckMedco, recently spun off to the Medco PBM away from direct Merch ownership, no doubt will realize artificially low prices on drugs purchased from Merch pharmaceutical manufacturer. Additionally, mail order pharmacies are able to purchase large volumes of drugs, therefore obtaining lower prices. How is this done, by dispensing large volumes of prescriptions very efficiently-- efficiently as can be because they are not "bothered" by patient distractions such as counseling patients on appopriate use of drugs (as required by OBRA'90), or by being reachable for patient questions, a core service provided by community pharmacists virtually FREE OF CHARGE. Try calling another professional and having your questions readily answered within minutes of being asked for no fee as a community pharmacist would, then try calling a mail order pharmacy and talking to anyone about anything and it can easily be seen that mail order pharmacy is not indicative of the retail pharmacy trade as a whole.

It is also stated that manufacturers find it difficult to capture data relating to PBM pricing and how it relates to AMP. This could be because there is NO TRANSPARENCY involoved in PBM price negotiations, as well as the rest of their business practices. They operate in a void with little regulation, often practicing medicine and pharmacy by dictating what medications their members will be on. This lack of transparency is apparent when it is stated in this proposed rule that it is unknown how much of the rebates are passed from the PBM to the insurer and to the pharmacies. Let me be perfectly clear that NONE is passed on to pharmacies. And that an unknown amount is passed on to insurers. It would be interesting to see if the federal government could even discover this figure.

GENERAL

GENERAL

This act is largely a folly that will not accomplish it's aims. First, the recent GAO report showing that pharmacists will lose approximately 40% from the acquisition cost of generic drugs if this act is implemented, as is, while leaving brand name drugs untouched shows the ineptness of what the act is trying to do. If pharmacists are losing money on generics will it be any surprise when they encourage physicians and patients to take brand name drugs which will be the only drugs that pharmacists can dispense and still make money on? And, in so doing, would this not end up further increasing costs? That is assuming that any retail pharmacies would even continue to participate with these paltry reimbursement rates (of which my pharmacy will not) that would not even cover the acquisition cost of the drugs that we purchase much less our time counseling the patient and overhead associated with filling the prescription. We would essentially be paying to do the work. Hardly a motivating cause for pharmacists to provide services. In effect, this act would eliminate almost all retail pharmacies from filling prescriptions for programs that use this form of AMP calculation in their reimbursement formula, and those that continued to do so would surely not stay in business long if they lost money filling the prescriptions. When brand name utilization is at record highs, and no retail pharmacies remain open, will the deficit reduction act have met it's proposed goals?

The biggest problems I can see with this bill is that generic drug utilization, the very drugs that cost pennies to dollars to buy, will be in the cross hairs. These are the drugs that should be MANDATORY for all medicaid recipients to be on. They should not only be incouraged to be on these drugs, but Brand name drugs should not even be allowed it a gencric is available. Our local county health plan does this on a daily basis by implementing a formulary that is generic intensive. This is able to be done because there are generics in almost every class of drug that can be given in place of brand drugs. When there is not, the physician can make a request for the brand name drug. In so doing, their prescription costs, while unknown to me, would be fractions of the costs of plans that cover many brand drugs (even with rebates). Targeting pharmacies where margins are often less than 1-2% on brand name drugs, and then further cutting profits on the only drugs that are cost effective (generics) is a prescription for disaster, as opposed to deficit reduction.

Submitter : Dr. Jay Currie **Date:** 02/20/2007

Organization : Dr. Jay Currie

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

I agree that we need to do all we can to get the best price for medications being reimbursed by the government. However, as described in this proposed rule, the method of determination of the AMP is intrinsically unfair to pharmacists. As an example, included in the calculation are rebates and other incentives paid to pharmacy benefit managers (PBMs) by manufacturers. Yes, this is a factor in the net cost of drugs, but this is money kept by the PBMs and these rebates are never seen by pharmacists. They are not passed on to pharmacists as they purchase the drugs from manufacturers or from wholesalers. The same is true of the non-market pricing that mail-order houses can obtain which are not available to other pharmacists. It is not fair to reimburse pharmacists based on a pricing structure that is not available or even applicable to them. As a measure of this unfair structure, the GAO issued a report, GAO-07-239R, December 22, 2006, indicating that by using the proposed formula, pharmacists would be reimbursed 36% less than their acquisition costs for a drugs. Further reduction in this reimbursement as the President has proposed in the 2008 Federal Budge would result in disasterous consequences to the drug distribution infrastructure in this country. Additionally the Chief Counsel to the HHS Inspector General testified before the House Oversight and Govt Reform Committee on 2/9/07 regarding how pharmaceutical companies and middlemen in the drug pricing system manipulate prices withing the health care system. This is done to their gain. Pharmacists are often significantly disadvantaged in this system and the government ultimately pays more for drugs as well. A system needs to be put into place for drug pricing that leverages the best price from the drug manufacturers, not from pharmacists who cannot buy the drug at that best price.

GENERAL

GENERAL

I am writing to express my concern regarding the proposed CMS calculation of average manufacturer price (AMP) in the determination of federal upper limit (FUL) for reimbursement as described in [CMS-2238-P].

How can reimbursing at less than acquisition cost, with the small fees paid in addition to this cost be fair to the care providers. They cannot keep a practice open loosing money on each transaction.

The proposed rule expresses concern over government price-fixing of drug prices. However, given the reimbursement paid to pharmacists by Medicare Part D, PDPs and under this system for Medicaid implementation by the States, for a large share of the market, the government is fixing prices for what is paid to the care provider. This concern should also be noted.

Given the complexity in our health care reimbursment system, we need reform in how pharmacists are reimbursed for product dispensed to beneficiaries. The current system has not intrinsically changed since prior to computers being used in the process. The technology is available today to take the pharmacists out of the middle of this transaction and optimize the pricing leverage that should be in the system.

I would urge you to consider this type of reform, but in the mean time, we must be extremely cautious in further punishing the pharmacist in this process. The PBMs are making more from processing the claims than the pharmacists are in providing product and services to the beneficiary. There is considerable money to be saved in the system, but it is not from the pharmacist, it is from the drug companies who set the prices to the pharmacists, and from the PBMs who set the reimbursement to the pharmacists. Let's go where the money is!

Pharmacists have born an unreasonable financial burden in the implementation of the Medicare Drug Card Program and in the final implementation of the MMA Medicare Part D Program. This change in Medicaid reimbursement will dramatically impact the drug distribution infrastructure in this country and will negatively impact access to care for all in this nation, especially in rural areas. I urge you to re-evaluate these proposed rules and engage pharmacists to assist in developing a strategy to go after the real savings to be had in the system.

I offer you my assistance and the assistance of pharmacy's professional organizations in this effort.

Jay D. Currie, Pharm.D.
102 Ink Road NW
Mount Vernon, IA 52314-9722
319-895-8518

Submitter : Mr. Reid Barker **Date:** 02/20/2007

Organization : Utah Pharmacists Association

Category : Pharmacist

Issue Areas/Comments

Background

Background

The Utah Pharmacists Association (UPhA) is a State Pharmacy Organization that represents over 450 Chain and Independent retail pharmacies in the state of Utah. These pharmacies provide prescription services to Medicaid and Medicare patients in urban, suburban and rural communities. Prescription services are also provided to non-Medicaid and Medicare patients through contractual agreements with PBM s, regional and national health plans and various governmental organizations.

As a group, UPhA is concerned that the proposed cuts to pharmacy reimbursement will impact the ability of many Utah pharmacies to remain profitable and thus affect their ability to stay in business to serve Medicaid patients. In many rural areas, there is only one pharmacy for miles and it is an independent. If these pharmacies were to close their doors, the health care of all patients in these areas would suffer, especially Medicaid patients who may find more of a hardship to travel larger distances to obtain their prescriptions.

The proposed AMP based reimbursement will result in pharmacies dispensing Medicaid prescriptions below their costs. Independent retail pharmacy will be especially hard hit and 40% of all prescriptions are filled by Independent pharmacies. To remain competitive retail pharmacies have been forced to operate with ever eroding profit margins. These thin margins cannot support a cut of the magnitude that the AMP based reimbursement will impose. UPhA understands that budget cuts are imminent, but retail pharmacies should not be expected to subsidize the Medicaid budget.

It is the opinion of UPhA that CMS should issue a final regulation that protects Medicaid beneficiaries access to their local community pharmacist, creates incentives to use generic drugs, and strengthens the pharmacy infrastructure.

We appreciate the opportunity to share our comments.

GENERAL

GENERAL

Please see attachment.

CMS-2238-P-1096-Attach-1.PDF

1096

1850 South Columbia Lane, Orem, UT 84097

801-762-0452
801-762-0454 Fax
upha@upha.com

February 15, 2007

Centers for Medicare and Medicaid Services

File Cod: CMS-2238-P

Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Md 21244-1850

(42 CFR Part 447)

To Whom It May Concern:

The Utah Pharmacists Association (UPhA) is a State Pharmacy Organization that represents over 450 Chain and Independent retail pharmacies in the state of Utah. These pharmacies provide prescription services to Medicaid and Medicare patients in urban, suburban and rural communities. Prescription services are also provided to non-Medicaid and Medicare patients through contractual agreements with PBM's, regional and national health plans and various governmental organizations.

As a group, UPhA is concerned that the proposed cuts to pharmacy reimbursement will impact the ability of many Utah pharmacies to remain profitable and thus affect their ability to stay in business to serve Medicaid patients. In many rural areas, there is only one pharmacy for miles and it is an independent. If these pharmacies were to close their doors, the health care of *all* patients in these areas would suffer, especially Medicaid patients who may find more of a hardship to travel larger distances to obtain their prescriptions.

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It is the opinion of UPhA that CMS should issue a final regulation that protects Medicaid beneficiaries access to their local community pharmacist, creates incentives to use generic drugs, and strengthens the pharmacy infrastructure.

We appreciate the opportunity to share our comments.

Definition of Retail Pharmacy Class of Trade and Determination of AMP

CMS believes, based in part on the OIG and GAO reports, that sales and discounts to mail order pharmacies shall be included in the AMP price calculation along with independent and chain retail pharmacies.

Retail Pharmacy Class of Trade means that sector of the drug marketplace which dispenses drugs to the general public and which includes all price concessions (except prompt pay discounts) related to such goods and services. CMS proposes to exclude from AMP the prices of sales to nursing home pharmacies. CMS will include in AMP the prices of sales and discounts to mail order pharmacies. Inclusion of these lower mail order pharmacy prices would decrease AMP, thereby decreasing manufacturers current rebate liabilities the State Medicaid programs and other entities.

Comments:

Mail order pharmacies should be excluded for the following reasons:

1. ***All major mail order pharmacies in the U.S.A. are owned by PBM's. The alignment of the PBM, its customers and their mail order division permits them to leverage manufacturers for substantial rebates which are not available to retail pharmacies.***

2. ***CMS states that the exclusion of mail order and PBM prices would substantially reduce the number of transactions included in AMP. Mail order pharmacies provide some prescriptions to Medicaid patients PBM mail order companies provide approximately 20% of the prescriptions dispensed to the non-Medicaid market.***

3. ***Mail order pharmacies favor the purchase in very large package sizes (NDC-11) yielding the lowest per unit price in the marketplace. These package sizes are neither accessible to nor feasible in a typical independent retail pharmacy due to smaller sales volume, inventory management and return on investment factors. It is not economically feasible for small independent pharmacies to purchase large package sizes as a standard of operations.***

4. ***PBM's operate mail order facilities in the U.S.A. and they earn certain rebates, discounts and other price concessions that are not available to retail pharmacies. Inclusion of PBM price concessions in the calculation of AMP places retail pharmacies at a significant price disadvantage because these price concessions are not available to our pharmacies.***

5. ***PBM's do not distribute drugs except through their privately owned mail order facilities. Drugs dispensed and distributed through retail pharmacies are purchased and owned by the retail entities. PBM's "credit" their sales revenues as if they own the inventory, but they do not. Rebates earned by a PBM for sales of drugs at the retail pharmacy are not, in any fashion, shared with the pharmacy.***

6. ***PBM's are <u>not</u> wholesale distributors therefore there is no method for distributing these lower cost drugs to the retail sector.***

As a result mail order pricing should NOT be considered in the AMP calculations.

<u>Conclusion:</u>

<u>If the Final Rule permits</u> the inclusion of mail order pricing in the <u>calculation</u> of AMP then these mail order pharmacies will have an unfair competitive <u>advantage</u> over retail pharmacy where 80% of consumers currently access these products.

<u>Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade-pg. 31-33</u>
<u>Inclusion in Best Price of PBM rebates, discounts and other price concessions-pg. 53</u>

<u>AMP Must Differ From Best Price</u>

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 should exclude rebates paid to PBMs from AMP calculations: These rebates are not available to our retail pharmacies, and indeed, none of these funds are ever received by our pharmacies. 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.

<u>How PBM price concessions should be reported to CMS-pg. 33</u>

<u>PBM Transparency is Necessary to Assess Manufacturer Rebates</u>

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. PBMs have been allowed, due to a lack of regulation, to keep most if not all of their information hidden, thus there is no transparency in the PBM Industry.

<u>Use of the 11-digit NDC to calculate AMP-pg. 80</u>

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 NDC code.

Our pharmacies already purchase the most economical package size as determined by individual pharmacy volume. They 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-digit NDC would NOT adequately cover pharmacy acquisition cost. ***The 11-digit NDC must be used when calculating the FUL.***

Financial Impact on Our Pharmacies

The GAO findings demonstrate the devastating impact the proposed rule will have on our pharmacies and especially our 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 state dispensing fees.

The impact on our 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 unlikely that Utah would set their Medicaid dispensing fee high enough to cover the average $12.39 per prescription cost of dispensing for Utah pharmacies as determined by the most recently completed Grant Thornton, LLP Cost of Dispensing Study.

UPhA would respectfully ask that CMS consider what is fair and equitable for retail pharmacies in determining what and how AMP should be calculated.

THREE OF OUR BOARD MEMBERS EXAMINED FINANCIAL DATA FROM THEIR PHARMACIES TO DETERMINE THE EXACT FINANCIAL IMPACT OF AMP ON GROSS AND NET PROFITS. The table below summarizes the data.

IMPACT OF AMP PRICING ON STORE PROFITS	**STORE A**	**STORE B**	**STORE C**
% of all prescriptions that are Medicaid	12.0%	2.8%	7.2%
% of dollar volume that is Medicaid	11.4%	2.5%	7.0%
% of Medicaid prescriptions that are Generic drugs	65.1%	61.9%	65.5%
Current average GROSS PROFIT per Medicaid RX			
Combined brand and generic drugs	$16.75	$17.42	$18.50
Brand drugs	$6.64	$14.00	$8.49
Generic drugs	$19.10	$19.54	$23.75
Proposed AMP gross profit per Medicaid Rx	$5.29	$8.13	$4.38
Proposed AMP effect on gross profit <Loss>	**<$169,150>**	**<$9,269>**	**<$35,026>**
Current net profit per Medicaid RX	$4.36	$5.03	$6.11
Proposed AMP net profit per Medicaid RX <Loss>	**$<7.10>**	**<$4.26>**	**<$6.59>**
Proposed AMP effect on net profit <NET LOSS> ***(Amount below pharmacy's acquisition cost!)***	**<$104,796>**	**<$4,247>**	**<$9,325>**

The following assumptions are made:

AMP is calculated as FUL (current cost minus 36%) times 150%
The Utah Medicaid dispensing fee will be increased by $1 from $3.90 to $4.90 (this is pure speculation at this point in time)
The current cost to dispense a prescription in Utah is $12.39 from the Grant Thornton Cost of Dispensing Study
The net loss is defined as the amount BELOW THE PHARMACY'S ACTUAL ACQUISITION COST!

THE DETAILS OF THE CALCULATIONS ARE PROVIDED BELOW.

STORE A (the average of two small pharmacies with one owner)

1. *Medicaid represents 12.0% of the total prescriptions dispensed and 11.4% of the total prescription dollar volume. 91% of the total dollar business in these two stores is prescriptions.*
2. *65.1% of all Medicaid prescriptions dispensed are generic.*
3. *Current average gross profit per Medicaid prescription is:*
    a. *Brand Prescriptions $6.64*
    b. *Generic Prescriptions $19.10*
    c. *Brand and Generic Prescription overall average gross profit $16.75 which allows for a $4.36 profit on each Medicaid prescription using the Grant Thornton $12.39 average cost of dispensing calculation for Utah pharmacies.*
4. *Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:*
    a. *$8.54 (average acquisition cost on each generic Medicaid prescription) x 36%=$5.47 (average FUL per generic Medicaid prescription)*
    b. *$5.47 x150% =$8.20 (average AMP per generic Medicaid prescription)*
    c. *$8.20 + $4.90 (current Utah Medicaid dispensing fee is $3.90 and it has been indicated to UPhA by the Utah State Medicaid Division that they are considering giving the pharmacies a $1.00 increase to cover AMP deficits) =$13.10 (average total reimbursement per generic Medicaid prescription)*
    d. *$13.10-$8.54 (current average acquisition cost of each generic Medicaid prescription)=$4.56 (average gross profit per generic Medicaid prescription after AMP is implemented)*
    e. *Brand and Generic Medicaid Prescription overall gross profit will be $5.29 per prescription after AMP is implemented. This will result in a net loss of $7.10 on every Medicaid prescription dispensed using the Grant Thornton Cost of Dispensing Study.* ***This will result in a net loss of $104,796 in total profit to these two small pharmacies.***

STORE B

1. *Medicaid represents 2.8% of the total prescriptions dispensed and 2.5% of the total prescription dollar volume. 96% of the total dollar business in this store is prescriptions.*
2. *61.9% of all Medicaid prescriptions dispensed are generic.*
3. *Current average gross profit per Medicaid prescription is:*
    a. *Brand Prescriptions $14.00*
    b. *Generic Prescriptions $19.54*

c. *Brand and Generic Prescription overall average gross profit $17.42 which allows for a $5.03 net profit on each Medicaid prescription using the Grant Thornton $12.39 average cost of dispensing calculation for Utah pharmacies.*

4. *Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:*
   a. *$9.63 (average acquisition cost on each generic Medicaid prescription) x 36%=$6.16 (average FUL per generic Medicaid prescription)*
   b. *$6.16 x150% =$9.24 (average AMP per generic Medicaid prescription)*
   c. *$9.24 + $4.90 (current Utah Medicaid dispensing fee is $3.90 and it has been indicated to UPhA by the Utah State Medicaid Division that they are considering giving the pharmacies a $1.00 increase to cover AMP deficits) =$14.14 (average total reimbursement per generic Medicaid prescription)*
   d. *$14.14-9.63 (current average acquisition cost of each generic Medicaid prescription)=$4.51 (average gross profit per generic Medicaid prescription after AMP is implemented)*
   e. *Brand and Generic Medicaid Prescription overall gross profit will be $8.13 per prescription after AMP is implemented. This will result in a* ***net loss of $4.26 on every Medicaid prescription dispensed*** *using the Grant Thornton Cost of Dispensing Study.* ***This will result in a net loss of $4,247 in total profit to this small pharmacy.***

STORE C

1. *Medicaid represents 7.2% of the total prescriptions dispensed and 7.0% of the total prescription dollar volume. 97% of the total business in this store is prescriptions.*
2. *65.5% of all Medicaid prescriptions dispensed are generic.*
3. *Current average gross profit per Medicaid prescription is:*
   a. *Brand Prescriptions $8.49*
   b. *Generic Prescriptions $23.49*
   c. *Brand and Generic Prescription overall average gross profit $18.50 which allows for a $6.11 profit on each Medicaid prescription using the Grant Thornton $12.39 average cost of dispensing calculation for Utah pharmacies.*
4. *Using the GAO estimate that AMP will be 36% below the acquisition cost that the pharmacies can purchase their generics at:*
   a. *$12.82 (average acquisition cost on each generic Medicaid prescription) x 36%=$8.20 (average FUL per generic Medicaid prescription)*
   b. *$8.20 x150% =$12.30 (average AMP per generic Medicaid prescription)*
   c. *$12.30 + $4.90 (current Utah Medicaid dispensing fee is $3.90 and it has been indicated to UPhA by the Utah State Medicaid Division that they are considering giving the pharmacies a $1.00 increase to cover AMP deficits) =$17.20 (average total reimbursement per generic Medicaid prescription)*
   d. *$17.20-12.82 (current average acquisition cost of each generic Medicaid prescription)=$4.38 (average gross profit per generic Medicaid prescription after AMP is implemented)*
   e. *Brand and Generic Medicaid Prescription overall gross profit will be $5.80 per prescription after AMP is implemented. This will result in a* ***net loss of $6.59 on every Medicaid prescription dispensed*** *using the Grant Thornton Cost of Dispensing Study.* ***This will result in a net loss of $18,181 in total profit to this small pharmacy.***

Here are some **actual acquisition costs** of 10 random generic drugs. This is the average acquisition costs from the four pharmacies used in the example above. These are provided to CMS as a basis for AMP comparison only.

Drug name	Qty	Acquisition cost	Proposed AMP
Oxycodone/APAP 7.5/500	30	$12.13	$11.64
Mupirocin 2% Oint	22g	11.09	10.64
Diazepam 5 mg	60	1.45	1.39
Prenatal Plus	30	1.13	1.08
Amoxicillin 875 mg	60	19.14	18.37
Ibuprofen 800mg	90	3.36	3.22
Clonazepam, 1mg	90	4.34	4.16
SMZ-TMP DS	28	4.12	4.03
Hydrocodone/APAP 10/500	120	13.70	13.15
Hydrocodone/APAP 5/500	14	1.30	1.24
Totals		$71.76	$68.92

This table of acquisition costs shows that AWP will be **below** the cost of an average pharmacy. Now add a dispensing fee of $4.90 that is $7.49 below the average cost to fill a prescription ($12.39 per RX in Utah) and **the loss is only magnified.**

AS YOU CAN SEE FROM THESE CALCULATIONS, THE IMPLEMENTATION OF AMP AS IT IS CURRENTLY OUTLINED WILL HAVE A DISASTROUS EFFECT ON OUR PHARMACIES, ESPECIALLY ON OUR INDEPENDENT PHARMACIES.

UPHA AND THE PHARMACIES WE REPRESENT ARE WILLING TO HELP IN REDUCING THE COST OF HEALTH CARE TO THE AMERICAN PEOPLE AND ARE WILLING TO FURTHER INCREASE THE GENERIC UTILIZATION AND THERAPEUTIC SUBSTITUTION THAT WILL DRASTICALLY DECREASE THE COST OF MEDICAID PRESCRIPTION DRUGS.

IT IS OUR BELIEF THAT AMP WILL GREATLY DECREASE THE NUMBER OF RETAIL PHARMACIES IN OUR STATE AND THUS DECREASE PATIENT ACCESS TO HEALTH CARE FOR THOSE WHO NEED IT MOST. WE RESPECTFULLY ASK THAT CMS CONSIDER THE DETRIMENTAL OUTCOMES THAT WILL BE REALIZED IF AMP IS IMPLEMENTED AS CURRENTLY OUTLINED.

If you have any questions please feel free to contact our office.

Sincerely,

Reid Barker
Executive Director

Submitter : Mr. John Stenger Jr **Date:** 02/20/2007

Organization : The Medicine Chest Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Suggested change in cost basis for community pharmacy reimbursement from a discount from Average Wholesale Price to AMP.

GENERAL

GENERAL

With regard to the implementation of Medicare Part D in 2006, there are and have been concerns from various perspectives. From my perspective as a practicing community pharmacist, the implementing of Medicare Part D has put our area under increased financial pressure. While Part D may have considered a boon to other areas such as drug manufacturers, pharmacy benefit managers and insurance companies, I can not from my experience say the same for community pharmacy.

The proposed change in cost basis for the medications dispensed under Medicare Part D from a discount from Average Wholesale Price to AMP will make a bad situation for Community Pharmacy worse.

I believe pharmacies are providing a valid healthcare service. For us to continue to provide this valuable service we need fair reimbursement to cover costs related to providing our service.

I am requesting that community pharmacy not be penalized further by additional attrition in payment for the services we render. Please delve further into the profit structure of the insurance companies involved along with PBMs and have then share more equitably in fee reductions for their services as well

Submitter : Mr. Michael Jackson **Date:** 02/20/2007

Organization : Florida Pharmacy Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1098-Attach-1.DOC

#1098

Florida Pharmacy Association

Supporting Florida Pharmacy Since 1887

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 Florida Pharmacy Association (FPA) is the oldest and largest organization representing the profession of pharmacy in Florida. We would like to thank you for allowing us to provide comment to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of average manufacturer pricing (AMP) as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. This issue is extremely important to our state's pharmacy provider. Florida estimated population for the 2000 census is over 15 million according to the US Census Bureau. Of that 15 million nearly 2.8 million citizens in this state are over the age of 65. It is this population that is most affected by changes in pharmacy services.

While Florida has several urban population centers, this state also has a significant number of rural areas where the only health care provider available to deliver pharmacy services are family owned small businesses. While our comments are related to proposed regulations we have grave concerns on how these changes will affect the rural community pharmacies ability to care for the frail and the elderly. There are also other concerns that we have over the viability of those pharmacies providing specialty services in urban areas.

Summary

The Florida Pharmacy Association continues to support federal efforts that are designed to positively affect the affordability of and access to prescription drugs and healthcare professionals. Our profession has invested considerable resources and sacrificed operating margins to help our government implement the Medicare Part D program last year. 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 which address the methodology CMS will employ to determine AMP when the final regulation goes into

effect. The methodology set forth in §447.504 will create 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 will create 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 FPA 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 closed system pharmacies such as nursing home pharmacies (LTC) because they do not dispense to the general public. We would also include in AMP the prices of sales and discounts to mail order pharmacies."

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

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own

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

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Indeed there have been several attempts to move Medicaid patients to mail order services in this state of which we have not seen significant success. 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. FPA 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. The FPA 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

The Florida Pharmacy Association 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 the FPA generally believes 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 reetail 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, we have no evidence that 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. Small family owned pharmacies in rural communities cannot foresee such arrangements. 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 and 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 'clawback' 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

[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.

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

[3] §447.510(d)(2)

'rebate period' based reporting to manipulate AMP. Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual time-frame reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP.

Furthermore, this ability would exist for a period of three (3) years, the allowable time for revisions. This undue flexibility, afforded to find a market price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

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

The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the IG will act as a damper to market manipulation. The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanisms ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP.

Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

Record Keeping

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

Additional Comments

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

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be

restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

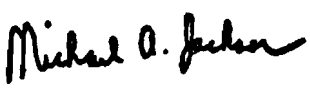
We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies.

Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

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

Thank you.

With kindest regards,



Michael A. Jackson, R.Ph.
Executive Vice President and CEO
Florida Pharmacy Association
610 North Adams Street
Tallahassee, Florida 32301
(850) 222-2400
mjackson@pharmview.com

Submitter : Dr. Dana Caldwell **Date:** 02/20/2007

Organization : Cobblestone Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1099-Attach-1.PDF

1099

Cobblestone Pharmacy & Compounding Center
Your "Good Neighbor" Pharmacy in Paradise
Dr. Dana B. Caldwell & Paul Vesely, Pharmacists

6585 Clark Road, Suite 100
Paradise, CA 95969
530-877-3712, fax 877-5739
Toll Free 1-888-233-9055
E-mail: cobblestone@pacbell.net

February 15, 2007

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

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

I am a sole proprietor of Cobblestone Pharmacy in Paradise, California and have been serving this community and surrounding areas for 33 years. I am writing to give my views on the new proposed regulation that would define AMP and implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

If the proposed regulation is adopted, I believe the changes in reimbursement will have a significant negative economic impact on my business. My ability to operate my business and pay the expenses to just stay in business is very questionable. My ability to provide pharmacy services to Medicaid beneficiaries and the general public will be severely curtailed.

This regulation should not be adopted in the present form; substantial changes and revisions must be made.

I have worked very hard to make the new Medicare Part D program viable and to provide the services to our elderly population who are the primary beneficiaries of the Medicare Part D program. That program and the limited and decrease reimbursement from the payers has already had a great impact on my business and now this proposed regulation is about to cut our reimbursement rate even lower. This has to stop...NOW.

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 that a traditional retail pharmacy is able to purchase medications. AMP should not include any "rebates" or "promotional incentives" paid by manufacturers to PBMs or Mail Order pharmacies. PBMs and Mail Order pharmacies are NOT traditional retail pharmacies serving their communities. These "rebates" and "promotional incentives" are not passed on to traditional retail pharmacies.

Release of flawed and inaccurate data concerning AMP will adversely affect community retail pharmacy if used for reimbursement purposes. CMS has already delayed release of this date and I urge that release of this date be delayed again.

Define AMP to Reflect Retail Pharmacy Purchasing Costs:

CMS' proposed regulatory definition is severely flawed because it does not reflect the prices at which retail pharmacies purchase medications.

EXCLUDE any PBM price concessions - rebates, discounts or other price adjustments provided by the manufacturer to the PBM.
EXCLUDE the prices of sales to Mail order pharmacies and any discounts they receive.
EXCLUDE any Medicare Part D sales of medications – rebates paid by the manufacturer to the PDP or MA-PD.
EXCLUDE SPAP price concessions
EXCLUDE Manufacturer coupons redeemed by any entity other than the consumer
EXCLUDE sales to hospital pharmacies, in-patient or out-patient.

Retail pharmacy does not benefit from any of these special pricing purchasing agreements or rebates. AMP should be calculated only for prices that traditional retail pharmacies who serve the general public pay for prescription medications.

Delay New Generic Rates that Would Significantly Underpay Retail Pharmacies:

The new Federal Upper Limits (FUL) will severely cut the rate of reimbursement paid to pharmacies; these cuts will be devastating to many retail pharmacies. Implementation of these FULs must be suspended. A recent GAO report found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new AMP-based FUL system.

Require that States Increase Pharmacy Dispensing Fees:

CMS should mandate that states increase dispensing fees paid to pharmacies to offset potential losses on generic drug reimbursement. 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.

Thank you for accepting these comments. I am a member of the American Pharmacists Association, the California Pharmacists Association and other pharmacy groups that are requesting that changes be made in the AMP regulation.

Sincerely,

Dana B. Caldwell
Dr. of Pharmacy

"Pill-er of the Community"...We Deliver Personal Service

CMS-2238-P-1100-Attach-1.DOC

CMS-2238-P-1100-Attach-2.DOC

CMS-2238-P-1100-Attach-3.PDF

CMS-2238-P-1100-Attach-4.DOC

Submitter : Stephen Floyd **Date:** 02/20/2007

Organization : Headland Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

The Government and CMS are in essence controlling the free enterprise market, by setting prices. and the prices as shown by the recent "Cost of dispensing" Study clearly show the AMP proposed rule will lower the reimbursement level to Pharmacies to the point a Retail independent Pharmacy such as the one I own will not be able to participate in government controlled programs, and will in effect drive me out of business.

Collection of Information Requirements

Collection of Information Requirements

Amp must be defined so as to allow an independent Pharmacy a cost basis which covers cost and allows a fair profit margin in order for a Pharmacy to remain in business. The Medicare Part D program has already sent windfall profits to the third party managers as touted by recent financial disclosures by PBMs such as Humana which stated profits soared. However due to Medicare Part D and take it or leave it non-negotiable contracts My Independent Pharmacy's profits are down by 4 to 5 thousand dollars per month in gross profits, not net which has also been grossly negatively affected.

GENERAL

GENERAL

Please listen to our Pharmacy leaders, they speak the truth!
The Following attachment addresses the issues more completely than I ever could. How can government ignore the facts below and continue to turn it back on the COMMUNITY PHARMACIST OF THIS UNITES STATES OF AMERICA?

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The GAO, Lobbyist from PBM's and insurance companies have totally misrepresented the plight of retail pharmacy, and our congressman have totally disregarded the survivability of Independent Retail Pharmacy in passing this not only the Medicare Part D program which has already caused many small town pharmacies to fail and have to close, while favoring the large insurance companies, and PBM' with executives for these companies making millions of dollars in salaries.

Regulatory Impact Analysis

Regulatory Impact Analysis

Comments made that Pharmacist make too much money, let me tell you for what a Congressman, and upper level government officials make and the number of hours put in a day on their job, let me tell you I absolutely feel all are grossly overpaid for the utility of services we receive. The time and the intensity of the job a pharmacist has to perform while on the job is astronomical compared to the job and intensity that government employees do.

Response to Comments

Response to Comments

The impact this continued assault on my Independent Small Town Pharmacy, will absolutely cause me to go bankrupt and have to close leaving a town of 8,000 with out a pharmacy in the town. Government creates these programs, and sets the rules, where is it written that an Independent Retail Pharmacy is not allowed to make a profit. Does the Government not allow the company that builds jet engines for our F-16' to make a profit, or the companies that have remolded the Capital to make a profit, or the secretaries who work for the government to be paid a salary that allows them to live, Why does government not allow Pharmacist to make a profit. The Reason is that government does not understand the retail Pharmacy business. What other business must pay its obligations in purchases every 2 weeks in full, in order to continue to order product to sell. Yet as in the Medicare Part D program Pharmacy is not paid nor was any provision made to provide payment in less than 30 days to Pharmacist for products and services. The Government has in effect created this problem of AMP, by government contracts with manufactures for DOD, VA and multi-tiered classes of trade. Thereby creating many levels of pricing by the manufacturers, for DOD, VA, Mail-order, and unregulated mail-order prescriptions from out of the country. If this AMP rule is put in effect you will finish destroying the long established Prescription distribution system which is the safest and most efficient system there is. Level the playing field on drug pricing by making the discounts extended to the PBM's and Mail-order, and Government contracts to retail pharmacy, and allow a reasonable profit structure as any business deserves. If government is going to get in business, the why not just nationalize all pharmacies create a GS rating for Pharmacist, give us government holidays, and government insurance, I would probably be better off, than where I am now trying to operate a single independent retail pharmacy with the yoke that government is placing around Pharmacies neck. At the present course, the Bush administration will leave a legacy of not just the "W" that turned the World upside down, but the administration that destroyed the Pharmacy distribution system of the United States of America. When Retail Pharmacy as we know it today is gone.....I wonder what will happen Drug Prices then, if you can even get a prescription filled.

 1100-3

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.

1100

Please listen to our Pharmacy leaders, they speak the truth!
The Following attachment address the issues more completely than I ever could. How can government ignore the facts below and continue to turn it back on the COMMUNITY PHARMACIST OF THIS UNITES STATES OF AMERICA?

OIG
From:
Charlie Sewell, Vice President, Government Affairs
Date:
March 16, 2006
Re:
NCPA Comments on AMP provisions of Deficit Reduction Act of
2005

The National Community Pharmacists Association (NCPA) appreciates your continued interest in community pharmacy. We also want to thank you for the time you took in our recent conference call to discuss the issues, challenges and problems arising from implementation of the Deficit Reduction Act of 2005 ("the Act"). At your request, we are providing you with this response and comments on implementation of the Act and how its problematic use of a nebulously defined benchmark could have significant, harmful effects on Medicaid recipients, community pharmacies, local economies and states.

NCPA's Request:

In sum, NCPA requests that: 1) you use your authority to ensure that the definition of AMP covers all of pharmacists' acquisition costs; 2) the study of pharmacy reimbursement called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the rules on implementing that Act no later than September 1, 2006 to provide adequate time for community pharmacies to prepare for the implementation of these major changes in the Medicaid program.

1

The Troubling Result From Using AMP:

NCPA represents the nation's community pharmacists, including the owners of more than 24,000 pharmacies that dispense nearly half of the nation's retail prescription medicines. Because many Medicaid recipients depend on their local community pharmacies to provide them with needed medication, NCPA is compelled to alert you to language in the Act that negatively affects the costs savings that could otherwise benefit drug purchasers, States and the federal government.

As you know, the Act greatly reduces pharmacy reimbursement on generic drugs for Medicaid prescription drug recipients. The law ties reimbursement to a price index known as the Average Manufacturers Price (AMP). Leading generic drug manufacturers estimate that, as currently defined by the Manufacturers Rebate Agreement, **AMP will, on average, only reflect 50% of actual ingredient**[1] **cost for generic drugs**. Considering the unknown reliability of AMP and insufficient dispensing fees, the planned Federal Upper Limit (FUL) as contained in **the Act will effectively gut the reimbursement for generic drugs** under the Medicaid program. In stark contrast, brand name drugs are unaffected, and will be the only drugs on which pharmacists will be able to recoup their costs.

The result of promoting the use of brand name drugs over generics would be very costly. For every one percent of market share filled with a brand name drug that could be filled with a generic, Medicaid – and thus needy beneficiaries and taxpayers – will lose hundreds of millions of dollars. The lowest generic fill rate among states failing to promote generic drugs is 42%. If AMP is not correctly defined, and if dispensing fees are not increased, the potential for savings from generic drug utilization will be lost. An inadequate reimbursement level and concomitant decrease in use of generics will drive many pharmacies from the Medicaid program. Access in rural areas of the country could be particularly

[1] The new Medicaid law requires that CMS disclose, starting July of 2006, the AMP pricing data to state Medicaid programs and the public. Unfortunately, the Secretary is not required to implement a regulation defining AMP until July 2007, one year after the AMP data are made public.

harmed. This resulting lack of access to quality prescription care will drive state Medicaid expenses
higher as more patients require emergency room or nursing home care.
This outline of resulting harm is realistic, yet difficult to quantify. Estimating the real financial impact
on retail pharmacies is extremely difficult because CMS has not publicly released AMP or issued clear
guidance on how manufacturers should calculate AMP.
Based on how AMP is currently reported by manufacturers, it is clear that harmful consequences would
follow from using the current AMP. NCPA respectfully urges you to use the wide statutory authority
granted HHS regarding the definition of AMP to ensure that it covers 100% of pharmacists' acquisition
costs. Doing so would ensure adequate reimbursements for generic drugs, thus promoting savings to the
government and the health care system.

Problems With Using AMP as the Bench Mark to Determine Reimbursement Amounts and Rates:

In theory, AMP data approximates the prices at which retail pharmacies purchase medications from
manufacturers via wholesalers.[2]
For various reasons that are discussed below, however, AMP data is
not at all likely to reflect the prices at which retail pharmacies purchase drugs. Because AMP was
created, and is used, as a benchmark for rebate payments paid by manufacturers to state Medicaid
programs, there is an inherent incentive on the part of the manufacturer to report the lowest price
possible – a price that does not reflect true market costs for community pharmacy.
This fundamental problem in creating, using and monitoring the use of AMP is manifest in the following
structural flaws:

- Currently, each manufacturer defines AMP differently, thus creating great inconsistencies in
what is reported to CMS. In a February 2005 study (GAO-05-102), the Government Accounting
Office reported that these inconsistencies are documented in the four Office of Inspector General
(OIG) reports on audits of manufacturer-reported prices since the programs inception in 1991
(the reports were issued in 1992, 1995, 1997 and 2001). The GAO reported that the OIG reviews
found "considerable variation in the methods that manufacturers use to determine AMP and

some methods could have reduced the rebates state Medicaid programs received." (GAO-05-102

[2] AMP is defined by statute as the average price paid to a manufacturer for the drug by wholesalers for drugs distributed to the real pharmacy class of trade. *See* 42 U.S.C. §1396r-8(k)(1). There is no definition in the statute for "retail pharmacy class of trade."

3

at p.5). Furthermore, "in four reports issued from 1992 to 2001, OIG stated that its review efforts were hampered by unclear CMS guidance on how manufacturers were to determine AMP, by a lack of manufacturer documentation, or by both." (*Id.*, p.4).

The GAO study found that **clear guidelines on how AMP is to be calculated have not been issued by CMS, nor has CMS resolved price determination problems.** "OIG found problems with manufacturers' price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved" (*Id.*).

- Examples of some manufacturers taking advantage of the opportunity to alter AMP include:
  - Sales to mail order pharmacies and nursing homes when calculating AMP. Because mail order and nursing homes pay lower prices than retail pharmacies, including them in the calculation lowers the AMP below the price a traditional retail pharmacy pays.
  - Rebates paid to health plans and Pharmacy Benefit Managers (PBMs) when calculating AMP. These discounts are typically extended to bulk purchasers such as chain pharmacies, major wholesalers, and mail-order facilities that buy directly from the manufacturer. These discounts are simply not available to independent pharmacies, further widening the gap between AMP and market price. These price concessions, however, are not available to retail pharmacies and therefore do not lower the pharmacies' costs of purchasing prescription drugs. Including PBMs' sales and discounts may lower the AMP to a level that does not reflect the cost to a retail pharmacy.
  - As the manufacturer must pay rebates based on AMP, the manufacturer then has an incentive to report the lowest numbers possible.
- Wholesaler costs and margins will not be covered by AMP. Federal law also makes few provisions for state determined dispensing fees which will become critical in ensuring that the professional services of pharmacists remain available to Medicaid patients.

o State MAC lists currently are lower than the FUL – significantly lower for some products
and in some states. If states follow their current practice, often states will reimburse below
the 250%. A study is needed to evaluate what currently happens and to find out how much
below 250% of AMP states are reimbursing.

4

Conclusion:

Since all reimbursement cuts will come from generic prescription drugs, the AMP must be defined to
cover acquisition costs or a perverse incentive will be created to dispense brands that could end up
costing the program much more. To avoid the drastic consequences employing AMP in a situation for
which it was not designed, NCPA respectfully requests that: 1) HHS use its authority to ensure that the
definition of AMP covers all of pharmacists' acquisition costs; 2) the study of pharmacy reimbursement
called for in the Act include an analysis of state-determined dispensing fees to ensure that pharmacy
operating costs are adequately covered under state reimbursement formulas; and 3) HHS promulgate the
rules on implementing that Act no later than September 1, 2006 to provide adequate time for community
pharmacies to prepare for the implementation of the major changes in the Medicaid program.

Submitter : Mrs. Tess Smith **Date:** 02/20/2007

Organization : Danny's Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1101-Attach-1.TXT

#1101

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist Danny's Drugs, a community retail pharmacy located at 20029 Alberta Ave, Oneida, TN. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

While the AMP data is not currently publicly available, so that retail pharmacies can actually determine what the relationship will be between the proposed AMP-based FULs and the prices

retail pharmacies pay to acquire the drugs, the GAO has conducted an analysis of this relationship. The GAO used the highest expenditure and the highest use drugs for Medicaid in the analysis. The GAO reported that retail pharmacies will be reimbursed, on average, 36% less than their costs to purchase the drugs included in the analysis. A business can not be sustained if it is forced to continuously sell its products below its actual acquisition costs.

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Tess Laxton Smith
130 Laxton Ln
Helenwood, TN 37755

cc: Senator Lamar Alexander
Senator Bob Corker
Lincoln Davis

Submitter : Mr. David Ference **Date:** 02/20/2007

Organization : Mr. David Ference

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Response to Comments

Response to Comments

The impact of this regulation, if enacted as proposed, will be so financially severe and damaging that my company will be forced to cease dispensing Medicaid prescriptions. It is my observation that any savings from enactment as proposed will be more than negated by increased costs associated with the complications of reduced access to medication for Medicaid patients.

CMS-2238-P-1102-Attach-1.PDF

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799.....717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332.....717-859-4611
336 West Main Street, Leola, Pa. 17540-2107.....717-656-3794
1021 Sharp Avenue, Ephrata, Pa. 17522-1135.....717-733-1215
508 Harshey Avenue, Lancaster, Pa. 17603-5702.....717-299-4757

02/15/2007

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

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

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

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

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

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

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

3. **Removal of Medicaid Data**

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

David J. Ference, R.Ph.
Staff Pharmacist
Royer Pharmacy

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : Mr. Harry Rieck **Date:** 02/20/2007

Organization : Merck & Co., Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached comments from Merck & Co., Inc.

CMS-2238-P-1103-Attach-1.PDF

1103

Merck & Co., Inc.
U.S. Human Health
P.O. Box 4
West Point, PA 19486-0004

February 20, 2007

VIA EXPRESS MAIL AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–8015.

Re: **Comments on Proposed Rule Related to the Deficit Reduction Act and the Medicaid Drug Rebate Program, MS-2238-P**

Dear Acting Administrator Norwalk:

Merck & Co, Inc. (Merck) is pleased to submit the following comments regarding the Proposed Rule to implement provisions of the Deficit Reduction Act of 2005 (DRA) that was published by the Centers for Medicare and Medicaid Services (CMS) in the *Federal Register* on December 22, 2006 (Proposed Rule).[1]

Merck has long been involved in the Medicaid rebate program, not only through its participation, but also by its recommendation of policies to further the successful implementation of the program. Prior to the enactment of the rebate program, Merck had implemented its own voluntary "Equal Access to Medicines Program," which represented the first initiative by a major pharmaceutical manufacturer to provide voluntary rebates to state Medicaid programs. Subsequently, Merck played a constructive role in both providing technical comments on the statutory language adopted in the Omnibus Budget Reconciliation Act of 1990 that established the Medicaid rebate program and on regulatory guidance adopted by the then-Health Care Financing Administration. More recently, in April and August 2006 respectively, Merck provided input to both the United States Department of Health and Human Services Office of Inspector General (OIG) and

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[1] Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

to CMS concerning implementation of the DRA. In September 2006, Merck provided data in response to CMS's request for "Sample AMP" calculations.

Merck appreciates the opportunity to submit the following comments on the Proposed Rule regarding the calculation and reporting of Average Manufacturer Price (AMP) and Best Price. Merck joins in the comments submitted today by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO). Merck submits these comments to supplement the PhRMA and BIO comment letters on matters that Merck believes are of particular importance and on which Merck believes modifications from the Proposed Rule are required to achieve greater efficiency, to increase the likelihood of consistency in price reporting, and to reduce the complexity of price calculations. Merck hopes that these comments are helpful to CMS as it formulates its Final Rule and remains willing to assist CMS in any manner that CMS believes would be beneficial to this process.

A. Definitions Section (447.502)

1. Bona Fide Service Fees

The Proposed Rule would exclude "bona fide service fees" from AMP and Best Price, and would define a bona fide service fee as: "a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not an entity takes title to the drug."[2] As the Proposed Rule notes, this is the same definition of bona fide service fee that CMS recently adopted in the context of Average Sales Price (ASP) calculations.

In the ASP context, CMS has announced several important principles relating to the fair market value component of the bona fide service fee definition that Merck believes should apply to AMP and Best Price calculations as well.[3] To address concerns expressed by commenters in the ASP context that the fair market value criterion might

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[2] 71 Fed. Reg. 77174 at 77176, 77180.

[3] These interpretations were announced in the Medicare final physician fee schedule rule for 2007, published in the Federal Register on December 1, 2006.

not encompass fees for services "that can only be performed by the entity to which the fee is paid," CMS clarified that bona fide service fees mean expenses that a manufacturer "generally would have . . . paid for . . . at the same rate had these services been performed by other or similarly situated entities."[4] CMS further clarified that it was not necessary for manufacturers to calculate a fair market value for each individual service purchased from an entity; instead, "it may be appropriate to calculate fair market value for a set of itemized services, rather than fair market value for each individual itemized service, when the nature of the itemized services warrants such treatment."[5] In addition, CMS made clear that the appropriate methods for determining whether a fee represents fair market value "may depend on the specifics of the contracting terms, such as the agreed-upon mechanism for establishing the payment (for example, percentage of goods purchased)." CMS also emphasized that, because "manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value," CMS was "not mandating the specific method manufacturers must use to determine whether a fee represents fair market value."[6] Because a standard methodology for determining fair market value will simplify price reporting calculations, Merck believes that CMS should explicitly confirm that these particular principles also apply to determining whether a fee constitutes fair market value in the Medicaid context.

In addition to the fair market value component, the bona fide service fee definition as proposed also requires that such fees must not be "passed in whole or in part to a client or customer of an entity [that receives the fee]." As CMS is aware, manufacturers such as Merck generally do not know whether certain of their customers, such as PBMs, pass through or retain fees that are paid to them. Accordingly, to address this uncertainty, Merck believes that CMS should establish in the Final Rule that, unless a manufacturer and its customer agree by contract that part or all of a particular fee that would otherwise qualify as a bona fide service fee should be passed on to another party, the manufacturer may presume that the fee is not passed through to a third party and therefore can treat the fee as a bona fide service fee. This approach would be easy to apply and would offer certainty to manufacturers, thus increasing the likelihood of accurate and consistent AMP calculations and Best Price determinations.

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4 Id.

5 Id.

6 Id.

The rule that we have proposed for addressing this issue also would be consistent with the suggestion previously made by the Health Industry Group Purchasing Association (the trade association for GPOs) concerning GPO fees, for which, as with fees to PBMs, the ultimate recipient is unknown to the manufacturer. In its letter to CMS, HIGPA recommended that fees to GPOs should not be treated as price concessions "unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization."[7] In our view, this would be a sensible, easily-applied standard for distinguishing fees, both to GPOs and to other customers, that are intended as price concessions on the manufacturer's products from those that are not.

With respect to GPO fees in particular, CMS may also want to clarify that such fees do not affect AMP calculations when the GPO negotiates purchase prices for member hospitals for drugs used in the inpatient setting, since the underlying sales to hospitals would be excluded from AMP in this circumstance.

2. Bundled Sales

CMS proposes the following new definition of "bundled sale":

> Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug[8] or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or, where the resulting discounts or other price concessions are greater than those which would have

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[7] January 2, 2007 Health Industry Group Purchasing Association letter to CMS, at 2.

[8] Merck's understanding is that the use of the term "drug" in the Proposed Rule refers to the term "covered outpatient drug" as defined in the Medicaid Rebate Act. As noted below, Merck believes that this point should be clarified in the Final Rule.

> been available had the bundled drugs been purchased separately or outside the bundled arrangement.[9]

The new definition would replace and expand the definition in the existing Medicaid Rebate Agreement, which provides:

> Bundled Sale refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

The new definition that CMS has proposed significantly changes and expands the existing definition, for example:

- Under the proposed definition, contracts involving the "purchase of the same drug" apparently can result in a "bundled sale," whereas under the current contractual definition a "bundled sale" requires "the packaging of drugs of different types."

- Under the proposed definition, "drugs of different types" refers to drugs that have different nine-digit National Drug Codes (NDC-9), whereas previously the definition of "bundled sale" did not refer to "drugs of different types" at the NDC-9 level.

- The proposed definition expands the scope of "bundled sales" to include contracts under which the only condition for a discount or other price concession on a drug is the inclusion of the drug on a formulary, the achievement of market share, or some other unspecified "performance requirement." Under the current definition, a bundled sale exists only if a price concession on a drug is contingent on a "purchase requirement" for a drug of a different type. The proposed rule's apparent focus on "performance requirements," as opposed to "purchase requirements,"

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[9] CMS, "Medicaid Program; Prescription Drugs; Proposed Rule," 71 Fed. Reg. 77174, 77195 (Dec. 22, 2006) (to be codified at 42 C.F.R. § 447.502); see also id. at 77176.

could mean that a bundled sale would exist even if a particular arrangement does not require a customer to purchase any drugs, much less more than one drug type.

- The phrase "some other performance requirement" as used in the proposed definition is undefined and open-ended, and could raise questions about whether virtually any contract should be treated as a "bundled sale."

The proposed definition of "bundled sale" is overbroad, and the method by which discounts would be allocated appropriately among drugs within the new definition is unclear. The broad scope of the new proposed definition could create both unnecessary disruption to the marketplace and confusion and complexity from a price reporting perspective. The purpose of requiring manufacturers to reallocate discounts among drugs constituting a "bundled sale" is to ensure that the AMP and Best Price reported for each drug within the bundle accurately reflects the value of the discounts offered on each product. The Proposed Rule never explains how (or if) its proposed changes would improve the accuracy of AMP or Best Price calculations in any respect. We are not aware of any improvement in accuracy of either AMP or Best Price calculations that would result from the proposed expansion of the definition of "bundled sale" in the Proposed Rule. CMS should not require manufacturers to reallocate the discounts that customers actually paid unless there is a compelling reason why the reallocation would improve the accuracy of AMP and Best Price.

The consequence of CMS's proposed expansion of the definition of "bundled sale" is that manufacturers would be required to reallocate discounts across products (or even across different dosage forms or strengths of a drug or across sales of the same drug during different months or quarters), for a wider variety of arrangements. Thus, AMP and Best Price calculations would become even more complex, and the risk of error and the burdens imposed on manufacturers would substantially increase. In turn, this complexity could result in inconsistencies among the methodologies that manufacturers use to apportion bundled discounts in their AMP and Best Price calculations.

Now that AMP is potentially a reimbursement metric that will be calculated and reported on a monthly basis (and will have to be certified as accurate), the heightened risks of error and inconsistency among manufacturers are of even greater concern. CMS recognized these risks when addressing "bundled sales" in the context of ASP calculations -- which, unlike AMP, is reported quarterly. There, CMS concluded that: (a)

it did not have sufficient information concerning the types of arrangements that manufacturers had with various customers and could not predict how those arrangements might evolve over time; (b) it was premature to issue specific guidance on bundled sales; and (c) in the absence of specific guidance, manufacturers could make reasonable assumptions regarding how discounts under bundled sales are allocated, so long as the methodology chosen resulted in an accurate ASP calculation and did not create inappropriate financial incentives.[10]

Merck believes that CMS should take a similar approach to bundled sales in the Medicaid program. With AMP as a reimbursement metric, the objective in the Medicaid program should be the same as the objective in the Medicare Part B program -- to ensure accurate calculations and not to create inappropriate financial incentives. Merck does not believe that any facts have changed since the promulgation of the Physician Fee Schedule Rule that warrant a different treatment of bundled sales for AMP and Best Price purposes than for ASP purposes. Indeed, the fact that AMP will be reported monthly and certified by manufacturers amplify the need for simplicity in the calculation process. Moreover, Merck believes that CMS should continue to take caution to avoid changes in a manufacturer's price calculations that increase their complexity and that are not required

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[10] Specifically, CMS noted as follows: "Since we do not yet fully understand the variety of bundling arrangements that exist in the marketplace and how they are likely to evolve over time, we believe it is important to be cautious in establishing a specific methodology that all manufacturers must follow for ASP purposes. Consequently, we are not establishing a specific methodology that manufacturers must use for the treatment of bundled price concessions for the purposes of the ASP calculation at this time. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Act, federal regulations, and its customary business practices. Our intent in not being prescriptive in this area at this time is to allow manufacturers the flexibility to adopt a methodology with regard to the treatment of bundled price concessions in the ASP calculations that, based on their particular circumstances, will best ensure the accuracy of the ASP calculation and not create inappropriate financial incentives."

See CMS, "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; Final Rule," 71 Fed. Reg. 69624, 69675 (Dec. 1, 2006) (emphasis added).

by statute, unless such changes are necessary to improve the accuracy and consistency of AMP and/or Best Price calculations. In this regard, we note that neither the Medicaid Rebate Act nor the DRA directs CMS to make changes via rulemaking to the contractual definition of "bundled sales."

Merck's Recommendations Concerning "Bundled Sale" Arrangements

Based on the foregoing, Merck respectfully requests that CMS take the following actions in the Final Rule:

- CMS should retain the definition of "bundled sale" that is set forth in the Medicaid Rebate Agreement.

- In the alternative, if CMS decides that a definition of "bundled sale" that goes beyond the Medicaid Rebate Agreement's current definition of a "bundled sale" is necessary, CMS should: (1) explain specifically why the expansions in the definition of a "bundled sale" are needed to improve the accuracy and consistency of AMP and/or Best Price calculations, and exactly how the new, broader definition would produce more accurate figures and would warrant the additional burdens imposed on manufacturers; (2) delete the phrase "other performance requirements" from the proposed definition, or provide additional specificity regarding the meaning of that phrase; (3) provide specific examples of each type of arrangement that would be encompassed by the new "bundled sale" definition; and (4) avoid unnecessary marketplace disruption by allowing manufacturers to apply the new definition of "bundled sale" only to agreements entered into subsequent to the effective date of the Final Rule.

- CMS should also confirm that "bundled sale" arrangements are limited to arrangements that involve covered outpatient drugs. That is, the Final Rule should reiterate the guidance now contained in the Medicaid Drug Rebate Operational Training Guide (p. F11d) on arrangements that include products other than covered outpatient drugs: "Valid bundled sales only include drug products that meet the definition of a covered outpatient drug as defined in the drug rebate agreement and statute. If a non-drug product . . . is included in the bundled sale, it is not eligible for inclusion in the Medicaid Drug Rebate Program."

- With respect to the allocation methodology, CMS should adopt the same approach that it took in the ASP context, where CMS decided that it was premature to establish a specific allocation methodology. Instead, CMS concluded that manufacturers "may make reasonable assumptions" in their ASP calculations, "consistent with the general requirements and the intent of the Act, federal regulations, and its customary business practices." Merck believes that CMS should adopt a similar approach with respect to AMP and Best Price. In the alternative, if CMS does propose an allocation methodology, Merck requests that CMS develop methodologies specific to each type of transaction that CMS identifies as a "bundled sale" and that CMS give manufacturers and other interested parties an opportunity to comment on those methodologies.

B. Retail Pharmacy Class of Trade (447.504)

1. Closed Mail Order Pharmacies

AMP is defined by statute as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade" (excluding prompt pay discounts starting in 2007).[11] The Proposed Rule would define the "retail pharmacy class of trade" as "any independent pharmacy, chain pharmacy, mail order pharmacy, [PBM], or other outlet that purchases, or arranges for the purchase of drugs from a manufacturer . . . and subsequently sells or provides the drugs to the general public."[12] Similarly, the Proposed Rule describes the retail pharmacy class of trade as "that sector of the drug marketplace . . . which dispenses drugs to the general public . . . ."[13]

Merck agrees with the approach of identifying entities within the retail pharmacy class of trade as those that dispense drugs to the "general public" and believes that this approach is consistent with Congressional intent. We note, however, that mail order pharmacies will not always fall into this class, because some mail order pharmacies are "closed" pharmacies that only serve individuals covered by certain payors or health

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11 42 U.S.C. 1396r-8(k)(1)(A).

12 Fed. Reg. at 77196 (proposed) 42 C.F.R. § 447.504(e)).

13 Id. at 77178.

plans. Consequently, CMS should clarify in the Final Rule that the retail pharmacy class of trade includes those mail order pharmacies that "sell[ ] or provide[ ] drugs to the general public," but not closed mail order pharmacies. Prices to closed mail order pharmacies should thus be excluded from AMP calculations.

2. Third Party Rebates

The Proposed Rule provides that "to the extent manufacturers are offering . . . price concessions to [a] PBM that are not bona fide service fees, we propose that these lower prices be included in AMP."[14] Consistent with this treatment of PBM rebates, the Proposed Rule would also include in AMP rebates paid to third-party payors such as Medicare Part D plans, qualified retiree prescription drug plans, and State Pharmaceutical Assistance Programs.[15]

Merck supports the general approach CMS has proposed of including rebates to PBMs and third-party payors in AMP calculations. However, this approach could reduce AMP, which will shortly become a reimbursement metric. Federal upper limits for multiple source drugs will be 250% of AMP starting this year, and some States might decide to use AMP in their Medicaid reimbursement formulas for other drugs once AMPs become public. As noted in our August 2, 2006 letter to CMS, Merck believes it is critically important for pharmacy reimbursement to correlate to pharmacy acquisition cost. Because AMP as defined in the Proposed Rule would include rebates that are not necessarily offered to retail pharmacies, it will be important for CMS to caution the States about the need to evaluate the relationship between AMP and pharmacy acquisition costs carefully before adopting any type of AMP-based reimbursement formula.

To help ensure that AMP-based Medicaid reimbursement formulas have a percentage markup over AMP that preserves Medicaid beneficiaries' access to medicines, CMS should re-emphasize in the Final Rule that it "encourage[s] States to analyze the

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[14] Id. at 77179.

[15] Id. at 77180. It is unclear whether the Proposed Rule would require manufacturers to include supplemental Medicaid rebates in AMP. CMS should clarify this point in the Final Rule.

relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs."[16]

3. Price Concessions to PBMs

As noted above, the Proposed Rule provides that "to the extent manufacturers are offering . . . price concessions to [a] PBM that are not bona fide service fees, we propose that these lower prices be included in AMP."[17] The proposed regulatory text would similarly provide that "[d]iscounts, rebates or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade" are included in AMP.[18] However, the Proposed Rule also includes language that could create confusion about the treatment of price concessions to PBMs in AMP calculations; in particular, the Proposed Rule notes that AMP includes price concessions to PBMs "that affect the net price recognized by the manufacturer" for drugs provided to the retail pharmacy class of trade.[19] To promote greater uniformity in AMP calculations and preclude the possibility of confusion regarding the treatment of PBM price concessions, CMS should state clearly in the Final Rule that any price concessions to PBMs should be included in AMP calculations.[20]

4. Non-Purchasing HMOs

Like the Medicaid Rebate Agreement, the Proposed Rule would expressly exclude sales to health maintenance organizations (HMOs) from AMP calculations.[21] However, the Proposed Rule does not distinguish between HMOs that actually purchase drugs and distribute them to members through the HMO's own closed pharmacies, and

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[16] Id. at 77176.

[17] Id. at 77179.

[18] Id. at 77196 (proposed 42 C.F.R. § 447.504(g)(3)).

[19] Id. at 77179.

[20] We agree with CMS that bona fide service fees paid to PBMs (or others) should be excluded from AMP and Best Price. CMS should make clear that these fees are not properly considered price concessions, rather than use language suggesting inaccurately that bona fide service fees are price concessions but nonetheless are excluded from AMP and Best Price.

[21] 71 Fed. Reg. at 77179.

those HMOs that do not purchase drugs but instead reimburse retail pharmacies for drugs dispensed to HMO members. The latter category of HMOs act as third-party payors. Thus, as with other retail pharmacy sales that are reimbursed by third-party payors,[22] sales of drugs that are dispensed by retail pharmacies and reimbursed by those HMOs (and the amount of any concessions associated with those sales) should be included in AMP. To enhance consistency, CMS should clarify in the Final Rule that sales of (and price concessions associated with) drugs dispensed at retail pharmacies that are reimbursed by non-purchasing HMOs also are included in AMP.

C. Coupon Programs (447.504(g)(11) and 447.505(c)(12))

Among the types of programs that Merck utilizes to assist patients are coupon programs and voucher programs. Merck uses the terms "coupons" and "vouchers" to describe two distinct types of programs which may fall under the rubric of "manufacturer coupons" as used by CMS in the Proposed Rule. Although "coupon" and "voucher" programs may appear similar, they are different in purpose and function. Merck believes that an understanding of this distinction is essential for CMS to regulate their impact on AMP and Best Price calculations.

As Merck uses the term, "coupons" are certificates provided to patients that entitle them to discounts on their prescription drug purchases, either at the point-of-sale (through a reduction in the amount the consumer is required to pay the dispensing pharmacy) or subsequent to the purchase (by sending the coupon to the manufacturer or a clearinghouse with proof-of-purchase in order to receive a cash reimbursement from the manufacturer). In either case, the amount of the discount provides a dollar-for-dollar reduction in the amount paid out-of-pocket by the patient. Whether the coupons are redeemed by the dispensing pharmacy or directly by the patient, the entire discount represented by the coupon goes to the patient. In point-of-sale coupons, the dispensing pharmacy receives reimbursement for the discount passed on to the patient plus a small handling fee for administering the transaction. The impact of the handling fee on Merck's AMP and Best Price should be evaluated under the rules that CMS establishes for determining bona fide service fees. However, with respect to the drugs dispensed subject to the discount conferred by the coupon, the pharmacy receives no part of the

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[22] The Proposed Rule provides that drugs reimbursed by Medicaid, Medicare Part D plans, and State Pharmaceutical Assistance Programs are included in AMP when the drugs are dispensed by retail pharmacies. Id. at 77180.

discount and is prohibited from charging more than its usual and customary price less the discount. If the patient is a member of a managed care plan, the discount on the product is limited to the amount of the patient's copayment or coinsurance.

"Vouchers," by contrast, are certificates provided to patients that entitle the patient to receive a specified number of units of a drug free-of-charge. In this respect, vouchers function similarly to product samples. The manufacturer in a voucher program contracts with a vendor, which in turn contracts with the pharmacy. The pharmacy dispenses the drug free-of-charge to the patient and is then reimbursed by the vendor according to a formula negotiated between the vendor and the pharmacy, plus a dispensing fee. The vendor bills the manufacturer for this reimbursement expense (which is designed to be revenue neutral to the retail pharmacy), plus a service fee. Again, the service fee to the vendor should be evaluated under the definition of "bona fide service fee" adopted in the final rule. Since the manufacturer indirectly reimburses the dispensing pharmacy through the negotiated formula, the dispensing pharmacy does not submit a reimbursement claim for those units to any public or private insurance program of which the consumer may be a beneficiary. Although vouchers are submitted for redemption through a pharmacy, the discount has no effect on the acquisition price paid by the pharmacy for the prescription drug dispensed upon the presentation of a voucher.[23]

CMS proposes to require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP," but "to include coupons redeemed by any entity other than the consumer in the calculation of AMP."[24] Similarly, CMS proposes to require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price," but "to include coupons redeemed by any entity other than the consumer in the calculation of best price."[25] In the context of Best Price calculations, CMS premises its proposed disparate treatment of manufacturer coupons on its belief that "the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose

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[23] The mechanics of how coupons and vouchers are processed and redeemed are outlined in more detail in Exhibit A.

[24] 71 Fed. Reg. 77174, 77181 (Dec. 22, 2006); see also id. at 77197 (to be codified at 42 C.F.R. §§ 447.504(g)(11) & (h)(9)).

[25] Id. at 77183; see also id. at 77197 (to be codified at 42 C.F.R. §§ 447.505(c)(12) & (d)(8)).

sales are included in best price," but that "the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy)."[26] Although CMS does not state so explicitly, this rationale presumably underlies CMS's proposed treatment of manufacturer coupons in AMP calculations as well.

Although CMS does not propose a definition of "manufacturer coupon," we assume that this term encompasses "coupons" as described above. In addition, we are concerned that "vouchers" may also be included in potential interpretations of "manufacturer coupon," whether or not this was CMS's intent. We respectfully submit that CMS's proposed treatment of coupons (and possibly vouchers) in AMP and Best Price calculations is not appropriate. In our view, coupons redeemed directly by patients to the manufacturer should not be treated any differently from coupons redeemed to the manufacturer through other parties. CMS suggests that coupons redeemed "by entities other than consumers" somehow affect the prices those entities pay for drugs dispensed subject to those coupons. CMS thus appears to believe that, by honoring coupons presented by patients, which the entities then submit to manufacturers for redemption, the redeeming entities receive a price concession. This belief is contrary to Merck's experience, in which coupons (and vouchers) are intended solely for the financial benefit of patients, regardless of the means by which they are redeemed.

When a patient presents a coupon to a pharmacy that dispenses prescription drugs, the pharmacy provides the patient with a discount equal to the coupon's face value. When a patient presents a voucher, the pharmacy provides the drug to the patient for free. Upon "redeeming" the coupon or voucher to the manufacturer, the pharmacy receives a reimbursement that correlates to the coupon or voucher's value. Consequently, the value of the coupon or voucher "passes through" the redeeming entity to the patient and has no effect on the acquisition price paid by the redeeming entity to purchase the units of the drug dispensed subject to the coupon or voucher. The transaction that establishes the price the redeeming entity paid to acquire the drug occurs well before the patient ever presents the coupon or voucher to the redeeming entity. Indeed, the transaction in which the drug is acquired often involves only a wholesaler and a retail pharmacy; the

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[26] Id. at 77183.

manufacturer may not even be a party.[27] Because the redeeming entity in the case of both coupons and vouchers does not retain any portion of the discount conferred to the patient, the coupon or voucher has no effect on the price the entity paid for the prescription drugs it dispenses to the patient. The coupon/voucher, accordingly, is not a cost-saving program offered to an entity other than the patient, and the value of the coupon or voucher should not be included in manufacturers' calculations of either AMP or Best Price.

Moreover, CMS's proposed approach could have unintended adverse consequences on both coupon and voucher programs, which offer substantial financial benefits to patients. This is especially true with regard to voucher programs, if CMS considers vouchers under the umbrella of "manufacturer coupons." Although vouchers function similarly to product samples (like samples, vouchers allow a patient to try a drug without cost for a limited time to enable the patient's physician to determine the safety and efficacy of the drug for the particular patient), they have many advantages over product samples. From the physician's standpoint, vouchers are easier to safeguard, store and distribute to patients; indeed, an increasing number of physician practices will not accept samples and will only accept vouchers. Also unlike samples, vouchers offer advantages because they require a prescription before they can be used and a pharmacist must fill the prescription. For the patient, vouchers allow the dispensing pharmacy an additional opportunity to track prescription drug use and thereby monitor for adverse drug interactions. Thus, they provide another opportunity for the patient to ask questions of a healthcare practitioner. Manufacturers should not be penalized from a pricing standpoint for offering vouchers that are redeemable at the point of sale.

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[27] If coupon or voucher programs were "relevant" to AMP or Best Price, it is not clear how the manufacturer should account for the value of such a program in its price calculations. If the pharmacy buys the drugs from a wholesaler, the manufacturer would not: (a) know the acquisition price for the drug that the pharmacy paid (because it is not a party to the agreement between the distributor and the pharmacy); or (b) have the ability to trace the units dispensed to the patient using a coupon or voucher to a sale from the manufacturer to a wholesaler. Moreover, if the Proposed Rule were to become effective, would the net price for AMP or Best Price purposes require the manufacturer to subtract from the acquisition price: (a) the dispensing fee paid to the redeeming entity, (b) the discount paid to the consumer, (c) the reimbursement amount paid to the redeeming entity; or (d) some combination of these elements?

With regard to coupon programs, CMS's proposed approach could also result in manufacturers requiring patients to redeem coupons directly to them. This would burden patients by requiring them to put forth the full out-of-pocket cost of the prescription and to wait 6-8 weeks for reimbursement after mailing proof-of-purchase forms to the manufacturer. It also potentially could require manufacturers to pay for additional infrastructure to administer such coupon programs. Merck does not believe that such additional steps are necessary or warranted. Coupons serve the valuable purpose of encouraging patients to obtain the medications their physicians have prescribed by reducing the cost of such medications to the patients, and we are concerned that CMS's proposal could reduce or unduly burden patient participation in those programs.

Based on the foregoing, Merck respectfully requests that CMS take the following actions in the Final Rule:

Coupons

- Adopt a definition of "manufacturer coupon" that encompasses cost-saving programs offered to patients but that recognizes the different means by which coupons may be redeemed. Merck proposes that CMS adopt the following definition:

  > "Manufacturer coupon" means "any certificate provided to a consumer that provides by its terms that the consumer is entitled to a discount on his or her purchase of drugs, either: (A) at the point-of-purchase, through a reduction equal to the face value of the coupon up to the amount the consumer is required to pay the entity that dispenses the drugs, or (B) subsequent to the purchase, through receipt of a cash reimbursement from the manufacturer (or a vendor under contract to the manufacturer to administer the coupon program) where the reimbursement amount is equal to the lesser of the amount the consumer paid to the dispensing entity or the face value of the coupon."

- Require manufacturers to exclude from their AMP and Best Price calculations:

- Any manufacturer coupon redeemed by a consumer either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the coupon program; and

- Any manufacturer coupon redeemed by an entity other than a consumer (after being presented to and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program.

➢ Specify that manufacturers should also exclude from their AMP and Best Price calculations: (A) the reimbursement amount paid to the redeeming entity for the manufacturer coupon; and (B) any fees paid to an entity other than a consumer that redeems a manufacturer coupon where the fee satisfies the definition of "bona fide service fee" adopted by CMS in the Final Rule.

Vouchers

CMS does not expressly address in the Proposed Rule how manufacturers should treat in their AMP and Best Price calculations drugs that are ultimately dispensed to patients upon presentation of vouchers. Merck believes that CMS should confirm that manufacturer vouchers are not subject to CMS's guidance regarding "manufacturer coupons." If CMS does decide to treat manufacturer vouchers explicitly in the Final Rule, Merck respectfully requests that CMS take the following actions with regard to vouchers:

➢ Adopt a definition of "manufacturer voucher" that encompasses cost-saving programs offered to patients but that recognizes the different means by which vouchers may be redeemed. Merck proposes that CMS adopt the following definition:

> "Manufacturer voucher" means "any certificate provided to a consumer that provides by its terms that the consumer is entitled to a specified number of units of a drug free-of-charge, without (A) any co-payment from the consumer, or (B) reimbursement to the entity that dispenses the drug from any insurance program of which the consumer may be a beneficiary."

- Require manufacturers to exclude from their AMP and Best Price calculations:

  - Any manufacturer voucher redeemed by a consumer either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the voucher program; and

  - Any manufacturer voucher redeemed by an entity other than a consumer (after being presented to and honored by such entity) either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the voucher program.

- Specify that manufacturers should also exclude from their AMP and Best Price calculations: (A) the reimbursement amount paid for any manufacturer vouchers; and (B) any fees paid to an entity other than a consumer that redeems a manufacturer voucher where the fee satisfies the definition of "bona fide service fee" adopted by CMS in the Final Rule.

The approach that we have suggested is the most practical and fair method for all parties because the relevant price of a covered outpatient drug for AMP and Best Price purposes is the price that the manufacturer charges to the wholesaler or retail pharmacy (if the manufacturer sells directly to the retail pharmacy) for the drug, not the reimbursement amount paid to the entity at which a voucher is redeemed or the financial value of a voucher to the patient.

If CMS does not adopt the approach that we have suggested above, Merck respectfully requests clear guidance from CMS as to how manufacturers should account

for coupons and vouchers in their calculations of AMP and Best Price.[28]

D. Authorized Generic Agreements (447.506)

Section 6003 of the DRA directed innovator manufacturers, effective January 1, 2007, to take sales of authorized generic products into account in the calculation of the innovator manufacturer's AMP and Best Price. With respect to AMP, the DRA required that, "in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [FFDCA],"[29] the innovator manufacturer's AMP "shall be inclusive of the average price paid for such drugs by wholesalers for the drugs distributed to the retail pharmacy class of trade."[30] With respect to Best Price, the DRA provides that the innovator manufacturer's Best Price "shall be inclusive of the lowest price for such authorized [generic] drug available from

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[28] The Medicaid Rebate Act defines Best Price as the lowest price charged "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i). Accordingly, Merck is concerned with the Proposed Rule's discussion of Best Price, which provides: "[w]e propose to consider any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as 'other arrangements'. . . that . . . should be included in the calculation of Best Price." 71 Fed. Reg. at 77182. To avoid any confusion, CMS should confirm explicitly in the Final Rule that Best Price is the lowest price realized by the manufacturer net of all price concessions to a specific Best Price-eligible customer. This clarification would recognize the Medicaid Rebate Act's requirement that Best Price must be determined by reference to customer-specific prices, rather than prices derived by aggregating price concessions to different customers.

[29] DRA section 6003(a)(2)(B)(iii). Section 505(c) of the FFDCA addresses new drug applications (NDAs) that the FDA must approve as a prerequisite for a company to market drugs and certain biologics (such as human growth hormone and insulin).[29] By contrast, FDA approves abbreviated new drug applications (ANDAs) under 505(j) (for certain generic products) and biologics license applications (BLAs) (for certain biologics) under section 351 of the Public Health Service Act (PHSA). Therefore, Section 6003 by its terms, including the reference to Section 505(c) of the FFDCA, applies to authorized versions of products marketed under NDAs, but does not apply to products marketed under ANDAs or BLAs.

[30] Id.

the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, [HMO], nonprofit entity or governmental entity."[31]

The DRA is silent concerning how manufacturers should blend sales of an authorized generic version of their drugs with their own sales of the drug for purposes of the AMP calculation. It also does not expressly address whether the Best Price determination takes into account the transfer price of the authorized drug from the innovator manufacturer to the authorized generic manufacturer, or the lowest price of the authorized drug from the authorized generic manufacturer to its Best Price-eligible customers, or both.

Section 447.506 of the Proposed Rule suggests a definition of the term "authorized generic" and proposes to require manufacturers to include "the direct and indirect sales of [an authorized generic] drug in its AMP" and "the price of [an authorized generic] drug in the computation of best price for the single source or innovator multiple source drug . . . to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States." However, like the DRA, the Proposed Rule neither specifies a procedure for blending sales by the authorized generic manufacturer in the innovator company's AMP nor identifies the prices that must be taken into account in determining Best Price. In the preamble to the Proposed Rule, CMS appears to conclude that the only relevant price for Best Price purposes is the price from the authorized generic manufacturer to its customers:

> we would require that sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs be included by the primary manufacturer in the sales used to determine the best price for the single source or innovator multiple source drug approved under Section 505(c) of the FFDCA during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity or governmental entity within the United States. The primary manufacturer must include in its calculation of best price all sales of the authorized generic drug which have been sold or marketed by a secondary

[31] DRA section 6003(a)(2)(B)(iii).

> manufacturer or by a subsidiary of the brand manufacturer.[32]

Merck agrees that, for Best Price purposes, the relevant price for a drug that is the subject of an authorized generic agreement should be the lower of: (a) the lowest price charged by the innovator manufacturer in a Best Price-eligible sale; or (b) the lowest price charged by the authorized generic manufacturer in a Best Price-eligible sale. We also agree that the transfer price -- that is, the price at which the innovator manufacturer sells the drug to the authorized generic manufacturer -- should not be taken into account in Best Price, even if the transfer price would otherwise be the lowest price at which the drug is sold. Transfer prices may involve complex royalty or profit-sharing arrangements that would be difficult for the innovator manufacturer to incorporate into its Best Price and for CMS to evaluate. In such situations, the amount of the royalty or profit share likely will not be known until long after the reporting period has ended. Therefore, Merck supports the approach that CMS has suggested in the preamble to the Proposed Rule. To avoid any confusion, we request that the wording of the regulation be clarified so that the Final Rule will more closely track this approach, making it clear that the transfer price is not a Best Price-eligible sale for the innovator manufacturer.

With respect to both AMP and Best Price, as Merck explained in its August 2, 2006 letter to CMS, we recommend that CMS adopt a specific methodology for blending authorized generic sales with sales by the innovator manufacturer. We believe that there are two potential blending methodologies available to CMS:

1. CMS could require manufacturers of innovator drugs and manufacturers of authorized generic version(s) of those innovator drugs to calculate AMPs and to determine Best Prices for their own products, using only the sales data specific to those products (as identified by their National Drug Code (NDC) numbers), and to include in their AMP reports the number of units sold during the rebate period. CMS could also require innovator drug manufacturers to identify the NDC(s) associated with authorized generic versions of their innovator drugs marketed under their NDAs. CMS would be responsible for using this information to calculate weighted AMPs and to determine Best Prices for the innovator drugs and then for reporting this information to innovator drug manufacturers.

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[32] 71 Fed. Reg. 77174, 77184 (Dec. 22, 2006).

2. CMS could require manufacturers of innovator drugs to obtain information from manufacturers of authorized generic version(s) of their innovator drugs, either the AMPs or Best Prices themselves or the underlying sales data. Manufacturers of innovator drugs then would use this information, in combination with sales data for their innovator drugs, to calculate AMPs and to determine Best Prices for their innovator drugs. If this approach were taken, CMS should allow the innovator manufacturer to rely on a certification from the authorized generic manufacturer as to the accuracy of the information provided.

Merck recommends that CMS adopt the first option in the Final Rule.[33] Merck's concern with the second option is that the thirty days available to manufacturers to calculate AMP and to determine Best Price would make it difficult for innovator drug manufacturers to obtain information from the manufacturers of authorized generic versions of their innovator drugs, to take any steps they may consider appropriate to verify the accuracy of that information, and then to calculate AMPs and determine Best Prices for their innovator drugs. With a short time period to complete these tasks, innovator drug manufacturers could have reduced confidence in the accuracy of their AMPs and Best Prices.

The first blending option would avoid this concern by making manufacturers responsible only for the accuracy of their own price information, while also enabling CMS to exercise effective oversight with respect to the information being submitted by both the innovator and the authorized generic manufacturer. Additionally, Merck

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[33] If CMS does adopt a manufacturer blending procedure, we urge CMS also to specify that the innovator manufacturer need not begin applying the blending procedure until the quarter following the launch of the authorized generic product. If an authorized generic agreement is effective in the middle of a quarter, our view is that, for ease of administration, CMS should permit innovator manufacturers to defer accounting for authorized generic sales in its AMP or Best Price until the quarter following the launch of the authorized generic drug. Additionally, CMS should take steps to avoid the need for disclosure of potentially business sensitive information, such as transaction-level data, from authorized generic manufacturers to innovator manufacturers.

believes that the first option would avoid risks associated with requiring a private company to obtain pricing and utilization information from a competitor.[34]

Merck's Recommendations Regarding Authorized Generic Arrangements

- With respect to AMP and Best Price, CMS should include a provision in the Final Rule that would expressly require manufacturers of innovator drugs and manufacturers of authorized generic version(s) of those innovator drugs to calculate AMPs and to determine Best Prices for their own products, using only the sales data specific to those products (as identified by their NDC numbers), and to include in their AMP reports the number of units sold during the rebate period. CMS should also require innovator drug manufacturers to identify the NDC(s) associated with authorized generic versions of their innovator drugs marketed under their NDAs. CMS should be responsible for using the information provided to calculate weighted AMPs and to determine Best Prices for the innovator drugs and then for reporting this information to innovator drug manufacturers. For authorized generic agreements that are effective in the middle of a quarter, CMS should not begin to apply this blending procedure until the following quarter.

- CMS should confirm that the Best Price of a drug that is the subject of an authorized generic agreement is the lower of: (a) the lowest price charged for the drug by the innovator manufacturer in a Best Price-eligible sale; and (b) the lowest price charged for the drug by the authorized generic manufacturer in a Best Price-eligible sale. CMS should also confirm in the language of the Final Rule the principle expressed in the preamble to the Proposed Rule: that Best Price does not include the transfer price at which the innovator manufacturer sells the drug to the authorized generic manufacturer.

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[34] See Statement 6, "Provider Participation in Exchanges of Price and Cost Information," of the Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, which is available at http://www.ftc.gov/reports/hlth3s.htm#6).

E. Rolling Average Methodology (447.510)

CMS proposes to require manufacturers to calculate monthly AMP using the same methodology as for quarterly AMP, except that: (a) the monthly AMP would cover one month instead of one quarter; (b) the monthly AMP would not be subject to revision; and (c) manufacturers would be permitted to estimate end-of-quarter rebates or price concessions in monthly AMP calculations.[35] CMS requests comments on whether it should adopt a 12-month rolling average methodology to apply to lagged price concessions in both the monthly and quarterly AMP calculations. Under the approach adopted by CMS, manufacturers would continue to report revisions to AMP that result from information learned after the quarterly reporting date.

As noted in Merck's August 2, 2006 letter, Merck believes that, because of the role that AMP may play in product reimbursement, an important objective of the Medicaid program going forward should be to minimize unnecessary instability and volatility in AMP calculations. To accomplish this goal, Merck continues to believe that CMS should revise the AMP calculation to eliminate the need to adjust AMPs after they have been reported. In this regard, we applaud CMS's decision to preclude routine restatements of monthly AMP.

However, Merck does not believe that the three-month rolling average methodology proposed by CMS covers a sufficient amount of time to ensure accurate and stable reported AMPs. Instead, Merck would urge CMS to adopt a "twelve-month rolling average methodology" for monthly (and quarterly) AMPs similar to the methodology used to estimate the value of lagged discounts when calculating ASP, another reimbursement metric.[36] Adoption of the twelve-month rolling average methodology, allowing smoothing of all lagged pricing information (including chargebacks), not only would have the benefit of consistency across the Medicaid and Medicare programs, but also would enable companies to use a sufficient period of time in the rolling average

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[35] 71 Fed. Reg. 77174, 77185-86 (Dec. 22, 2006).

[36] See 42 C.F.R. § 414.804(a)(3). In this regard, Merck applauds CMS's proposal that manufacturers exclude product returns from the AMP calculation. This proposal will align AMP reporting with ASP reporting and also will remove a potential source of volatility from the AMP calculation.

calculation to improve the accuracy of the monthly (or quarterly) AMPs that may be used to determine pharmacy reimbursement.

In the event that CMS implements this change to the AMP calculation, Merck also recommends that CMS describe in the Final Rule the (presumably limited) circumstances in which CMS would either expect or permit manufacturers to recalculate AMPs. In particular, CMS should provide guidance to manufacturers regarding whether, in light of the need to maximize stability in reimbursement metrics, restatements remain an appropriate means for correcting subsequently discovered AMP calculation errors.

F. Effective Date

The DRA requires CMS to promulgate rules concerning AMP by no later than July 1, 2007. Many of the changes that would result from promulgation of the Final Rule will require time for manufacturers to implement. For example, the issues raised concerning coupon and voucher programs could affect millions of coupons and vouchers that are currently on the market. Similarly, the changes to the definition of retail pharmacy class of trade, and to AMP and Best Price generally, will require companies to revise their price reporting processes and to re-program and test their information technology systems. Whatever decisions that CMS ultimately makes in the Final Rule concerning these and other issues, manufacturers will need time to implement them. The reprogramming and testing of systems will take considerable time and effort and cannot be started until manufacturers know what the Final Rule requires.

Accordingly, to allow for reprogramming and testing of systems to occur and for manufacturers otherwise to come into compliance with the requirements of the Final Rule, Merck recommends that CMS give manufacturers a period of not less than four quarters from the date that the Final Rule is issued before the changes made in the Final Rule that are not required by the DRA become effective. This window, through at least July 1, 2008, would afford both manufacturers and CMS time to prepare their processing systems for the changes that the Final Rule will require. If such a "ramp up" period is not granted, not only would there be a heightened risk of error and inconsistency in the periods immediately following the issuance of the Final Rule, but also reimbursement to retail pharmacies could be adversely affected because AMPs are not reported accurately. For these reasons, Merck strongly urges CMS to allow manufacturers a period of time of not less than twelve months to make the necessary system modifications

and to put procedures in place to mitigate the risk that AMP (and Best Price) are not calculated and reported accurately.

* * * *

Merck appreciates the opportunity to comment on the Proposed Rule. Merck also recognizes and appreciates the considerable effort that CMS put into the development of the Proposed Rule, and we hope that our comments will be useful to CMS as it develops the Final Rule. Merck would be pleased to provide any additional information upon request.

Sincerely,

Harry J. Rieck

Harry J. Rieck
Senior Director
Customer Contract Management
Merck & Co., Inc.

Submitter : Mr. William Sherman **Date:** 02/20/2007

Organization : Mr. William Sherman

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment CMS-2238-P William T. Sherman - General Comments.pdf for signature.

02/15/2007

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

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

Acting Administrator Leslie Norwalk,

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

William T. Sherman, R.Ph.
Owner and Chief Executive Officer
Royer Pharmacy

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Response to Comments

Response to Comments

The financial impact studies of this proposed regulation have shown that it will result in a financial loss to the pharmacy for every Medicaid prescription dispensed. Consequently, if enacted as proposed, my company will no longer be able to provide Medicaid services. The proposed savings are false because they do not consider the increased Medicaid program costs secondary to reduced access to medications. These areas include increased emergency room, hospital and doctor access because the patient didn't have their medication.

CMS-2238-P-1104-Attach-1.PDF

1104

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799 717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332 717-859-4911
335 West Main Street, Leola, Pa. 17540-2107 717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135 717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702 717-299-4737

02/15/2007

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

William T. Sherman

William T. Sherman, R.Ph.
Owner and Chief Executive Officer
Royer Pharmacy

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : **Mrs. Patricia Leaman** **Date: 02/20/2007**

Organization : **Mrs. Patricia Leaman**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - CMS-2238-P Patricia Leaman - General Comments.pdf for signature.
02/15/2007

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

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

Acting Administrator Leslie Norwalk,

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Patricia J. Leaman, R.Ph.
Lancaster, Pa. 17601

Owner
Royer Pharmacy

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Response to Comments

Response to Comments

GAO studies have shown that this proposed regulation will result in retail community pharmacists being paid %36 under net cost for generic medications dispensed to Medicaid patients. If enacted as proposed, the financial impact will be that my company must cease dispensing Medicaid prescriptions. The ultimate cost to the government if far greater than the projected 'savings'. The reduction in access to medication and the loss of help that my professional pharmacy staff provide will result in greatly increased expenses in emergency room, doctor and hospital costs. Medicaid patients depend on their pharmacist.

CMS-2238-P-1105-Attach-1.PDF

1105

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799 717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332.....717-859-4911
335 West Main Street, Leola, Pa. 17540-2107 717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135 717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702 717-299-4737

February 16th, 2007

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

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

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Patricia J. Leaman, R.Ph.
Owner
Royer Pharmacy

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : Kevin Camp **Date:** 02/20/2007

Organization : Camp Drugs, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the plan to implement AMP pricing for Federal reimbursement of Medicaid generic prescriptions. Once again, pharmacy reimbursements are being targeted instead of the real problem with drug manufacturers and insurance companies. Manufacturers and insurance companies are making record profits. Humana & Express Scripts both reported record profits in the 4th quarter of 2006 due to their Medicare Part D plans. Who is benefiting...Medicare patients or insurance companies? Back to AMP, how can a pharmacy afford to lose 50% on any generic that they dispense...this is what will happen if the AMP is mandated. We do not buy directly from manufacturers...we buy from wholesalers...we will not be getting medications at AMP but AWP. The wholesalers take their profit before we get the medications. If CMS mandates this, then all third party payors will likely follow...which will put thousands of pharmacies out of business. Please reconsider implementing AMP.

Submitter : **Ms. Robert Sherman** **Date: 02/20/2007**

Organization : **Ms. Robert Sherman**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - CMS-2238-P Robert Sherman - General Comments.pdf for signature.
02/15/2007

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

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

Acting Administrator Leslie Norwalk,

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Robert O. Sherman, R.Ph.

Akron, Pa. 17501
Pharmacist Manager and Owner
Primary store:
Royer Pharmacy located at:
113 S 7th St.
Arkon, Pa. 17501
717-859-4911

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Response to Comments

Response to Comments

The GAO, NCPA, Pennsylvania Pharmacists Association and many others have documented the severe negative financial impact this proposed regulation will have on retail community pharmacy. I concur with those studies. If enacted as proposed, I will be forced to cease providing Medicaid services. This will ultimately result in higher, not lower government costs as the reduced medication access will result in higher doctor, hospital and emergency room access by Medicaid patients. The long term ability of my company to survive and continue to provide employment and tax revenue is significantly and negatively impacted by this proposal.

CMS-2238-P-1107-Attach-1.PDF

1107

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799.....717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332.....717-859-4911
335 West Main Street, Leola, Pa. 17540-2107.....717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135.....717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702.....717-299-4737

02/15/2007

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

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

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

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

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

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

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

3. **Removal of Medicaid Data**

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Robert O. Sherman R.Ph

Robert O. Sherman, R.Ph.
Pharmacist Manager and Owner
Primary store:
Royer Pharmacy located at:
113 S 7th St.
Arkon, Pa. 17501
717-859-4911

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : Mrs. Melissa Graham **Date:** 02/20/2007

Organization : Simmons&GrahamPharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"SeeAttachment"

CMS-2238-P-1108-Attach-1.DOC

#1108

February 20, 2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,
Melissa Graham, R.Ph.
Simmons& Graham Pharmacy
Charleston, MO63834

Submitter : Mr. Eric Schuss **Date:** 02/20/2007

Organization : Bellco Health

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

Submitter : Mr. Thomas Kelly **Date:** 02/20/2007

Organization : Medicine To Go Pharmacies

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

This proposed regulation has never been tested in the market place. There has not been even a test trial in a population as small as a county, let alone a larger scale. Through research, and trials would allow for an honest assessment as to the outcome of this regulation before implementation on a national scale.

This regulation has been and forced through like bad state policy, and not vetted to the high standards good federal public policy and regulation.

By all appearances, this regulation was written by and for the brand name pharmaceutical industry to increase brand name sales. Unfortunately, this is corporate welfare at its worst. Moving market share through ill conceived legislation failed in the Soviet Union, and will most certainly fail here.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Federal regulations demand a full vetting process, especially when needed and valued health care services are involved. The proposed rules and summary pricing standards have not been provided for adequate public scrutiny and comment. Information gleaned from the G.A.O. indicates that the program is not sustainable based upon the conclusions drawn upon by -GAO-07-239R

Response to Comments

Response to Comments

The dead net result of the proposed regulation will result in far higher costs, not lower. Medicaid providers will not be able to sustain negative revenue due to currently proposed AMP regulations. The natural reaction will be to cease dispensing multi-source generics and dispense brand name products, which will still allow for some profitability. Many providers will have to exit the system all together, forcing those in most need of services to seek care from far more expensive emergency hospital rooms.

Submitter : **Ms. Karen Jonas** **Date: 02/20/2007**

Organization : **Pharmacy Consulting Services**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Background

Background

I am submitting comments today regarding the Centers for Medicare and Medicaid Services (CMS) December 20, 2006 proposed regulation that would provide a regulatory definition of Average Manufacturer s Price (AMP) as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy which is located in Michigan. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

Collection of Information Requirements

Collection of Information Requirements

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

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

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

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

3. Removal of Medicaid Data

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

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

Reporting of AMP data by the manufacturers on a quarterly basis verses monthly or weekly basis does not address the issue of price fluctuations when they occur. CMS needs to address this concern and create an exceptions and appeals process, similar to Medicare Part D, which would allow any provider, including pharmacies, a mechanism to request a redetermination process for a FUL. The redetermination process should include a 1-800 number that would be monitored by CMS and include a specific time frame for the redetermination process to occur in and a procedure by which a redetermined FUL would be updated. This process would mitigate the risk of pricing lag and create a fair reimbursement mechanism for community pharmacy that is timely.

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

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

Response to Comments

Response to Comments

I appreciate your consideration of these comments and support the more extensive comments that are being filed by the Michigan Pharmacists Association regarding this proposed regulation. Please feel free to contact me with any questions.

Sincerely,

Karen A. Jonas
13121 Willow Grove Drive

DeWitt, MI 48820
kjonasrph@comcast.net

cc. Members of Congress

Submitter : **Lonnie Hicks** **Date: 02/20/2007**

Organization : **Quinn Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

My pharmacy is located in Laurel, Mississippi and we are a major provider of pharmacy services to our community.

Collection of Information Requirements

Collection of Information Requirements

Regarding CMS proposed regulation on AMP and the new uper limit on generic drugs for medicaid.

GENERAL

GENERAL

Any changes to the reimbursement schedule should be done with the intent of encouraging generic usage. These proposed changes would do just the opposite and would lead to the use of more expensive brand name drugs.

Provisions of tbe Proposed Regulations

Provisions of the Proposed Regulations

When data is collected PBM's and mail order should be excluded. They are not dispenser to the vast majority of medicaid recepients. AMP should reflect the prices paid by retail pharmacy.

Regulatory Impact Analysis

Regulatory Impact Analysis

Medicaid pricing is already heavly regulated by both the federal and state governments. MAC is already in place.

Submitter : **Greg Jonas** **Date: 02/20/2007**

Organization : **Blue Care Network Pharmacy**

Category : **Health Care Provider/Association**

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

I am submitting comments today regarding the Centers for Medicare and Medicaid Services (CMS) December 20, 2006 proposed regulation that would provide a regulatory definition of Average Manufacturer s Price (AMP) as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy which is located East Lansing, Michigan. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Definition of Retail Pharmacy Class of Trade - Remove PBM and Mail Order Pharmacies

PBMs and Mail order pharmacies do not dispense medications to the general public and therefore should not qualify as community pharmacies. These providers also receive discounts and price concessions that the community pharmacy does not receive. AMP should reflect prices paid by retail community pharmacies.

2. Implement an Exceptions and Appeals Process for Market Fluctuations

Current reporting of AMP data to CMS in a quarterly manner does not address drug market price fluctuations that occur. CMS must create an exceptions and appeals process, similar to Medicare Part D, which would allow any provider, including pharmacies, to request a redetermination of a FUL. A redetermination process would mitigate risk of pricing lag and create a reimbursement mechanism for community pharmacy that is timely.

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

CMS should use the 11-digit NDC for determination of AMP since this represents the most common package size dispensed by retail pharmacies

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

Sincerely,

Greg Jonas
Blue Care Network Pharmacy
East Lansing, MI 48823
gregjonas@comcast.net

cc. Members of Congress

Submitter : Mr. Kerry Prickett **Date:** 02/20/2007

Organization : Mr. Kerry Prickett

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AMP in theory sounds like a good idea but it will be devastating to community pharmacists like myself when used as a benchmark to reimburse us for medicaid prescriptions. The GAO study on this issue confirms my point. Mail order pharmacies must be excluded from the retail pharmacy class of trade since they, like hospitals and nursing homes, are not brick and mortar pharmcies where patients can go for service. CMS should also exclude rebates paid to PBMs from AMP calculations. These rebates are not available to the retail pharmacy class of trade. If included AMP will be driven below available market price. This could shrink the rebates states receive. Another very important point is that PBM transparency must occur in order for this system to work. PBMs have been allowed, due to a lack of regulation from the federal and state level, to keep information hidden. They also self refer to their own pharmacies, a conflict of interest that is not allowed by any other health care entity. Other important points are: 1. AMP must be reported weekly.
2. 11 digit NDC number must be used to calculate AMP to ensure accuracy.
The GAO study demonstrates the impact this proposed rule will have on small independent pharmacies. I have a small independent pharmacy. I cannot stay in business and experience a 36% loss on each transaction. I cannot overcome this by aggressive purchasing, rebates, or even adequate dispensing fees. CMS must employ a complete and adequate definition of the cost to dispensc. I do not provide a commodity to my patients, I provide a service. Good pharmacists will be driven out of our profession if we are contiually the target for the high cost of health care in this country. I cannot provide the care I am morally and ethically required to give if I continue to face devastating cuts to fair reimbursement. My final point is that I love the work I do in pharmacy. Please listen to what we are saying.

Submitter : **Mr. Eric Schuss** **Date: 02/20/2007**

Organization : **Bellco Health**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1115-Attach-1.DOC

#1115

Bellco HEALTH

February 20, 2007

Leslie V. Norwalk, Esq.
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-2238-P; Proposed Rule: *Medicaid Program; Prescription Drugs*
71 Fed. Reg. 77173 (December 22, 2006)

Dear Ms. Norwalk:

On behalf of Bellco Health, I would like to take this opportunity to provide our comments on the Proposed Rule CMS-2238-P, (the "Proposed Rule"). This rule was published in the *Federal Register* on December 22, 2006.[1]

Bellco Health is a $2.4 billion national pharmaceutical distributor and health services organization that employs over 220 full-time employees. The Bellco Health family of companies includes:

- **Bellco Drug Corp.** a full-line, full-service pharmaceutical wholesaler
- **Bellco Generics**, a national generic drug distributor
- **American Medical Distributors, Inc.**, the country's leading distributor of biotech drugs and pharmaceuticals to the kidney dialysis market
- **Dialysis Purchasing Alliance, Inc.**, a leading group purchasing organization dedicated to kidney dialysis
- **Clinical Outcomes Resource Application Corporation,** a web-based clinical data collection and reporting company uniquely positioned to offer renal providers and manufacturers clinical reporting and resources.

Bellco Health is a member of the Healthcare Distribution Management Association ("HDMA"). As part of our membership activities, we have reviewed the HDMA written comment letter to the Centers for Medicare and Medicaid Services (CMS), on the proposed rule referenced above. Bellco Health fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.

[1] 71 *Fed. Reg. 77173* (December 22, 2006).

5500 New Horizons Blvd. • N. Amityville, NY 11701
phone: 631.789.6300 • toll-free phone: 1.800.645.5314 • fax: 631.841.6185 www.BellcoHealth.com

In particular, we would like to note the following:

- Bellco Health agrees with the decision to include a definition of "*bona fide* service fee". We also recommend that CMS reference the discussion of *bona fide* service fees in the preamble to the 2007 Physician Fee Schedule Final Rule, and stipulate that CMS intends to apply the *bona fide* service fee definition in the same way in both the AMP and Average Sales Price (ASP) final rules.
- We also agree with the exclusion of "prompt pay discounts" from the AMP calculation. We urge CMS to similarly exclude "prompt pay discounts" from the Best Price calculation. Additionally, since many in the industry have historically referred to "prompt pay discounts" as "cash discounts," whether to include cash discounts in the exclusion may be a point of confusion. We urge CMS to qualify the term "cash discounts" by recognizing an exception for customary prompt pay discounts.
- We believe that the Final Rule should exclude sales to mail-order pharmacies, rebates paid to PBMs on retail network sales, and sales to hospitals, regardless of whether a drug is used in an inpatient or outpatient setting the following sales, rebates and other concessions from AMP.
- While we appreciate CMS' recognition of the need for a FUL outlier methodology, we are concerned that the proposed approach may still leave pharmacies underpaid. We encourage CMS to consider the alternative options as described in the comments submitted by HDMA.

Thank you for this opportunity to provide our comments on Proposed Rule CMS-2238-P, and to endorse the comments of the HDMA as written. We hope these comments are constructive in your deliberation of developing an Average Manufacturer Price calculation that represents an equitable and reasonable approach to reimbursement for the products that we distribute.

Sincerely,

Eric Schuss
Chairman

Submitter : **Fredrick Maier** **Date: 02/20/2007**

Organization : **Fredrick Maier**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - CMS-2238-P Fredrick Maier - General Comments.pdf for signature.
02/15/2007

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

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

Acting Administrator Leslie Norwalk,

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Fredrick J. Maier, R.Ph.

Lebanon, Pa. 17042
Staff Pharmacist
Royer Pharmacy

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Response to Comments

Response to Comments

The financial impact if enacted as proposed will that I must cease dispensing Medicaid prescriptions. No business can continue to sell at a loss. This financial impact ripples through our economy in many ways. The Medicaid patient has reduced medication access and this results in higher emergency room, doctor, hospital and other health care costs. The retail community pharmacy industry is impacted so severely that their survival (and the professional services, employment, tax revenue they provide) and is jeopardized. The financial impact on Medicaid patients and retail pharmacy is dire.

CMS-2238-P-1116-Attach-1.PDF

1116

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799.....717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332.....717-859-4911
335 West Main Street, Leola, Pa. 17540-2107.....717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135.....717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702.....717-299-4737

02/15/2007

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

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

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

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

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

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

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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.

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

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

Tom

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

Sincerely,

Frederick J. Maier, R.Ph.
Royer Pharmacy Staff Pharmacist

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : **Mr. Lee Davis** **Date: 02/20/2007**

Organization : **York Drug**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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 2005.

GENERAL

GENERAL

As the owner of the only two pharmacies in Sumter County, Alabama. The changes this proposed rule suggest greatly disturbs me. I deal with the poor and the very poor everyday; the poor elderly, the rural elderly and frankly I do not see how I can continue to accept Medicaid with these proposed changes. Our margins have already been drastically reduced by Medicare Part D, and we simply cannot continue to absorb losses in revenue. I implore you to consider postponing the implementation of this ruling until all the facts and ramifications have been considered.

Submitter : Mr. Steve Giuli **Date:** 02/20/2007

Organization : Apotex Corp.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-1118-Attach-1.PDF

1118

APOTEX CORP.

2400 N. Commerce Parkway
Suite 400
Weston, FL 33326

February 20, 2007

Transmitted via email: www.cms.hhs.gov/eRulemaking

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Comments re: CMS-2238-P

Dear Administrator Norwalk:

Apotex Corporation appreciates the opportunity to submit these comments to the proposed rule implementing the provisions of the Deficit Reduction Act (DRA) pertaining to payment for Medicaid prescription drugs.

Apotex, one of the largest international generic pharmaceutical companies, distributes more than 260 generic products worldwide. Since 1974, we have focused our research and manufacturing on bringing quality, affordable medications to consumers here and abroad. Because our pharmaceuticals represent an excellent value, Medicaid is an especially important payer for our products. The comments below focus on issues we believe are particularly significant for our business operations.

1. Public Disclosure of AMP

Multiple source AMPs should be reported to states and posted on the CMS website in an aggregated format that combines individual manufacturer AMPs into one AMP for the drug.

The public disclosure of AMP enabled by Section 6001(b)(2)(C) of the Deficit Reduction Act (DRA) is a concept modeled after the disclosure of Part B Average Sales Prices

(ASPs). The DRA provides that, "the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v)." The DRA is silent on the question of how AMPs for multiple source drugs should be reported, enabling CMS to apply its interpretation.

Although the AMP changes are directed to Medicaid, the impact of those changes will be seen in other government health programs, such as Medicare. Analysts and policy makers routinely attribute the success of Medicare Part D to its emphasis on the use of generics, and expect the importance of generic drugs in pharmaceutical cost management to grow over the next several years. For example, on September 21, 2006, CMS Administrator Mark McClellan, MD, PhD testified before the Senate that, "The utilization of generic drugs has played an important role in the low costs and expected further cost reductions in the drug benefit. Due in part to increasing generic drug availability, strong competition in the prescription drug marketplace has led to slower rates of growth in overall prescription drug spending. Also, the availability of excellent coverage of generic drugs in the Part D drug benefit, as well as personalized information and support to help beneficiaries find out about how they can save using generics, have been important contributors to costs that are much lower than expected. Continuing to promote greater reliance on generics when available among Medicare beneficiaries is an important strategy to keep the new drug benefit affordable over the long term." [Available at: http://www.hhs.gov/asl/testify/t060921.html]

Medicaid's switch from average wholesale price (AWP) to AMP as a reimbursement benchmark will contribute significantly to the power of generics to tame drug cost inflation. In the course of implementing that switch, we ask you to not undercut the viability of the generic pharmaceutical industry by rushing to publicize our most sensitive and proprietary pricing information.

Publishing manufacturer-specific AMPs, moreover, raises significant antitrust concerns. As GPhA observed in its June 9, 2006 letter to Dr. McClellan, publication of aggregate data such as an industry wide average is supported by long-standing interpretations of the Sherman Act which condemns conduct that could facilitate anticompetitive collusion among competitors. In the health care industry in particular, the federal antitrust enforcement agencies have consistently recognized the potential anticompetitive impact of the sharing of specific companies' internal price-related information.

Recommendation: CMS should publish only the aggregated, industry-wide weighted AMPs for multiple source drugs.

2. Time to Implement Operational Changes

Complex administrative system changes and additions will be needed to implement the new definitions and reporting requirements in the final rule, but the proposed effective dates do not create adequate time to design and operationalize those changes. The price reporting certification created by sec. 447.510 of the proposed rule, and the consequences inherent in certification, require the utmost accuracy and reliability in the reporting of our data. The revised definition of AMP requires new data fields to be created and substantial reprogramming of sales reporting systems that must be tested and validated.

Recommendation: Provide at least 180 days to implement all reporting changes created by the final rule.

3. Definitions—Section 447.502

Pharmacy dispensing fee. To promote continued and aggressive dispensing of generic products, states should offset any cuts from the new AMP calculation with higher dispensing fees for generic medications.

Individual states currently determine the dispensing fee paid to pharmacies. With the reduction in generic drug reimbursement that will be triggered by the switch to AMP, dispensing fees become increasingly important in influencing the willingness and ability of pharmacies to promote generic utilization.

CMS proposes a definition of "Dispensing fee" and states that, "We are defining this term in order to assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers. We note that while we propose to define this term, we do not intend to mandate a specific formula or methodology which the States must use to determine the dispensing fee." 71 Fed Reg 246; p. 77176.

Given the latitude that states will have in determining the dispensing fee, and to ensure continuing and aggressive dispensing of generic drugs by Medicaid, we believe it is important that CMS direct state to adopt dispensing fees that are reasonable, fair and encourage the dispensing of generic drugs.

Recommendation: We propose that CMS require payment of dispensing fees that are reasonable, fair and encourage the dispensing of generic drugs.

4. Determination of Average Manufacturer Price—Section 447.504.

Clearly Identify Each Excluded Class of Trade Entity - Subsections *(g) Sales, rebates, discounts, or other price concessions included in AMP* and *(h) Sales ... excluded from AMP* lack the desired clarity to prevent manufacturer reporting errors and to ensure that, even where no error exists, all manufacturers are interpreting and conforming the computation of AMP in a uniform way. We believe that can be addressed by creating a list of specific entities for manufacturers to reference when computing AMP.

The list would be useful in addressing another problem as well. In sections (g) (3) and (h) (4) CMS proposes to include sales to hospitals where the drug is "used in the outpatient pharmacy" and conversely, to exclude sales "where the drug is used in the inpatient setting." When we sell our products to hospitals, we have no way of knowing which treatment setting they will be used in because purchases for all hospital needs are consolidated to obtain the best possible discount. Likewise, with long term care pharmacy sales, it may be operationally impossible for us to identify that sale. Our sales data are captured at the contract level, but any included or excluded class of trade customer could purchase product from any wholesaler source contract.

Recommendation: Where a class of trade is excluded from the computation of AMP, CMS should provide to manufacturers a list of identifiers, such as Drug Enforcement Administration (DEA) number or Health Industry Number (HIN), so that all parties are confident that only appropriate sales are being excluded. The "List of Excluded Class of Trade Entities" should be updated as frequently as AMP reports are filed.

5. Requirements for Manufacturers Section 447.510 (*12 Month Rolling Average)*

We support the application of a "smoothing" mechanism to the monthly and quarterly AMP calculations, especially for multiple source drugs, due to the large dollar value of

chargebacks customarily processed for wholesaler sales for generic products. We believe that the experience with smoothing for ASP pricing for Medicare Part B drugs has been overall favorable, particularly in HCPCS codes that apply to multiple source products. As a result, generic manufacturers should be encouraged to smooth data in the AMP calculation for reimbursement to accommodate transaction timing.

Recommendation: We support allowing manufacturers to use 12-month rolling average estimates of all lagged discounts to calculate the monthly and quarterly

AMP, based on a similar methodology that is currently allowed for calculating ASP.

6. Eliminating Outliers in the Establishment of Upper Limits for Multiple Source Drugs—Section 447.514

We believe the proposed methodology to eliminate price outliers does not accomplish the stated objective "to ensure that a drug is nationally available at the FUL price and that a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs..." (Proposed rule at p. 77188).

We are unaware of any evidence or experience, and CMS has offered no data, supporting the theory of why products whose AMPs are 29 percent of the next highest AMP should qualify as outliers but at 30 percent they are routinely and nationally available. Regulatory benchmarks and metrics created for one purpose, even when arbitrary and capricious, tend to become widely adopted because of the government's imprimatur. CMS should resist creating new standards in the absence of credible data supporting the decision.

Recommendation: There is a better alternative that appropriately accounts for all products at all prices – establishing FUL as the weighted average AMP, which would be the same multiple source AMP that we propose be published on the CMS website.

7. Private Labeled Drug Products - Sec. 447.502 Definition of Manufacturer

Under current Medicaid rebate rules, manufacturers pay rebates on drugs whose NDCs they legally possess. If manufacturer A produces a drug for B, and B owns the NDC, then B has the rebate obligation. See the following definition of "manufacturer" in the sample rebate agreement (available at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf)

> (l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

The definition of "manufacturer" in the rebate statute (Social Security Act sec. 1927 (k) (5) is broad enough ("engaged in") to cover both parties in a private labeling relationship.

> (5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in— ...
> (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Given the above statutory definition, the NDC refinement in the rebate agreement is an important added directive for determining who has the rebate obligation for private labeled product. We are concerned that the proposed rule definition of manufacturer will, in effect, become a directive to CMS to change the rebate agreement's definition. The definition in the proposed rule includes the following:

> (4) With respect to drugs subject to private labeling arrangements, the term ''manufacturer'' will also include the entity that does not possess legal title to the NDC.

If, based on the above, CMS revises the definition in the rebate agreement, manufacturer A would potentially be charged a rebate for Medicaid sales of someone else's (B's) product, an outcome that would be unjust and irrational. The rebate reporting and payment obligation should be on manufacturer B, as it is under the current system. We believe the revision proposed below would accomplish that without taking those sales out of the AMP computation.

> ***Recommendation***: Revise paragraph (4) to read "With respect to drugs subject to private labeling arrangements, ***for the purpose of computing AMP,*** the term ''manufacturer'' will also include the entity that does not possess legal title to the NDC."

Respectfully submitted,

Steve Giuli
Director of Government Affairs
& Industry Relations

Submitter : Mr. Robert Riffert **Date:** 02/20/2007

Organization : The Beaverton Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

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

Collection of Information Requirements

Collection of Information Requirements

I am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer s price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Beaverton, MI. The Beaverton Pharmacy is a major provider of pharmacy services in the community and your consideration of these comments is essential.

Regulatory Impact Analysis

Regulatory Impact Analysis

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

I appreciate your consideration of these comments and support the more extensive comments that are being filed by the Michigan Pharmacists Association regarding this proposed regulation. Please feel free to contact me with any questions.

Submitter : Mr. Jeffrey Walton **Date:** 02/20/2007

Organization : Coleman Family Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I independantly own and operate a small pharmacy where a high percentage of my patients are dependent on Medicaid. As I understand this proposed legislation, the formula for determining AMP will take into consideration several discounts to which a small pharmacy like mine does not have access. This will very likely force me to decline accepting Medicaid at my pharmacy, thus denying access to my Medicaid patients to the health care they need, as well as jeopordizing my entire business. To be an appropriate benchmark for reimbursement, AMP must be defined to reflect the actual cost paid by retail pharmacy. This would be accomplished by excluding all rebates and price conscessions made by manufacturers which are not available to retail pharmacy; by excluding all mail order and PBM pricing from AMP calculation; and by reporting AMP at the 11-digit NDC level to ensure accuracy. Please consider the impact this will have on small, independent pharmacies, like mine.

Submitter : **Mrs. Velinda Pickel** **Date: 02/20/2007**

Organization : **Mrs. Velinda Pickel**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment - 'CMS-2238-P Velinda Pickel - General Comments.pdf' for signature.
02/15/2007

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

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

Acting Administrator Leslie Norwalk,

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.

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

Sincerely,

Velinda R. Pickel, R.Ph.
Leola, Pa. 17540

Pharmacist Manager
Royer Pharmacy
508 Hershey Ave.
Lancaster, Pa. 17603
717-299-4737

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Response to Comments

Response to Comments

The GAO and many pharmacy organizations have documented the negative financial impact this regulation will have on the retail community pharmacist and his ability to provide Medicaid services.
The impact of reduced Medicaid medication access will increase, not decrease, government costs as patients utilize their doctor, hospital or emergency room because they don't have their medication or the professional pharmacy services that allow them to maximize their therapeutic effect. The long term impact to the government and economy of the potential closing of numerous retail pharmacies is not considered by the current analysis.

CMS-2238-P-1121-Attach-1.PDF

X

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799 717-733-6541

113 South Seventh Street, Akron, Pa. 17501-1332 717-859-4911

335 West Main Street, Leola, Pa. 17540-2107 717-656-3784

1021 Sharp Avenue, Ephrata, Pa. 17522-1135 717-733-1215

508 Hershey Avenue, Lancaster, Pa. 17603-5702 717-299-4737

02/15/2007

Centers for Medicare and Medicaid Services

Attention CMS 2238-P Mail Stop C4-26-05

7500 Security Blvd

Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation

CMS 2238-P RIN 0938-AO20

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

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

Sincerely,

Velinda R. Pickel

Velinda R. Pickel, R.Ph.

Pharmacist Manager

Royer Pharmacy

508 Hershey Ave.

Lancaster, Pa. 17603

717-299-4737

cc. Members of Congress

Senator Arlen Specter

Senator Robert P. Casey, Jr.

Representative Joseph Pitts

Submitter : Ms. Teal Rabon **Date:** 02/20/2007

Organization : Value Medical Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attached letter

CMS-2238-P-1122-Attach-1.PDF

February 18, 2007

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

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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacist employed in Greenville, South Carolina. We are a provider of pharmacy services in the community and the State of South Carolina primarily to indigent patients and your consideration of these comments is essential.

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

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the "general public." The more extensive comments submitted by the South Carolina Pharmacy Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

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

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent and would result in FULs that are lower than a retail pharmacy's acquisition cost.

3. Removal of Medicaid Data

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

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

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

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

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

In conclusion, I support the more extensive comments submitted by the South Carolina Pharmacy Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Teal D. Rabon

Teal D. Rabon, RPh
Pharmacy Director
Value Medical Pharmacy
107 Kiowa Lane
Piedmont, SC 29673
1-800-861-4965
www.valuemedical.com

cc. Governor Mark W. Sanford, Senator Jim W. DeMint, Representative James Gresham Barrett, Senator Kevin L. Bryant, Representative Daniel T. Cooper

Submitter : JOE REYNOLDS **Date:** 02/20/2007

Organization : APCI

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

CLOSURE OF MOST PHARMACIES IN RURAL AMERICA(COMPLETE DESTRUCTIN OF PHARMACY CARE.
*DUE TO LACK OF PAYMENT TO SUSTAIN A LIVELIHOOLD FOR PHARMACIST
*RURAL PHARMACIES DO NOT HAVE THE POPULATION TO MASS PRODUCE RX
*RURAL PHARMACIES DO HAVE MORE TIME TO CONSULT WITH CLIENTS
*POPULATION SHIFT (YOUNG MARRIED, CHILD BEARING AGEj)
*URBAN AGE SHIFT, SR CITIZENS
*PHARMACY CLOSURES FORCE MAIL ORDER
*NATIONAL EMERGENCY - NO GUARRENTEE MAIL WILL RUN
*CONCENTRATION OF RX SERVICDES MORE EASILY TO DISRUPT DISTRIBUTION, THAN THE CORNER DRUG STORE
*OUTLOOK NOT GOOD

SOLUTION: ALL PROFESSIONS TO BE PAID HIGHER FEES FOR SERVICES IN RURAL AREAS, (LESS THAN 3000 PEOPLE)THAN IN URBAN AREAS

RURAL AMERICA CAN ONLY SERVICE IF IT HAS PROFESSIONIALS SO THAT YOUNG FAMILIES CAN SETTLE. CONCLUSION DO NOT CUT THE PAYMENTS SO THAT RURAL AMERICA CAN SURVIVE!

Submitter : Mr. John Ochs **Date:** 02/20/2007

Organization : Central Drug Store

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

AMP for Medicaid should be calculated based ONLY on what community pharmacies pay for medications, since they serve most medicaid recipients. According to the GAO, community pharmacies will pay 36% more for medications than AMP. This will cause many, if not most, community pharmacies to stop serving medicaid recipients, so that they will not have good access to prescription services. It will also cause many pharmacies to go out of business. AMP must be recalculated to allow community pharmacies to at least cover their costs, and make a profit.

Submitter : **Julie McCusker** **Date: 02/20/2007**

Organization : **Julie McCusker**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Coudersport, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Definition of "Retail Class of Trade"-Removal of PBms and Mail Order Pharmacics

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

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

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

3. Removal of Midicaid Data

Including these data elements in "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 Minipulation

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

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

Sincerely,

Julie McCusker, R.Ph
Buchanan Brothers' Pharmacy, Inc.
101 Main Street
Coudersport, PA 16915

Submitter : Gene Ragazzo **Date:** 02/20/2007

Organization : Hopewell Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1126-Attach-1.DOC

#1126

VIA ELECTRONIC SUBMISSION

Hopewell Pharmacy
1 West Broad St.
Hopewell, NJ 08525
PH: 609-466-1960
Fax: 609-466-8222

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

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

As an owner of an independent pharmacy store in New Jersey serve a diverse Medicaid patient population for pharmacy care needs, I am very troubled by the CMS proposed regulation referenced above that seeks to define and establish an average manufacters' price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that my independent pharmacy can afford to continue provide Medicaid generic pharmacy prescription services to my Medicaid prescription patients without incurring unsustainable financial losses.

Below are my specific comments on and recommended changes to the proposed rule:

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

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 calculating the AMP.

"Retail pharmacy class of trade" definition should only 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.

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

Treatment of Manufacturer coupons with regard to Best Price.

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

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.

PBM price concessions reporting to CMS.

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.

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 rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

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.

Impact on small pharmacies demonstrated by (General Accountability Office (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.

In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

- 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.*

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

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,

Gene Ragazzo, R.Ph.
Hopewell Pharmacy

Submitter : Mr. Herb Tolentino **Date:** 02/20/2007

Organization : Cameron County Department of Health and Human Serv

Category : Local Government

Issue Areas/Comments

GENERAL

GENERAL

Needless to say, I am extremely disappointed over the fact that Title V providers were not listed as an entity in 340B, as we serve the same population!

I think this is a gross over-site. Any monies the Federal Government saves by not providing these pharmaceuticals (Birth Control Pills), they are going to spend on increased maternity bills and increased welfare checks.

There are some women who will not qualify for the Women's Health Program, and a few of these women may be able to purchase their own birth control pills. This in turn, will make the pharmaceutical companies very happy.

One option we are looking at, and so are other Local Health Departments, is to get out of the Family Planning business.

In our County, there are going to be thousands of women that will just have to do without. Since the population we serve is almost 100% Hispanic, this could be a civil case in the making.

Submitter : Mr. Cory Minnich **Date:** 02/20/2007

Organization : Mr. Cory Minnich

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachement 'CMS-2238-P Cory Minnich - General Comments.pdf' for signature.
02/15/2007

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

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

Acting Administrator Leslie Norwalk,

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

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

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

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

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

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

Sincerely,

Cory D. Minnich, R.Ph.
Lititz, Pa. 17543

Pharmacist Manager
Royer Pharmacy
1021 Sharp Ave.
Ephrata, Pa. 17522
717-733-1215

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Response to Comments

Response to Comments

The regulatory impact of this proposal will be swift and negative.
Retail community pharmacists will be forced to stop dispensing Medicaid prescriptions because of the regulation proposes payments at 36% BELOW COST for generic medications. Medicaid patients will lose access to a vital source of healthcare information when their pharmacist can no longer afford to fill their prescription. They will also lose access to the undocumented but vast efforts expended by their community pharmacist to help them negotiate the labyrinth of formulary and other government imposed regulations. The long term impact will be the loss of numerous community pharmacies and their contribution of professional services, employment and tax revenue.

CMS-2238-P-1128-Attach-1.PDF

1128

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799.....717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332.....717-859-4911
335 West Main Street, Leola, Pa. 17540-2107.....717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135.....717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702.....717-299-4737

02/15/2007

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

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

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

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

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

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

3. **Removal of Medicaid Data**

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

Sincerely,

Cory D. Minnich, R.Ph.
Pharmacist Manager
Royer Pharmacy
1021 Sharp Ave.
Ephrata, Pa. 17522
717-733-1215

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : **Christie Keglovits** **Date: 02/20/2007**

Organization : **Christie Keglovits**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Coudersport, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

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

Sincerely,

Christie Keglovits, R.Ph
Buchanan Brothers' Pharmacy, Inc.
101 Main Street
Coudersport, PA 16915

Submitter : Mr. Paul Reinhart **Date:** 02/20/2007

Organization : Michigan Department of Community Health

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1130-Attach-1.PDF

1130

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

JANET OLSZEWSKI
DIRECTOR

February 15, 2007

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

Re: Proposed Rule: Medicaid Program – Prescription Drugs

The Michigan Department of Community Health, which administers the state's Medicaid program, is submitting the enclosed comments on the proposed prescription drug rule (CMS-2238-P). This proposed rule includes changes to federal regulations at 42 CFR §447.500 – §447.520 which implement requirements of Sections 6001 (a) – (d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA); revise existing regulations setting upper payment limits for outpatient drugs; and codify selected parts of 1927 of the Social Security Act pertaining to the calculation of Average Manufacturer Price (AMP) and Best Price by drug manufacturers.

Michigan Medicaid staff would like CMS to pay special attention to our comments dealing with the following key issues:

- The proposed definition of dispensing fee
- Analysis of atypical manufacturer pricing practices
- File specifications to distribute Average Manufacturer Price and Federal Upper Limits to States
- Additional measures to ensure drugs are available nationally at Federal Upper Limits under the revised calculation stipulated by the Deficit Reduction Act of 2005 (DRA)

Michigan Medicaid is committed to implementing the prescription drug provisions of DRA and appreciates the opportunity CMS afforded us to comment on its proposed regulations. If you have any questions on our comments, please contact Susan Moran of my staff at 517-241-8055 or MoranS@michigan.gov.

Sincerely,

Paul Reinhart

Paul Reinhart, Director
Medical Services Administration

Michigan Medicaid Comments

Proposed Regulations for Medicaid Program – Prescription Drugs (CMS-2238-P)

State Contact for Questions:

Susan Moran
Medical Service Administration
400 S. Pine Street, 7th Floor
Lansing, Michigan 48933
517- 241-8055
MoranS@michigan.gov

Michigan Medicaid Comments – Proposed Rule Medicaid Program; Prescription Drugs (CMS-2238-P)

The Michigan Department of Community Health, which administers the state's Medicaid program, is submitting comments on the proposed prescription drug rule (CMS-2238-P). This proposed rule includes changes to federal regulations at 42 CFR §447.500 – §447.520 which implement requirements of Sections 6001 (a) – (d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA); revise existing regulations setting upper payment limits for outpatient drugs; and codify selected parts of 1927 of the Social Security Act pertaining to calculation of Average Manufacturer Price (AMP) and Best Price by drug manufacturers. The following Michigan Medicaid comments are listed in the order that appeared in the proposed regulations – not by priority.

Comments on Provisions of the Proposed Regulations

DEFINITIONS - §447.502

Michigan Medicaid staff is commenting on the definitions that CMS proposed for dispensing fee, estimated acquisition cost, and multiple source drug, as follows.

Definition Dispensing Fee - In the proposed regulations, CMS explained "We are defining this term in order to assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers. We note that while we propose to define this term, we do not intend to mandate a specific formula or methodology which the States must use to determine the dispensing fee..." [1] CMS also stipulated in rebate program guidance "If States adjust their payment methodologies to reflect the ingredient cost of the prescription drug; we suggest that they also reevaluate their dispensing fees to ensure that these fees are *reasonable*... "[2] From CMS comments provided along with the proposed rule, Michigan Medicaid staff understands that a State retains flexibility to set its own dispensing fees, but has the following concerns with the proposed definition and its application to Medicaid programs.

First, the proposed, new definition of dispensing fee, however, appears to imply that States set dispensing fees based on *costs* in excess of the drug ingredient costs for filling a prescription – rather than allowing a reasonable market-based amount. As such, the total Medicaid payment for both ingredient cost and dispensing fee may exceed amounts paid by commercial insurers and by Medicare prescription drug sponsors.

Second, the proposed definition inadvertently infers that a pharmacy is entitled to a dispensing fee every time a covered outpatient drug is dispensed. Such a definition does not assure efficient filling schedules for maintenance drugs (e.g., State policies that allow thirteen prescriptions for the same drug over one year) and encourages pharmacies to split prescribers' orders to receive more reimbursement (e.g., split a 30-days supply prescription into a 15-days supply) – particularly in the nursing home setting.

Third, Michigan Medicaid staff notes that the proposed definition refers to "point of sale" which seems to preclude dispensing to Medicaid populations in nursing homes, home- and community-based settings, etc. A more appropriate replacement would be "point of service."

Michigan Medicaid staff recommends the following modifications to (1) assure that States are afforded the flexibility CMS intended; (2) avoid dispensing fee payments for prescription splitting and other atypical frequency patterns; and (3) clarify that state Medicaid programs should not have to fully reimburse a pharmacy for its dispensing, but only reasonable costs representative of rates in the marketplace.

> Dispensing fee means the ~~fee which~~ **PAYMENT** –
>
> (1) **FOR DISPENSING A COVERED OUTPATIENT DRUG WHICH IS CONSISTENT WITH MARKET-BASED RATES PAID BY OTHER COMMERCIAL PAYERS AND MEDICARE;** ~~is incurred at the point of sale and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed~~

[1] Proposed Rule 42.CFR 447, Medicaid Program; Prescription Drugs, Federal Register, Vol. 71, No. 246, Friday, December 22, 2006, p. 77176

[2] Medicaid Drug Rebate Program, News for State Medicaid Directors, Release No. 144, December 15, 2006. Regulations at 42 CFR §447.512 and 447.514 also refer to a reasonable dispensing fee.

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy;

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Michigan Medicaid staff is questioning whether point (3) from the proposed definition of dispensing fees has relevance for state Medicaid programs. CMS should provide examples and types of administrative costs incurred by States in the operation of their prescription drug program that would not be included.

Definition of Estimated Acquisition Cost – The definition of Estimated Acquisition Cost listed in the proposed regulations is the same as contained in current regulations. It means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler *in the package size of [the] drug most frequently purchased by providers* [emphasis added]. Michigan Medicaid staff notes this definition with its references to package size does not coincide with the CMS decision to provide Average Manufacturer Prices (AMPs) and to set Federal Upper Limits (FULs) without regard to package sizes.

Definition of Multiple Source Drug – Michigan Medicaid staff finds this definition confusing. The proposed definition of multiple source drug listed in the proposed regulation stipulates "...with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product which —

(1) Is rated as therapeutically equivalent. For the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at *http://www.fda.gov/cder/orange/default.htm* or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857;

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA; and

(3) Is sold or marketed in the United States during the rebate period."

First, it applies explicitly to a "rebate period" when the FULs set on multiple source drugs are based on "date of service." Second, it implies that a drug entity cannot be *multiple source* unless it has two sources "rated as therapeutically equivalent" – which is untrue.

Michigan Medicaid staff strongly recommends maintaining the current definition of multiple source drug listed at 42 CFR §447.301 with a note specifying "Federal upper limits are placed on multiple source drugs complying with requirements listed at 42 CFR §447.512 and §447.514.[3] CMS then should list proposed language on the equivalency under 42 CFR §447.512 (Drugs: Aggregate Upper Limits of Payment) and §447.514 (Upper Limits for Multiple Source Drugs).

DETERMINATION OF AMP - §447.504

CMS indicated in the proposed regulations that States are *not* required to use AMPs to set their payment amounts for ingredient costs. CMS, further, clarified that it believes Congress intended that States have drug pricing data based on actual prices instead of previously available data[4] that do not necessarily reflect actual costs paid by wholesalers and retail pharmacies. Michigan Medicaid comments on this section follow.

[3] 42 CFR §447.301 "Multiple source drug" means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

[4] Michigan Medicaid staff assumes the previously available data to be Average Wholesale Price (AWP) and Wholesale Acquisition Cost (WAC).

AMPs without Package Size Reporting Not Useful for Pharmacy Payment on Brand Name Drugs – Michigan Medicaid staff welcome the public disclosure of AMP, but such availability may have limited use as a basis for pharmacy payment on brand name drugs.

First, AMP that is a weighted average of all package sizes, as proposed by CMS, would not provide a definitive basis to set "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of [the] drug most frequently purchased by providers."[5] Also, a weighted AMP may not cover the actual acquisition costs of pharmacies purchasing smaller package sizes – unless States used significant mark-up percentages. Then other pharmacies purchasing larger package sizes would be over paid.

Second, AMPs provided by CMS are to be updated monthly. This lags significantly behind the weekly price updates Michigan Medicaid now receives. States have noted the AMPs files sent to date have had missing drug products for which AMPs are not reported. The reporting lag and omissions may result in denied or inadequate pharmacy reimbursement if AMPs were used as the basis of pharmacy payment for brand name drugs.

AMPs Very Useful To Analyze Current Reimbursement Methodologies – Michigan Medicaid staff agrees AMPs will be useful to validate the appropriateness of current reimbursement methodologies.[6] Studies could identify manufacturers whose products consistently have atypically large spreads between AMP and AWP or WAC. Then States individually may implement alternative payment rates on products distributed by these manufacturers – preventing revenue enhancing schemes widely publicized by the OIG, which still retaining the usefulness of their current reimbursement techniques.

CMS Should Analyze Atypical Manufacturer Pricing and Recommend Remedies to Congress – Michigan Medicaid staff requests that CMS performs analyses to identify atypical manufacturer pricing practices. Further, CMS should recommend remedies to Congress, which address aberrant manufacturer pricing. Remedies could include additional rebate penalties (similar to the current penalty applied when a manufacturer's AMP of a drug exceeds the CPI-U) or denied status as an approved manufacturer under the Medicaid program.

REQUIREMENTS FOR MANUFACTURERS - §447.510

Automated Editing of Manufacturer Pricing Data At Point of Entry - CMS explained in the proposed regulations that manufacturers will be required to enter pricing data in a uniform system. As CMS develops this system, Michigan Medicaid requests that editing be included to screen prices and flag atypical amounts for correction at point of entry.

Often States have noted missing *Unit Rebate Amounts* for selected drugs on the quarterly rebate files and missing AMPs on the monthly files provided by CMS. Michigan Medicaid staff requests the new system flag manufacturers that are habitually late with their pricing data for corrective action/penalties.

Omissions and inaccurate pricing have undoubtedly posed complications in the rebate program and will result in inappropriate calculations for the FULs on multiple source drugs adversely affecting pharmacy payments. As a result, Michigan Medicaid staff strongly urges CMS to implement the systems checks suggested and other measures to hold manufacturers accountable.

First DataBank Automated Access to AMP Data - Michigan Medicaid staff assumes that CMS will also use its proposed uniform system to provide States with access to the monthly and quarter AMPs discussed in the proposed regulations. Michigan Medicaid requests that First DataBank, the pricing source used by most States have access to the AMP data electronically. First DataBank access would centralize administrative tasks and allow efficient/cost-effective integration of AMPs into State data warehouses.

AMP Data Specifications – First, to avoid omitting AMPs distributed by approved manufacturers participating in the federal rebate program, CMS must compare the NDCs manufacturers reported with their NDCs listed on

[5] 42 CFR 447.502, definition of estimated acquisition cost applicable drugs other than multiple source drugs with a FUL
[6] States typically use payment methodologies based on discounted AWP or marked up WAC.

databases available from national drug compendia sources including *both* First DataBank and Medispan. This exercise would help assure all NDCs and their AMPs are reported provided by manufacturers to CMS.

Second, CMS must include the following data elements in the AMP files made available to States and to First DataBank. As proposed by CMS different packages of a product will have the same price. However, Michigan Medicaid staff recommends that the AMP file include a primary key based on the full 11-digit National Drug Code (NDC), not just the first 9-digits. This approach will streamline importing AMPs into State databases, allow for quality assurance checks for missing drugs, and reduce administrative costs. Michigan Medicaid staff would be willing to develop specifications and test the format with CMS.

- National Drug Code, 11-digit
- Brand Name
- Strength
- Dose Form
- Metric Billing Unit, as defined by NCPDP, e.g., each, milliliter, or gram
- Termination Date
- Metric Unit AMP
- AMP Begin Date
- AMP End Date
- File Reporting Date, e.g., 2007-02 for the monthly for February 2007

Add the Monthly AMP Calculation Under 447.504 "Determination of AMP – Adding references to both the quarterly and monthly AMPs under "Determination of AMP – §447.504" would provide greater clarity compared with the proposed approach of burying the requirements for the "monthly AMP" under "Manufacturer Reporting - §447.504.

DRUGS: AGGREGATE UPPER LIMITS OF PAYMENT – §447.512

Certification of Brand Name Drugs – §447.512 (c)

Eliminate Handwritten Override Requirement - Proposed regulations at §447.512 (c) specify FULs do not apply "if a physician certifies ***in his or her own handwriting*** [emphasis added] that a specific brand is medically necessary for a particular recipient..." The handwritten requirement, adopted in the late 1970s, is unnecessary in the current environment where most States require prescribers to obtain prior authorization (often verbally over the phone) to justify brand name overrides for FULs or state Maximum Allowable Cost (MAC) prices. This requirement is also counterintuitive given recent electronic-prescribing initiatives and electronic health information exchanges. Michigan Medicaid recommends deleting "in his or her own handwriting" from this subsection.

FUL Aggregate Test – Some states are able to set their own Maximum Allowable Cost (MAC) rates on multiple source drugs (such as, IV solutions) not evaluated by the FDA or listed in the *Approved Drug Products with Therapeutic Equivalency Eval*uations. Michigan Medicaid staff requests that such saving efforts be incorporated in the "aggregate test." If approved, States would list rates and utilization for such products and a comparison would be made to a state's Estimated Acquisition Cost rate. Associated savings would be included in the FUL aggregate test.

UPPER LIMITS FOR MULTIPLE SOURCE DRUGS – §447.514

Michigan Medicaid has implemented an aggressive generic pricing program with weekly monitoring since 2003, and based on its experiences, encourages CMS to provide additional allowances in calculating/implementing FULs to assure that pricing levels for a drug are available across the nation. Michigan pharmacies have expressed concerns that the FULs as proposed will not accommodate their acquisition costs to procure non-innovator generic drugs. FUL setting while uniform across the nation should be cognizant of regional wholesaler differences and their variance in the generic lines available for pharmacy purchase. This is especially true for

small rural pharmacies. Following are Michigan Medicaid recommendations to help alleviate these concerns and assure that FULs issued under provisions of the Deficit Reduction Act of 2005 are available nationally.

Establishment and Issuance of a Listing – §447.514 (a)

FUL Issuance Cycle – Michigan Medicaid staff understands why CMS may not want to codify an issuance schedule for FUL updates. However, it would be helpful for State implementation efforts to know whether CMS intends to publish FULs monthly, quarterly, or by another schedule and how CMS intends to deal with generic unavailability for a particular drug due to unforeseen marketplace occurrences, such as generic drug shortages.

90-Day Lead Time Required for Lowered or New FUL Prices– Increases to FULs could be effective upon publication. States, however, must have at least a *90-day lead time* to implement reduced or new FUL rates. Such an advanced notice is required to allow States time to notify pharmacies of price changes; to analyze announced FUL prices; and to revise their own Maximum Allowable Cost (MAC) rates to meet the aggregate FUL test. Michigan Medicaid recommends the following modification to the proposed regulations.

> 447.514 (a) (2) CMS **SHALL** publishes **ON ITS WEBSITE** the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid issuances. **THE EFFECTIVE DATE OF LOWERED OR NEW FULS WILL BE 90 DAYS AFTER CMS PUBLICATION.**

FUL Issuance Format – Michigan Medicaid staff recommends that CMS publish on its website the FULs in a format that allows importing data into Excel. Data elements should include at a minimum the following. It is particularly critical that CMS provides an NDC for each FUL (preferably the one representing the FUL benchmark AMP, but the Innovator Multiple Source Drug's NDC would be helpful, as well). Including an NDC allows States to link the FULs to their payment databases for analysis. Michigan Medicaid staff would be willing to develop specifications and test the format with CMS.

- Generic Name
- Innovator Multiple Source Drug Name
- Strength
- Dosage Form, e.g., tablet, capsule, solution, etc.
- Metric Billing Unit, e.g., each, milliter, or gram
- FUL Price, based on metric billing units
- FUL Begin Date
- FUL End Date
- National Drug Code (NDC) which had the AMP used as the FUL benchmark AMP
- File Reporting Date, e.g., 2007-02 for the monthly for February 2007

Specific Upper Limits – §447.514 (b)

Average Manufacturer Prices (AMP), without regard to Package Size – As mentioned previously, Michigan Medicaid staff believes that AMPs provided without regard to a product's package size will have limited use for pricing brand name drugs.

Ensuring A Drug Is for Sale Nationally – §447.514 (a)

The proposed regulations specified that a FUL will be set equal to 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent (the FUL benchmark AMP). CMS invited comments on their goal that the use of AMP to calculate FULs will ensure a drug is available nationally at the FUL price. Michigan Medicaid supplies the following comments in response to this request.

Use Only NDCs of Approved Manufacturers to Set the FUL Benchmark AMP – The proposed regulations should indicate that the FUL benchmark AMP will be set only on products distributed by manufacturers approved for participation in the federal rebate program.

Do Not Use AMPs of Terminated NDCs to Set the FUL Benchmark AMP – The termination date that manufacturers report to CMS does *not* represent the date a manufacturer stopped production of a drug under a NDC, but rather the last date that a discontinued NDC could be dispensed from a pharmacy's inventory. Drugs often have shelf lives over two years. AMPs for NDCs, which are no longer sold by manufacturers, are not necessarily representative of current marketplace prices. As such, terminated NDCs should *not* be used as benchmarks in the FUL setting process. Michigan Medicaid staff recommends the following modification to proposed regulation to eliminate potential product unavailability at the FUL.

> 447.514(c) (1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) ~~beginning with the first day of the month after the actual~~ **AFTER A** termination date **IS** reported TO **OR IDENTIFIED** ~~by the manufacturer to~~ **BY** CMS.

Use the 25th Percentile Instead of Thirty Percent (30%) for the AMP Carve-Out Rule – CMS proposed the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug, which is not less than 30% of the next highest AMP, will be used to set a FUL. This wording is misleading and could be more easily understood if CMS provided an example of actual prices for a FUL group.

Michigan Medicaid staff recommends alternative language for the carve-out rule that would use percentiles instead of the complicated 30% test. For example, AMPs falling at or below the 25th percentile for a multiple source drug will *not* be chosen as the FUL benchmark AMP. Using a percentile cutoff would eliminate outlier AMPs and help assure a more representative FUL price.

> 447.514(c) (2) Except as set forth in paragraph (c)(3) of this section, in establishing the FUL, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that ~~is not less than 30 percent of the next highest AMP~~ **DOES NOT FALL AT OR BELOW THE 25TH PERCENTILE OF THE EQUIVALENT PRODUCTS** will be used to set the FUL.

Do Not Publish FULs when the Calculated FUL Mirrors the Innovator Price – If the calculated FUL exceeds the innovator brand name's AWP or exceeds the innovator brand name's AMP by 25%[7] or more, CMS should not publish the FUL. Such an exception would likely occur when the FUL group includes only the innovator single source drug and the first new generic or authorized generic drug enters the market. Michigan Medicaid staff, therefore, recommends that this exception be linked to that situation as drafted below.

> 447.514(c) (3) When the FUL group includes only the innovator single source drug and the first new generic or authorized generic drug enters the market, the criteria in paragraph (c) (2) of this section will not apply. **IF THERE ARE ONLY TWO SOURCES AVAILABLE FOR AN FUL GROUP AND THE CALCULATED FUL EXCEEDS THE INNOVATOR'S AWP OR EXCEEDS THE INNOVATOR'S AMP BY 25% OR MORE, AN FUL WILL NOT BE PUBLISHED BY CMS.**

Checks To Address Generic Unavailability at FUL Prices & FUL Redetermination Process – States have observed manufacturers often do not report NDC termination dates to CMS. As a quality assurance measure before setting a FUL benchmark AMP, CMS should (1) verify whether the NDC of a potential FUL benchmark AMP has been billed by Medicaid pharmacies during the previous quarter and (2) provide for a redetermination process based on input from pharmacies and states – perhaps through a 1-800 line for providers; and verify with other industry sources (e.g., drug wholesalers and pharmacies) whether the FUL rate is available on the market. Michigan Medicaid recommends the following two subsections be added to the final regulations.

> **447.514(c) (4) AN AMP MEETING THE LOWEST FDA-RATED EQUIVALENT PRODUCT AND ALL OTHER CRITERIA IN THIS SUBSECTION SHALL NOT USED TO SET THE FUL UNLESS ITS CORRESPONDING NDC HAS BEEN BILLED THE PREVIOUS QUARTER IN ALL FIFTY STATES.**
>
> **447.514(c) (5) AN APPEAL PROCESS WILL BE MAINTAINED TO ACCEPT REQUESTS FOR REDETERMINATION OF A PROPOSED OR EXISTING FUL, BECAUSE OF UNAVAILABILITY OR PRODUCTION ISSUES. IF A DRUG IS NOT AVAILABLE NATIONALLY AT THE FUL (AS CONFIRMED BY DRUG WHOLESALERS, STATE MEDICAID AGENCIES, OR PHARMACIES); CMS SHALL REVISE OR SUSPEND THE FUL.**

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[7] Twenty-five percent was recommended based on finding from the Office of Inspector General's report *Medicaid drug Price Comparisons: Average Manufacturer Price to Published Prices*, OEI-05-05-00240, June 2005.

UPPER LIMITS FOR DRUG FURNISHED AS PART OF SERVICES – §447.516

This section stipulates "The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under *prepaid capitation arrangements* [emphasis added]." Michigan Medicaid requests clarification on this language, especially whether it is applicable to pharmacy-only capitated plans.

Michigan pays cost effective, competitive capitated rates to its health plans that manage all Medicaid covered services. Pharmacy costs for multiple source drugs are not distinguishable within the capitation rate and therefore, compliance with the FUL aggregate test could not be evaluated.

FFP: CONDITIONS RELATING TO PHYSICIAN-ADMINISTERED DRUGS – §447.520

Identification of Physician-Administered Drugs – Michigan Medicaid staff requests that CMS provide state Medicaid programs an electronic list of the physician-administered drugs for which Federal Financial Participation (FFP) would be lost if a State did not bill manufacturer rebates. The requested list must include all single source physician-administered drugs and the top 20 multiple source drugs along with their Healthcare Common Procedure Coding System (HCPCS) codes. The file's format should allow importing its data into Excel for analysis.

Modify NDC-HCPCS Crosswalk Posted on the CMS Website – One way to provide States with physician-administered codes, for which manufacturers rebate billing must be made, would be for CMS to modify the Medicare ASP NDC-NCPCS Crosswalk currently posted on its website. Modifications needed would include, but not be limited to, the following.

- Add physician-administered drugs not routinely covered by Medicare, but covered by Medicaid.
- Add a field to identify the sole-source drugs and top 20 multiple source drugs that are included in the mandate of 42 CFR §447.520.
- Identify the National Drug Codes distributed by *approved* rebate manufacturers so that physicians may determine whether a product will be reimbursable under Medicaid.

CMS Remedy Needed for Physician-Administered Drugs Billed As Medicare Crossover Claims – Michigan Medicaid staff recommends that CMS provide a less administratively burdensome remedy to address Medicare crossover claims for physician-administered drugs. This remedy must assure that if a NDC is submitted on a Medicare claim that the same NDC is crossed-over to Medicaid programs. CMS suggested that States reject physician-administered drug crossover claims, if NDCs are missing, and require healthcare providers to bill paper claims. However, this alternative conflicts with the intent and spirit of HIPAA and with the cost-effective movement toward electronic billing formats by most insurers and healthcare providers. Also, such an alternative would cause significant payment delays, increase administration costs, and pose undue burden on providers to extent they may refuse to provide these services for beneficiaries who are dually insured or even discontinue participation with the Medicaid program.

States should not be penalized with FFP loss if the NDC was actually submitted on a Medicare crossover claim, but not forwarded to Medicaid. Further, states should not be penalized when Medicare does not have front end editing that requires NDC entries for physician-administered drugs.

Exemption of* 42 CFR §447.520 for *Physician-Administered Drugs with Coordination of Benefits – CMS commented that States assure NDCs are present for physician-administered drug claims with coordination of benefits (COB) with other insurers. Also, if the NDC is not eligible for manufacturer rebates under the federal program; States must deny payment. Michigan Medicaid staff believes that the Deficit Reduction Act of 2005 did not specifically mandate loss of FFP for physician-administered drug with COB claims.

The CMS decision to apply 42 CFR §447.520 for COB claims is likely to cause undue burden on the provider community and perhaps result in financial costs to beneficiaries. Eliminating or reducing FFP is not cost effective or efficient, since States are required to collect other third party liabilities. Michigan Medicaid policies instruct providers to follow the primary payer's rules when coordinating benefits. Michigan Medicaid staff

recommends that CMS does not penalize States for reimbursing cost sharing amounts for physician-administered drugs, when coordinating benefits with other insures.

Manufacturer Rebate Billings for 340B Entities – Health Resources and Services Administration (HRSA) staff have posted on their website the Medicaid identification numbers for 340B entities whose prescription must be excluded from State manufacturer rebate billings. Michigan Medicaid staff understands that these postings will soon be based on National Provider Identifier (NPI). Michigan Medicaid, further, recommends that the NPIs of providers, who will be billing physician-administered drugs from 340B entities, also be listed on the HRSA website.

Outpatient Hospital Paper Claims (UB-04) Incompatible with NDC Mandate – While the CMS 1500 claim form has a designated field to accommodate the NDCs, the UB 04 claim form does not. CMS verbally recommended that States adopt their own procedures for NDC entries on the UB 04; however, Michigan Medicaid staff recommends that one national standard be adopted now – instead of each state making systems changes to its payment system, only later to learn that these changes must be re-done to meet a subsequent HIPAA requirement.

Submitter : **Ms. Tracy Baroni Allmon** **Date: 02/20/2007**

Organization : **Caremark**

Category : **Health Care Industry**

Issue Areas/Comments

Background

Background

Caremark Rx, Inc. is a leading pharmaceutical services company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark processes over 550 million prescription drug claims annually, operates 7 mail pharmacies and 21 specialty pharmacies, and has network pharmacy contracts with over 62,000 participating retail pharmacies.

Caremark appreciates the opportunity to comment on the proposed rule for the calculation of AMP and best price. We believe these issues are of fundamental importance to all sectors of the prescription drug industry, and that the calculation of AMP in particular will have ramifications that extend well beyond the impact on manufacturer rebate payments under the Medicaid program. Given the many entities that will be affected by the manner in which AMP is calculated, as well as the new dual role for AMP as both a reimbursement and rebate metric, we believe that CMS should consider the following general principles as it finalizes the proposed rule:

" Fairness and Fidelity to Congressional Intent. In accordance with Congressional intent, CMS should try to faithfully capture the drug price paid by retail pharmacies, and should exclude those drug sales that are not reflective of the prices paid by retail pharmacies, and those price discounts that are not provided to retail pharmacies.

" Consistency. The rule should be consistent with established Medicaid rebate policies , definitions and terms set forth in current CMS guidance, such as Medicaid Program Releases and the National Rebate Agreement created under the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990). It should also be consistent in treating similarly-situated entities similarly, while recognizing entities that are not similarly-situated.

" Operational Simplicity. CMS should avoid including in the calculation of AMP data that is not readily available to manufacturers, or that would significantly increase the number of calculations and assumptions to be made.

" Impact on Competition. CMS should avoid requiring the disclosure of sensitive competitive pricing and financial information that is not currently known by manufacturers in order for manufacturers to calculate AMP.

" Clarity. CMS should provide clear and objective standards and rules, relying on existing safe harbors where available.

" Impact on Government Programs. CMS should consider that changes in the calculation of AMP will affect public programs. Changes that result in an increase in drug costs for government programs such as Medicare Part D and Medicaid, are contrary to the clear intent of Congress in OBRA 90 and the Deficit Reduction Act of 2005.

GENERAL

GENERAL

See Attachment

CMS-2238-P-1131-Attach-1.DOC

#1131

CAREMARK
It all starts with care

February 20, 2007

Leslie Norwalk
Acting Administrator
Hand-delivered:
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201
Electronically:
http://www.cms.hhs.gov/erulemaking

Re: Comments on Proposed Rule implementing the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. 42 CFR Part 447

Dear Ms. Norwalk:

Caremark Rx, Inc. is a leading pharmaceutical services company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark processes over 550 million prescription drug claims annually, operates 7 mail pharmacies and 21 specialty pharmacies, and has network pharmacy contracts with over 62,000 participating retail pharmacies.

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- **Fairness and Fidelity to Congressional Intent.** In accordance with Congressional intent, CMS should try to faithfully capture the drug price paid by retail pharmacies, and should exclude those drug sales that are not reflective of the prices paid by retail pharmacies, and those price discounts that are not provided to retail pharmacies.

- **Consistency.** The rule should be consistent with "established Medicaid rebate policies", definitions and terms set forth in current CMS guidance, such as Medicaid Program Releases and the National Rebate Agreement created under the Omnibus Budget Reconciliation Act of 1990 (" OBRA 1990"). It should also be consistent in treating similarly-situated entities similarly, while recognizing entities that are not similarly-situated.

- **Operational Simplicity.** CMS should avoid including in the calculation of AMP data that is not readily available to manufacturers, or that would significantly increase the number of calculations and assumptions to be made.

- **Impact on Competition.** CMS should avoid requiring the disclosure of sensitive competitive pricing and financial information that is not currently known by manufacturers in order for manufacturers to calculate AMP.

- **Clarity.** CMS should provide clear and objective standards and rules, relying on existing safe harbors where available.

- **Impact on Government Programs.** CMS should consider that changes in the calculation of AMP will affect public programs. Changes that result in an increase in drug costs for government programs such as Medicare Part D and Medicaid, are contrary to the clear intent of Congress in OBRA '90 and the Deficit Reduction Act of 2005.

With these general principles in mind, we offer the following specific comments.

A. Definitions

These comments on the proposed definitions in 42 CFR 447.500 apply for purposes of the determination of both AMP and best price.

1. Administrative Fees

We support the exclusion of legitimate service fees from AMP and best price since, by definition, these fees are paid for services, not the "drug" itself, and so do not fall within the statutory definition of AMP or best price. However, this exclusion only recognizes one of the two standard methods by which manufacturers have paid, and legally protected, service fees. Manufacturers traditionally pay administrative fees to entities that assist them in negotiating and contracting with multiple plan sponsors for participation in the manufacturer's rebate program. Absent this assistance, a manufacturer would otherwise be required to negotiate and contract with thousands of plans for rebates, and in turn implement and administer separate rebate programs for a daunting array of plan benefit designs and formularies. In addition to this centralized administrative role, these entities will usually undertake to calculate the amount of rebates applicable to the products for each plan sponsor and invoice the manufacturer for rebates, provide the manufacturer with detailed reports on product utilization and rebate

calculations, allocate and distribute rebates to plan sponsors, utilize internal control measures to protect against payment of unearned rebates, and provide other related services that the manufacturer may require.

For purposes of complying with the Federal anti-kickback statute, manufacturers have generally sought to structure these service arrangements to meet either one of two safe harbors created by the Office of Inspector General (OIG), namely, the Personal Services and Management Contracts safe harbor at 42 CFR 1001.952(d) or the Group Purchasing Organization (GPO) safe harbor at 42 CFR 1001.952(j).[1] Both of these safe harbors serve the same purpose as the exclusion for bona fide service fees in this proposed rule, in that they are intended to distinguish legitimate service payments from payments that are really disguised discounts or potentially illegal payments.

However, despite the alignment in purpose, an arrangement structured under the GPO safe harbor may not be compatible with elements of the bona fide service fee exclusion. Therefore we recommend that, in addition to the exclusion for bona fide service fees, CMS create an additional explicit exclusion for administrative fee arrangements that meet the GPO safe harbor. This will ensure consistency between the two regulatory frameworks and continued equal treatment of the two types of service fee arrangements. It will allow parties that have specifically structured their fee arrangements to meet the GPO safe harbor to avoid having to attempt to restructure their contracts and business arrangements down the line, which could otherwise potentially impact thousands of contracts or, even more problematic, potentially put the parties in the untenable position of having to choose which regulatory structure to meet, even though both are intended to protect legitimate administrative service fee arrangements that are not disguised payments for referrals or rebates.

Recommendation: Provide an explicit exclusion from AMP and best price for administrative fee arrangements that meet the GPO safe harbor under the anti-kickback statute.

2. Bona Fide Service Fee

We understand that CMS wishes to ensure that only legitimate service fees are carved-out, and not discounts disguised as service fees. However, we are concerned that the additional condition requiring that the manufacturer would have incurred the fee in the absence of the service arrangement will in fact exclude legitimate service fees paid for real services provided in connection with the service arrangement. For example, a rebate agreement might include, in addition to rebates and price concessions, a service fee payable for services related to administering this rebate agreement with respect to all the plan sponsor clients of the service provider. The services include calculating the rebates applicable to each plan sponsors' products, invoicing the manufacturer, preparing detailed reports on product utilization and rebate calculations for the manufacturer, allocating and distributing rebates to plan sponsors, and utilizing internal control measures to protect against payment of unearned rebates.

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[1] See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736.

All of these are legitimate services performed for the manufacturer that it would otherwise need to perform itself or contract for another party to perform, but they are also all related to the service agreement in the sense that the services would not be necessary if there were no agreement to provide rebates in the first instance. While CMS may not have intended to exclude these types of services by adding the condition that the services would otherwise have to be performed "in the absence of the service arrangement", we believe this is how it will be construed by most manufacturers. Therefore, we recommend that CMS eliminate this condition, since it does not relate to the issue of whether the fees are legitimate service fees, and the definition already contains the essential requirements, namely, that the payment be (i) for legitimate services (ii) that the manufacturer would otherwise have to perform or have others perform for it, and (iii) represent fair market value.

Recommendation: Eliminate the condition that the services would be required "in the absence of the service arrangement" or otherwise clarify that fees paid for bona fide administrative services related to the administration of a rebate contract will qualify as "bona fide service fees" as long as they are: (i) for legitimate services (ii) that the manufacturer would otherwise have to perform or have others perform for it, and (iii) represent fair market value.

3. Wholesaler

The definition of "wholesaler" is critical to the calculation of AMP, since AMP is defined by statute as "the average unit price paid to the manufacturer... by wholesalers"[2] for drugs distributed to retail pharmacies. Thus, the price must be for a drug (i) purchased, (ii) by a wholesaler, and (iii) distributed to retail pharmacies. If any one of these elements is not present, the transaction is not relevant for purposes of calculating AMP. Therefore, transactions between a manufacturer and a party that is not a wholesaler cannot, by definition be included in the calculation of AMP. In Manufacturer Release 28, CMS explicitly stated (emphasis added) "Drug prices to PBMs have no effect on the AMP calculations ***unless the PBM is acting as a wholesaler*** as defined in the rebate agreement". (Emphasis added) Similarly, in Manufacturer Release 29, CMS reiterated that "We generally consider drug prices to PBMs as having no effect on the AMP calculations ***unless the PBM is acting as a wholesaler*** as defined in the rebate agreement". (Emphasis added)

In the proposed rule, CMS proposes to expand the statutory definition of AMP by defining "wholesaler" to mean "any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, covered outpatient drugs, but that does not relabel or repackage the covered outpatient drugs." This definition differs from that in the national rebate agreement in that it specifically refers to PBMs and includes in the definition not only those who purchase the drugs, but also those who "arrange" for the purchase of drugs. Conversely, the national rebate agreement defines "wholesaler" as "any entity (including a pharmacy or chain of pharmacies) to

[2] Section 1927(k)(1) of the Social Security Act

which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug."

The national rebate agreement definition of "wholesaler" is consistent with the plain meaning and traditional understanding of the term. For example, "wholesaler" is defined in the dictionary as a "merchant middleman who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users mainly for resale or business use" [3], and the term "wholesale" as "the sale of goods in quantity, as to retailers."[4] Although each of these definitions is slightly different, they include one fundamental aspect, namely, that in order to be a wholesaler, the entity must buy and sell the product, and not simply "arrange for" its sale. If and when an entity buys drugs from a manufacturer for resale, then with respect to those transactions only, the entity is indeed a wholesaler. But if an entity does not purchase any drugs from the manufacturer, but simply "arranges" or negotiates rebates from manufacturers on behalf of the ultimate payers, then this does not meet the definition of "wholesaler," nor does it in any way resemble the role wholesalers are generally understood to perform.

PBMs do not act as wholesalers when performing the core PBM functions of administering drug benefits or "arranging" for the provision of related drug benefit services. It is not appropriate for CMS to distort the well-understood, plain meaning of the term "wholesaler," or the longstanding definition of the term in the national rebate agreement in order to pull in transactions that AMP was never intended to capture, nor traditionally has captured. CMS should retain the definition of "wholesaler" that was previously used in the national rebate agreement or understood generally, to mean an entity that purchases drugs from the manufacturer for resale. Failure to recognize a difference between wholesalers and PBMs would result in an AMP that is artificially low. This would be especially problematic now that AMP is being used as a reimbursement benchmark as well, since it would not accurately reflect the drug prices available to the very retail pharmacies it would be used to reimburse.

Recommendation: Define the term "wholesaler" consistent with its traditional meaning and the definition in the national rebate agreement to mean any entity that purchases drugs from a manufacturer for purposes of resale.

B. Definition of Retail Pharmacy Class of Trade and Determination of AMP

1. Mail Pharmacy Sales

CMS proposes to include all mail pharmacies in the definition of "retail pharmacy class of trade" for purposes of calculating AMP. According to CMS, mail pharmacies "are simply another form of how drugs enter the retail class of trade." This is in contrast to sales to nursing home pharmacies, which CMS proposes to exclude from AMP because "nursing home pharmacies do not dispense to the general public."

[3] Merriam-Webster Online Dictionary.
[4] Random House Webster's College Dictionary.

Even accepting CMS' proposed definition of "retail pharmacy class of trade" as turning solely on whether the pharmacy sells or provides drugs to the general public, CMS' assumption that all mail pharmacies serve the general public is not correct. Most mail pharmacies are like nursing home pharmacies in that they *do not* dispense to the general public. Their distinguishing feature is that services are limited strictly to members, either of the payer clients with whom they have contracted or of any private "discount" card program members. Thus, while the members of the general public could walk into any retail pharmacy with a prescription and seek to get it filled there and then or home-delivered, that same person could not send that prescription in to most mail pharmacies and expect it to be processed. Only if that person is a member of a group for which the mail pharmacy has contracted to provide mail pharmacy services, and for which the mail pharmacy can confirm eligibility, will the prescription be processed.

There are other distinguishing features upon which we believe the definition of "retail pharmacy class of trade" should depend – features that are equally, if not more, important than the population served by the pharmacy. For example, retail pharmacies are not able to shift market share for drugs as effectively as are other types of pharmacies, such as long-term care or mail pharmacies. In general, it is not part of normal business practice for retail pharmacies to independently contact the patient's prescriber to change a prescription to a therapeutically equivalent, but more cost-effective drug, for the patient. In contrast, mail pharmacies and long-term care pharmacies customarily do just that, based on formularies developed by the Pharmacy and Therapeutics Committee (P&T Committee) and adopted by the payer. As a result, retail pharmacies generally do not obtain the same market share rebates as mail service and long-term care pharmacies, even when they contract directly with the manufacturer. It stands to reason, therefore, that the OIG has consistently discussed sales to nursing home and mail-order pharmacies together, assuming that whatever rule applied to one would apply to the other, and indeed, recommending that sales to both be excluded from the calculation of AMP.[5]

Mail pharmacies differ from retail pharmacies not only in their identifiable patient population and degree of intervention, but also in the mix of drugs they sell, the average days' supply per prescription, and the volumes they purchase. All of these factors allow mail pharmacies to negotiate prices with manufacturers that are significantly lower than those received by retail pharmacies.

2. Specialty Pharmacy Sales

The proposed rule does not discuss specialty pharmacy sales at all, or indicate how CMS believes they should be treated for AMP calculation purposes. Specialty drugs represent a distinct and growing segment of the prescription drug market, and we believe it is important for the final rule to recognize specialty pharmacies as a distinct type of pharmacy. Like mail and LTC pharmacies, specialty pharmacies operate quite differently from retail pharmacies, are not open and accessible to the walk-in public and should clearly be excluded from the "retail class of trade".

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[5] See General Accountability Office (GAO), "Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States", February 2005, p.14, footnote 27.

Specialty drugs differ from traditional prescription drugs in that they are typically very high cost drugs, often biopharmaceuticals, that require special storage and handling (e.g. refrigeration, reconstitution, use of an administration device), and are provided to individuals who have serious chronic illnesses that often require additional ancillary services. In many cases the medications are injectables, for which patients may require the assistance of a physician or other health care provider. In addition, specialty pharmacy patients usually have more serious or complex medical conditions, and require a far higher level of service, often over an extended period of months or even years. In light of this, specialty pharmacies deliver a very different, and specialized, set of products and services as compared to retail pharmacies. Specialty pharmacy patients are frequently located hundreds of miles from the pharmacy, and drugs are shipped to the patient, and consultations between patients and health care professionals are via telephone. There are no "walk-in" specialty pharmacy patients.

As the above description demonstrates, specialty pharmacies are not only a completely different distribution channel for drugs, but a completely different type of business, providing complex drugs to an identifiable patient population in a different way than a retail pharmacy. As such, specialty pharmacies should be specifically excluded from the definition of "retail class of trade". As currently written, the definition of "retail pharmacy class of trade" depends solely on whether the pharmacy serves the general public, irrespective of whether the pharmacies differ in virtually every other meaningful respect. While this is certainly one factor that should be considered, given the greater complexity and diversity in the prescription drug market than even a decade ago, this alone should not be definitive, and other factors that distinguish between the well-recognized and markedly different types of pharmacies serving patients today should also be considered. If AMP is to be meaningful as a reimbursement benchmark, it should seek to capture the price of drugs to as similarly-situated a group of pharmacies as possible, with respect not only to the class of patients served, but also the types of drugs sold, the nature of the pharmacy facilities and activities, the method of drug storage and delivery, inventory policies, the method of drug administration, the level of patient education, other clinical and administrative services provided, and the location and nature of the pharmacies, to name only a few. All these factors affect the costs and operations of the pharmacy, including its drug costs which, after all, are what AMP is intended to capture.

Retail pharmacies generally maintain inventories of a greater variety of drugs with a lower per unit cost than specialty pharmacies, home infusion, or long-term care pharmacies. This is a function not only of the types of drugs retail pharmacies purchase (retail pharmacies purchase mainly oral medications and comparatively few that require special storage and handling) but also the retail pharmacy business model, since most retail pharmacies are located on prime real estate to attract the walk-in customer who not only fills prescriptions, but purchases other health care items and sundries. Conversely, most specialty and home infusion pharmacies are located in industrial areas, where there is little, if any, general consumer traffic, and where storage is far less costly, so they are able to maintain large refrigeration units, sterile and non-sterile preparation and packaging areas, and appropriate storage for administration devices. Specialized storage,

preparation, handling, and precisely-timed and controlled shipping are key components of the specialty pharmacy business model – quite different than the limited prescription drug storage and over-the-counter sales that are part of the retail pharmacy model. Specialty pharmacies also coordinate care with outside professional agencies such as home nursing visits, and routinely conduct extensive prescriber and patient outreach, and benefit verification, as well as certain disease management and education functions.

In almost every respect, the business of traditional "walk-in" retail pharmacies differs from that of specialty pharmacies. For this reason, CMS has recognized in Medicare Part D that retail pharmacies are distinct from not only long-term care pharmacies, but also from home infusion pharmacies, specialty pharmacies, and mail order pharmacies. Indeed, these types of pharmacies are all referred to by CMS as "non-retail" pharmacies, within Part D. Different rules apply to them with respect to access and reimbursable services, and CMS expects that Part D plans will have a different set of standard terms and conditions for each of these pharmacy types in the Part D plan's network. Similarly, in its merger review analysis of these very separate classes of trade, the Federal Trade Commission has repeatedly distinguished the provision of PBM services and specialty pharmacy services from retail pharmacy services, and defined each as noncompetitive and as operating in wholly separate relevant competitive markets.[6]

We believe that "retail pharmacy class of trade" should be defined consistently with the common use of the term "retail pharmacy" as a walk-in pharmacy, and within the meaning of Medicare Part D, and should exclude not only nursing home and other long-term care pharmacies, but also, at the very least, should exclude mail pharmacies, home infusion pharmacies and specialty pharmacies. If the term "retail pharmacy class of trade" is to have any meaning or purpose as capturing a distinct pharmacy type for purposes of drug purchasing, then it cannot simply lump together all these diverse types of pharmacies operating in clearly different market segments, and must go beyond the inchoate definition provided in the proposed rule.

Recommendation: "Retail pharmacy class of trade" should be defined consistently with the meaning of the term "retail pharmacy" for purposes of Medicare Part D, and should exclude all "non-retail" pharmacies, such as mail and specialty pharmacies, since these types of pharmacies not only serve different populations than those served by retail pharmacies, but also operate under very different business models, with different operating structures and different drug costs.

C. PBM Discounts, Rebates or Other Price Concessions

CMS proposes to include in the calculation of AMP the rebates and price concessions received by PBMs from manufacturers for drugs distributed to the retail class of trade.

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[6] See, for example, Federal Trade Commission Statement, "In the Matter of Caremark Rx,Inc./AdvancePCS," *http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf*; and "In the Matter of CVS Corporation, and Revco D.S., Inc.," *http://www.ftc.gov/os/caselist/c3762.htm.*

The apparent rationale for this decision is that the exclusion of these price concessions could result in "artificial inflation of AMP." While we agree that the exclusion of PBM rebates and other price concessions will cause AMP to be higher than it would be if these discounts were included, we disagree with the characterization of this higher amount as "artificial inflation." Instead, we believe the exclusion of these amounts results in a more accurate reflection of AMP, and that their inclusion artificially depresses AMP because PBMs are not wholesalers, nor are PBM rebates reflected in the prices paid by retail pharmacies.

1. PBMs are not wholesalers, and therefore transactions with them do not fall within the definition of AMP.
This issue is discussed in greater detail in Section A.3 above.

2. PBM rebates are earned for moving market share by performing formulary management activities pursuant to plan formularies developed by a clinically-driven P&T Committee. These rebates are not passed through to retail pharmacies.
Given that AMP is intended to function not only as a basis for calculating manufacturer rebate payments, but also as basis for calculating reimbursements to retail pharmacies, it is critical that AMP also properly and fairly reflect the prices paid by retail pharmacies. PBM rebates are determined by the drug utilization of a defined group of covered lives served by the PBM, unlike retail pharmacies, that purchase drugs and thus earn rebates solely on the volume of drugs purchased in response to the needs of the general public patronizing the pharmacy. Guiding the PBM rebate negotiations and purchases is the drug formulary implemented by the PBM and payers, under the guidance and oversight of the P&T Committee. Formularies are one of the most important tools used by PBMs and payers to manage the cost and quality of the drug benefit provided - a tool that is not available to or used by retail pharmacies in the same way, since they do not limit their services to plan members or have the incentive to manage drug utilization. Within a formulary, the PBM can recommend a list of preferred drugs that will offer payers the greatest savings. By creating a preferred drug list that covers the needs of most beneficiaries and a formulary that includes other recommended drugs - based on clinical efficacy, safety, and pharmacoeconomics - PBMs have additional negotiating leverage with drug manufacturers.

PBMs are able to negotiate rebate payments from manufacturers on behalf of their payer clients based on their unique ability to shift market share by directing their payer populations toward clinically appropriate, more cost effective drugs. Retail pharmacies do not have the means, resources or incentive to perform these services. As such, the rebates negotiated by PBMs are for all practical purposes unavailable to retail pharmacies.

While PBM rebates may be passed on, they are passed on to the PBM's payer clients, and not to retail pharmacies. As such, even when PBM rebates are shared, it is usually with payers, the sales to which are explicitly excluded from AMP (namely HMOs and managed care organizations), but in no event with retail pharmacies. Given that this unique role played by PBMs is wholly outside any function that could conceivably be

viewed as analogous to a wholesaler or to what a retail pharmacy could do, and the fact that PBM rebates, if passed through at all, are not passed through to retail pharmacies, there is no reasonable basis to include PBM rebates in the calculation of AMP.

3. Collecting and reporting PBM rebates raises operational and competitive concerns.
CMS requested comment on the operational difficulties of including PBM rebates and other payments in the calculation of AMP. We believe that these difficulties will be significant. Even more problematic is that efforts to make the reporting less complicated will have the counterproductive effect of undermining competition among the drug manufacturers and PBMs themselves, and thus increasing drug prices. As the FTC has noted, the percentage of rebates passed through by a PBM to a client cannot be viewed in isolation, because of the complex relationship and different transactions that may be occurring simultaneously between the parties.[7] Thus, in order to include PBM rebates and other payments in the calculation of AMP, it would be necessary for manufacturers to essentially require disclosure by PBMs of their internal pricing structures and financial arrangements with manufacturers, payers and pharmacies. This is highly sensitive proprietary competitive information that PBMs will not willingly, and should not have to, disclose. The Federal Trade Commission staff has repeatedly opined that requiring such disclosures would undermine the ability of PBMs to negotiate lower drug prices from manufacturers and pharmacies, resulting in an overall increase in drug prices in this sector. [8]

4. Inclusion of PBM rebates in AMP will likely increase drug costs for Medicare Part D and decrease Medicaid rebates contrary to Congressional intent.
We are concerned that the inclusion of PBM rebates and discounts in the calculation of AMP will have the unintended consequence of making some manufacturers less inclined to offer them, mainly out of a concern that they will unduly depress AMP, resulting in lower reimbursement to pharmacies and, ultimately, lower sales by the manufacturer. While it is true that a lower AMP should generally result in lower Medicaid rebate payments by manufacturers, this will not always be the case, and in any event, manufacturers are extremely sensitive to the potential negative effect of a lower AMP on drug sales generally as a result of lowering pharmacy reimbursements. This has already been seen with respect to ASP, where manufacturers have become less inclined to offer rebates and price concessions that will lower ASP, and will become more acute if and when, as is anticipated, AMP is adopted more broadly as a reimbursement benchmark for other purposes.

To the extent that a manufacturer believes it will lose sales if retail pharmacies choose to dispense alternate drugs with a higher AMP, they will be less willing to offer rebates and price concessions to PBMs and their payer clients, and drug prices will increase. This is of particular concern with respect to Part D sales, where it will work against the explicit intent of Congress to encourage manufacturers to offer deeper discounts by having these discounts excluded from best price. The inclusion in AMP of PBM rebates generally, but

[7] Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies", August 2005 (FTC Report) at 60.
[8] See, for example, FTC Staff Letter to The Honorable Terry G. Kilgore, October 2, 2006, pp.12-14.

particularly with respect to Part D drug sales, will likely have the negative effect of increasing drug prices generally, and to the Part D program in particular.

Similarly, the inclusion of PBM rebates in the calculation of AMP will potentially harm the Medicaid program, lowering Medicaid rebate payments from manufacturers as a result of relying on an artificially lower AMP. This is contrary to Congressional intent in enacting the Medicaid rebate program in OBRA 1990, when Congress stated that Medicaid "should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." [9] It also states that the program was designed to achieve significant Medicaid savings with a minimum amount of disruption to the program. Under the proposed rule, if rebates paid by manufacturers to PBMs are included in the definition of AMP, AMP will not reflect the payment made to manufacturers by wholesalers for the drugs distributed to the retail class of trade, but rather, in many cases will reflect the ultimate cost of the drug paid by the health plan or MCOs, sales to whom are explicitly excluded from AMP. We do not believe that it was Congress' intent to use this lower, already discounted, number as the base for calculating the minimum Medicaid discount. If the AMP is intended to reflect the price on which commercial discounts will be calculated, it does not seem reasonable to net out all of the price concessions that commercial insurers may receive, since it is these very price concessions that the Medicaid Program is attempting to approximate in calculating AMP in the first instance. Based on Congress' stated intent, we do not believe it is a reasonable or proper interpretation to include PBM rebates in AMP, particularly when one of the effects will be to reduce the rebates paid under the Medicaid program to below those to which Congress believed the program was entitled.

Recommendation: Exclude rebate payments to PBMs from the calculation of AMP because (i) PBMs are not wholesalers (ii) PBM rebates are typically not passed on to retail pharmacies or otherwise reflected in the drug prices paid by the "retail pharmacy class of trade", (iii) reporting of PBM rebates will cause operational difficulties and competitive concerns, and (iv) inclusion of PBM rebates in AMP will likely increase drug costs for Medicare Part D and lower Medicaid rebate payments in violation of Congressional intent.

D. AMP Reporting

The proposed rule implements the requirements of the DRA by requiring monthly reporting of AMP by manufacturers. Specifically, manufacturers must report AMP not later than 30 days after each month, including an estimate of rebates or other price concessions. In calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary. While we understand that AMP will not be utilized directly as a reimbursement rate on its own, and that even for purposes of calculating the federal upper payment limit for multiple source drugs under Medicaid it is part of a formula, nevertheless we are concerned about the inherent delay in reporting AMP when it is used as a reimbursement benchmark. Currently, changes in AWP – the existing reimbursement

[9] USCCAN, 1990, p. 2108,

benchmark – are typically passed through from the manufacturer to the ultimate payer within 24 hours, as a result of electronic feeds that re-adjust all pricing when a manufacturer price increase occurs. Under the proposed rule, the AMP reported to CMS is already 30 days old, and this AMP must then still be reported by CMS to States and posted on a public web site, and may be revised for up to 30 days. Thus, by the time AMP is posted publicly and available to be used for reimbursement purposes, it will be aged (by at least 60-90 days). This does not even take into account the added complications and delays if AMP were determined to include PBM rebates, since the determination of the amount of these rebate payments can occur up to 6 months or longer after the date the drug is dispensed.

This is of particular concern in light of the fact that manufacturer price changes are announced and implemented immediately to the drug purchaser. While there may be various ways to try to mitigate this impact, such as building in a cushion for price increases and inflation generally, on a drug-by-drug basis the impact could be significant, especially since it is not always obvious whether the impact should be upward on downward. We are concerned that this timing issue has not yet been addressed or even sufficiently recognized and appreciated, and believe that CMS should address it directly and in detail before states and others are encouraged to use AMP as a reimbursement benchmark.

Recommendation: Before AMP may be used as a reimbursement benchmark, CMS should address the timing issues associated with reporting AMP, and in particular, that manufacturer price changes will not be reflected in reported AMP for 60 days or longer.

E. Anticipated Effects

CMS concludes that the anticipated effect of the proposed rule on retail pharmacies will be less than one percent of revenue, on average, and that this impact is potentially even smaller when non-drug sales are considered. We believe this analysis seriously understates the potential financial impact on retail pharmacies for two reasons. First, as CMS points out, this analysis does not take into account decreases in state payments for drugs that are not on the FUL list, if and when States start to use AMP as a reimbursement mechanism generally. Since this is clearly the intent by making AMP available to states on a monthly basis and posting it on a public web site, the analysis leaves out what is likely to be the far more significant and profound financial impact on pharmacies, rendering the Impact Analysis misleading at best.

Second, although CMS refers to a loss of pharmacy revenue, the actual impact will fall directly to the bottom line, so that the $800 million decrease in 2007 and $2 billion decrease annually by 2011, will actually be decreases in profits, not revenue. Thus, while this may represent a 1% decrease in revenue, it actually represents a many times larger decrease in profits, depending on a pharmacy's profit margin. This is by no means insignificant. We are concerned that these inaccuracies have led CMS to the erroneous conclusion that the impact of pharmacies will be insignificant. As a result, we believe that CMS is insufficiently concerned about prospects that its "catch-all" method for

calculating AMP will result in an AMP that is far lower than what most retail pharmacies can achieve.

Recommendation: Revise the Impact Analysis to reflect (i) the projected impact of the use of AMP, rather than AWP, as a reimbursement benchmark for drugs other than those subject to the FUL, and (ii) the distinction between the impact on pharmacy profits versus pharmacy revenue.

Thank you again for the opportunity to comment on this important proposal. Please feel free to contact me at (202) 772-3501 with any questions or concerns.

Sincerely,

Russell C. Ring
SVP, Government Relations

Submitter : **Richard Buchanan** **Date: 02/20/2007**

Organization : **Richard Buchanan**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Coudersport, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Definition of "Retail Class of Trade"-Removal of PBms and Mail Order Pharmacies

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the "general public." The more extensive comments submitted by Pennsylvania Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elcments.

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

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

3. Removal of Midicaid Data

Including these data elements in "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 Minipulation

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

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

We believe that CMS should use thge 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 FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

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

Sincerely,

Richard Buchanan, R.Ph
Buchanan Brothers' Pharmacy, Inc.
101 Main Street
Coudersport, PA 16915

Submitter : Mr. alpesh patel **Date:** 02/20/2007

Organization : ps health llc

Category : Pharmacist

Issue Areas/Comments

Background

Background

i am pharmacist working for last 7 years in retail pharmacy

GENERAL

GENERAL

if proposed rule for amp for retail pharmacy reimbursement will be apply, according to my knolede dispensing cost for each prescription is atleast 10 dollars per script so if retail pharmacy reimbursement below 10 dollars per script whole retail pharmacy business will be in jeopardy and many pharmcies in us will be foreced to close.

thank you for giving oppertunity submit comment

Submitter : James Palmieri **Date:** 02/20/2007

Organization : Warren County Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1134-Attach-1.DOC

Warren County Pharmacy

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Leslie Norwalk
Acting Administrator
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7500 Security Boulevard
Baltimore, MD 21244-1850

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

As an owner of an independent pharmacy store in New Jersey serve a diverse Medicaid patient population for pharmacy care needs, I am very troubled by the CMS proposed regulation referenced above that seeks to define and establish an average manufacturer's price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that my independent pharmacy can afford to continue provide Medicaid generic pharmacy prescription services to my Medicaid prescription patients without incurring unsustainable financial losses.

Below are my specific comments on and recommended changes to the proposed rule:

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

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 calculating the AMP.

"Retail pharmacy class of trade" definition should only 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.

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

Treatment of Manufacturer coupons with regard to Best Price.

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

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.

PBM price concessions reporting to CMS.

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.

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 rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

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.

Impact on small pharmacies demonstrated by (General Accountability Office (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.

In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

- 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.*

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

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,

James V. Palmieri, R.Ph.
Warren County Pharmacy

Submitter : Mr. Thomas Kmezich **Date:** 02/20/2007

Organization : Columbia St. Mary's Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The Deficit Reduction Act of 2005 (DRA)must be revised before issuance of their final form. Specificly, the section that will require hospitals to report NDC numbers when billing Medicaid for drugs administered in hospital outpatient clinics and departments. This will most likely result in 340B hospitals losing any benefit from 340B discounts on all of the drugs within this category. Without such benefit, there is no incentive for the hospital to continue with participation. Please note that the individuals who will suffer are those that the program was designed to help, those who are disadvantaged and most vulnerable. Help us to continue to provide services to those in need.
Thank you.

Submitter : **Gregory Buchanan** **Date: 02/20/2007**

Organization : **Gregory Buchanan**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Coudersport, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Definition of "Retail Class of Trade"-Removal of PBms and Mail Order Pharmacies

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

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

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

3. Removal of Midicaid Data

Including these data elements in "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 Minipulation

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

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

Sincerely,

Gregory Buchanan, R.Ph
Buchanan Brothers' Pharmacy, Inc.
101 Main Street
Coudersport, PA 16915

Submitter : **Laura Ours** **Date: 02/20/2007**

Organization : **Buchanan Brothers' Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Sincerely,

Laura Ours, R.Ph
Buchanan Brothers' Pharmacy, Inc.
101 Main Street
Coudersport, PA 16915

Submitter : Mrs. Connie Woodburn **Date:** 02/20/2007

Organization : Cardinal Health

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-2238-P-1138-Attach-1.DOC

#1138

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
614.757.7000

CardinalHealth

www.cardinalhealth.com

February 20, 2007

VIA ELECTRONIC SUBMISSION

Leslie V. Norwalk, Esq.
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

CMS File Code: **CMS-2238-P**

Rule Title: **Medicaid Program; Prescription Drugs**

Federal Register
Publication Date: **December 22, 2006**

Dear Ms. Norwalk:

On behalf of Cardinal Health, I appreciate the opportunity to provide our comments on the Proposed Rule CMS-2238-P, "Medicaid Program; Prescription Drugs: Proposed Rule (the "Proposed Rule") published in the *Federal Register* on December 22, 2006.

Cardinal Health is a leading provider of products and services to the healthcare industry. As one of the largest national pharmaceutical wholesalers in the country, Cardinal Health delivers over 2 million products per day and makes daily deliveries to over 33,000 different customer sites. Through this operation, the company works closely with over 3,000 independent retail pharmacies through our distribution services. As a wholesaler, Cardinal Health recognizes the importance of the Proposed Rule and the impact the eventual implementation of the rule will have on the entire pharmaceutical supply chain.

Cardinal Health is a member of the Healthcare Distribution Management Association (HDMA). We have worked closely with the association in developing their written comments to the Centers of Medicare & Medicaid Services (CMS) on the Proposed Rule. Cardinal Health fully endorses the HDMA comments, and is, by submission of this letter, incorporating the HDMA comments by reference into our written comments for the record.

We appreciate your consideration of these comments and ask that you contact us if you have questions.

Sincerely,

Connie Woodburn

Connie R. Woodburn
Senior Vice President, Professional & Government Relations
Cardinal Health

Submitter : Dr. Joel Standefer **Date:** 02/20/2007

Organization : Standefer DrugCenter

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a small independent pharmacy owner that will not be able to survive to serve a large number of people in this small town if AMP is instigated. The unfair calculation of AMP contain sales and discounts available to large PBM and mail organizations that are not available to me. It is estimated to reduce my reimbursement to 36% below my cost. I support a fair and transparent method of reimbursement, but not a system that puts me out business for participating. This cut does nothing to reduce the very expensive brand name drug utilization, in fact disinsentivizes the use of the less expensive generics. Please reconsider this program which will be disasterous for the small town pharmacies and the patients dependent on them for their health care.

Submitter : **Michael Taylor** **Date: 02/20/2007**

Organization : **Buchanan Brothers' Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Westfield, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

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

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

Sincerely,

Michael Taylor, R.Ph
Buchanan Brothers' Pharmacy, Inc.
122 W. Main Street
Westfield, PA 16950

Submitter : **Joseph Marzo** **Date: 02/20/2007**

Organization : **Buchanan Brothers' Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Sincerely,

Joseph Marzo, R.Ph
Buchanan Brothers' Pharmacy, Inc.
122 W. Main Street
Westfield, PA 16950

Submitter : Renee Snyder **Date:** 02/20/2007

Organization : Buchanan Brothers' Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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Sincerely,

Renee Snyder, R.Ph
Buchanan Brothers' Pharmacy, Inc.
313 W. Main Street
Smethport, PA 16749

Submitter : **Jeanne Revak** **Date: 02/20/2007**

Organization : **Jeanne Revak**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment 'CMS-2238-P Jeanne Revak - General Comments.pdf'for signature.
02/15/2007

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

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

Acting Administrator Leslie Norwalk,

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.

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

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Sincerely,

Jeanne M. Revak, R.Ph.

Ephrata, Pa. 17522
Royer Pharmacy
2 E Main St.
Ephrata, Pa. 17522
717-733-6541

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Response to Comments

Response to Comments

CMS has received numerous impact studies and comments from the GAO, the NCPA, the Pennsylvania Pharmacist's Association and many others. These all document the fact that this proposed regulation would force retail community pharmacist to experience a major financial loss on every generic Medicaid prescription. I concur with these findings. The impact of this regulation, if enacted as proposed, would cost far more than it 'saves'. Retail pharmacies will be forced to stop dispensing Medicaid prescriptions (at a loss!). Medicaid patients will experience reduced access and compensate by increasing their use of more expensive alternatives including visits to emergency rooms, hospitals and doctors. The long term impact to the general economy of this regulation is not adequately studied. Areas of concern include the potential for increased Medicaid expenses and the loss of employment and tax revenue provided by the retail pharmacy industry.

CMS-2238-P-1143-Attach-1.PDF

1143

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799 717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332 717-859-4911
335 West Main Street, Leola, Pa. 17540-2107 717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135 717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702 717-299-4737

02/15/2007

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

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

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

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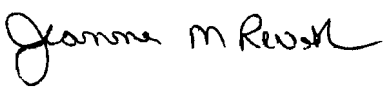
I believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies.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

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

Sincerely,



Jeanne M. Revak, R.Ph.
Royer Pharmacy Pharmacist
2 E Main St.
Ephrata, Pa. 17522
717-733-6541

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : **Erik Keglovits** **Date: 02/20/2007**

Organization : **Buchanan Brothers' Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Elkland, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Definition of "Retail Class of Trade"-Removal of PBms and Mail Order Pharmacies

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

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

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

3. Removal of Midicaid Data

Including these data elements in "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 Minipulation

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

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

We believe that CMS should use thge 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 packagc size dispensed by retail pharmacies. Current regulations specify that FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

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

Sincerely,

Erik Keglovits, R.Ph
Buchanan Brothers' Pharmacy, Inc.
206 Main Street
Elkland, PA 16920

Submitter : Garry Boggus **Date:** 02/20/2007

Organization : Propst Discount Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The use of AMP as a basis of reimbursement will have catastrophic effects on the retail pharmacy profession if not designed to ensure that pharmacies are reimbursed at a level that allows them to be profitable and have some return on their sizable investment. As a Pharmacist, I can't find out what AMP for a drug is right now to even try to calculate the effect on my business. A ne study for the Community Pharmacy Foundation determined the average cost of dispensing is $10.50 per prescription. Right now most PBM's set our dispensing fees between $1.00 to $2.50 per prescription. If CMS implements AMP pricing for medicaid, then the PBM's will follow suit and will be offering pharmacies AMP minus ?% plus $1.00 to fill prescription, and the Pharmacy profession is prohibited from collectively negotiating with them for better rates. The PBM's will tell us this is the rate we'll pay, take it or leave it. This will result in the closing of many Pharmacies and/or man others refusing to fill medicaid prescriptions, then it will trickle down to medicare part D prescriptions, then any prescription adjudicated by a PBM..... The retail pharmacy class of trade should not include mail order. Mail order pharmacies are not at all like a traditional community pharmacy, and do not provide the same level of professional services.. Are all Manufacturer rebates, price concessions and other discounts given to the PBM's being passed on in the Medicare Part D program? Are thes incentives being shared with the PBM' other business partners, i.e. CMS and Pharmacies? I am not aware of a case where a PBM is sharing these rebates with pharmacies, in actuality they impose service fees on the pharmacies in exchange for the ability to provide service to the patients. Therefore, since PBM's are not sharing thes incentives with pharmacies the should not be included in AMP calculations. Two large PBM's, Humana and Express Scripts, just anounced huge increases in 4th quarter profits for 2006..... Go to your local shoping mall and buy a shirt or a pair of shoes and the store likely makes a net profit in the 100 to 200% range. Go to your local pharmacy and get a prescription filled and the pharmacy likely makes a net profit in the 2-4% range. This is a very narrow profit margin and any erosion in this at all will result in pharmacies losing money and eventualy closing. What will be the effect of having 10-20% fewer pharmacies filling prescriptions do to the acess to services? How long will patients have to wait to get a prescription filled? How far will some people have to travel to get their prescriptions?

Submitter : **David Stahli** **Date: 02/20/2007**

Organization : **Buchanan Brothers' Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Elkland, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Definition of "Retail Class of Trade"-Removal of PBms and Mail Order Pharmacies

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

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

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

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Including these data elements in "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

We believe that CMS should use thge 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 FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

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

Sincerely,

David Stahli, R.Ph
Buchanan Brothers' Pharmacy, Inc.
206 Main Street
Elkland, PA 16920

Submitter : **Mr. Robert F. Anderson** **Date: 02/20/2007**

Organization : **Northfield Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

Implementation of this methodology that goes against the GAO findings that are accurate in terms of per prescription loss will lead to our pharmacy not being able to accept Medicaid patients, the ones that need our counseling and intervention more so than most of our patients. Mail order pharmacys buy at preferential rates not accessible to my store and PBM rebates do not make it down the food chain to help offset any losses.

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

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

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

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

Sincerely,

Rob Anderson, R.Ph

cc. Members of Congress :Senator Amy Klobuchar
Representative John Kline
Senator Norm Coleman

Submitter : Kathy Cooley **Date:** 02/20/2007

Organization : Buchanan Brothers' Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Subjet: 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 Eldred, PA. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.)

1. Definition of "Retail Class of Trade"-Removal of PBms and Mail Order Pharmacies

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

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

Sincerely,

Kathy Cooley, R.Ph
Buchanan Brothers' Pharmacy, Inc.
170 Main Street
Eldred, PA 16731

Submitter : **Mr. Robert Hannan** **Date: 02/20/2007**

Organization : **NACDS**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Please see attached

Collection of Information Requirements

Collection of Information Requirements

Please see attached

GENERAL

GENERAL

Please see attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Please see attached

Regulatory Impact Analysis

Regulatory Impact Analysis

Please see attached

Response to Comments

Response to Comments

Please see attached

CMS-2238-P-1149-Attach-1.DOC

1149

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 20th, 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 National Association of Chain Drug Stores (NACDS) is pleased to submit the attached comments to the Centers for Medicare and Medicaid Services (CMS) regarding our views on the proposed regulation published on Friday, December 22nd, 2006 in the *Federal Register*. That proposed regulation would provide a regulatory definition of AMP, as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS represents the nation's leading retail chain pharmacies and suppliers. Chain pharmacies operate more than 38,000 pharmacies, employ 112,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly $700 billion.

We ask that CMS address the following critical issues for our industry, both through modifications to the proposed regulation, as well as through changes to the proposed timeline for the release of AMP data.

Public Release and Use of AMP Data Should be Delayed

CMS should not post any AMP data on a public website before CMS finalizes its regulation with a clear, validated definition of AMP that accurately reflects the prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies.

We believe that present AMP data are flawed, yet CMS indicates it will publish these data on a public website this spring. Release of flawed AMP data could adversely affect community retail pharmacies if Medicaid programs and the commercial market use these data for reimbursement purposes. Because of its inherent flaws, CMS has already delayed release of these data, and we urge continued delay in the release of these data.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

AMP Definition Should be Revised 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 approximate prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs distributed to traditional community retail pharmacies should be included in the AMP definition.

Sales to mail order pharmacy, nursing home pharmacy, hospital outpatient, clinic sales, and manufacturers' coupons must be excluded because these are not sales to 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 because those discounts and rebates do not affect prices paid by wholesalers.

Given that wholesalers and retail pharmacies do not benefit from these PBM rebates and discounts, the resulting AMP would be lower than the average prices paid to manufacturer by wholesalers for drugs distributed to retail pharmacies. For these reasons, we think this proposed definition needs to be significantly modified.

CMS must also address how to account for the potential lag between the time the manufacturer calculates the AMP data and the time it is posted on a website. Without an adjustment to AMP, the posted AMPs may be outdated and may not reflect the existing prices at which retail pharmacies purchase medications.

New Generic FULs Should be Suspended

The new FULs for generic drugs proposed in the regulation – calculated as 250 percent of the lowest average AMP for all versions of a generic drug – 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 these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office (GAO) 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.

If AMP data are used to set the FUL, CMS should not use the lowest AMP. We believe that CMS should use a weighted average of 11-digit AMPs for generic products that are: 1) AB-rated in the FDA *Orange Book*; 2) widely and nationally available to retail pharmacies for purchase from the major national wholesalers in adequate and consistent supplies; 3) sold in package sizes of 100's or the most commonly dispensed package size. CMS must include an appeals mechanism in the final regulation which would allow providers, manufacturers and states an opportunity to seek removal or modification of an FUL which is not consistent with rapidly-changing market conditions.

States Need to Increase Pharmacy Dispensing Fees:

CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset anticipated 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 appreciate your consideration of these attached comments and ask that you please contact us with any questions. Thank you.

Sincerely,

Robert W. Hannan
President and CEO

accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly rather than by using a 12 month rolling average.
Use of the 11-digit NDC to calculate AMP.
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.
Impact on small pharmacies demonstrated by (General Accountability Office (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.

In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

? 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.

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

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,

Trushar Sheth, R.Ph., CCP,
PRESIDENT,
GIANNOTTO'S PHARMACY
973-482-8220

Submitter : Mr. Keith Gallus **Date:** 02/20/2007

Organization : Goodrich Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Please see attached sheet

CMS-2238-P-1151-Attach-1.DOC

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.

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. Thomas Kmezich **Date:** 02/20/2007

Organization : Columbia St. Mary's Community Pharmacies

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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, there is concern 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. The concern is 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. To assure fair and reasonable reimbursment, the cost base (AWP or AMP) cannot be separated from the dispensing fee. Inappropriate reimbursments will harm those patients that the programs were designed to help. Access to pharmacy care is imparative in todays healthcare and through this legislation, the patient is ultimately being denied that access. Thank you.

Submitter : **Date: 02/20/2007**

Organization : **Medicine Shoppe International**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-2238-P-1153-Attach-1.DOC

1153

MEDICINE SHOPPE INTERNATIONAL, INC.
a Cardinal Health company

1 RIDER TRAIL PLAZA DRIVE SUITE 300• EARTH CITY, MISSOURI 63045
PHONE 314.993.6000 • FAX 314.872.5500

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

Re: Comments on Medicaid Program: Prescription Drugs \ CMS 2238-P RIN 0938-AO20

As President of Medicine Shoppe International, Inc. (MSI), I write representing approximately 1,000 independently-owned, franchised Medicine Shoppe® Pharmacies (Medicine Shoppe) and Medicap Pharmacy® Stores (Medicap) and offer comments on the Centers for Medicare and Medicaid Services' (CMS) December 20th proposed regulation that would provide a regulatory definition of Average Manufacturers Price (AMP) as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

At the direction of MSI, our Medicine Shoppe and Medicap franchisees have repeatedly stepped up to the plate along with fellow chain and independent pharmacies to meet the Medicaid beneficiaries' needs, and we want to continue to do so. MSI is deeply concerned that this proposed regulation, if adopted, would have a significant negative economic impact on our pharmacies. It will jeopardize our ability to provide pharmacy services to Medicaid beneficiaries and the general public. This fundamentally flawed 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:

- **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 and this would provide realistic data upon which to base public policy.

  Mail order pharmacy sales should be excluded, just as nursing home sales are excluded, because these are not traditional retail pharmacies. Community pharmacies do not have access to the special prices offered by manufacturers to these classes of trade. Including these sales in the definition skews the calculation of AMP and does not result in certainty or a useful realistic price upon which to base public policy.

  In addition, manufacturers should not be allowed to deduct rebates and discounts paid to

MEDICINE SHOPPE INTERNATIONAL, INC.
a Cardinal Health company

1 RIDER TRAIL PLAZA DRIVE SUITE 300• EARTH CITY, MISSOURI 63045
PHONE 314.993.6000 • FAX 314.872.5500

Sincerely,

Terry Burnside
President
Medicine Shoppe International, Inc.

The Medicine Shoppe PHARMACY

MEDICAP PHARMACY

Submitter : Ms. Sue Idtensohn **Date:** 02/20/2007

Organization : Planned Parenthood of Greater Orlando, Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

We are asking that the DRA be modified to include charitable organizations and clinics for nominal pricing of contraceptives. Since the vast majority of our clients have no health insurance, they rely on Planned Parenthood to provide a discounted rate for their contraceptive drugs. Charging clients retail prices would increase the likelihood of unintented pregnancies, prevent women from seeking annual checkups and severely retrict our ability to help those most in need. Thank you for considering this change.

Submitter : Mrs. LISA SMITH **Date:** 02/20/2007

Organization : PHARMCARE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I WOULD LIKE TO OFFER A COMMENT FROM COMMUNITY PHARMACY'S POINT OF VIEW ON THESE PROPOSED CUTS BASED ON AMP. OUR PHARMACY HAS ALWAYS DONE OUR BEST TO USE GENERIC DRUGS TO KEEP THE COSTS DOWN NOT ONLY FOR OUR CUSTOMERS BUT ALSO THE PHARMACEUTICAL SYSTEM IN GENERAL HOWEVER IF WE ARE NO LONGER RECEIVING ENOUGH REIMBURSEMENT TO USE GENERICS WHERE DOES THIS LEAVE COMMUNITY PHARMACY? I READ A REPORT LAST WEEK THAT SAID THE OVERALL COST INCURRED TO FILL A PRESCRIPTION IS NOW AT LEAST $10.50. IF OUR PAYMENT IS CUT BY 36% WITH THE DEFINITION OF AMP THAT IS BEING CONSIDERED THERE IS NO WAY THAT WE WILL BE ABLE TO OFFER OUR PATIENTS THE SERVICE THAT WE DO NOW. OUR PATIENTS DEPEND ON US TO ANSWER THEIR QUESTIONS AS WELL AS OFFER A KIND WORD WHEN THINGS ARE GOING BAD PLEASE RECONSIDER THE DEFINTION OF AMP AND AT LEAST MAKE IT THE COST THAT IS ACTUALLY PAID BY RETAIL PHARMACIES SO WE CAN CONTINUE TO BE HERE FOR OUR PATIENTS. THANK YOU FOR LISTENING TO THIS COMMUNITY PHARMACIST FROM KENTUCKY.
SINCERELY,
LISA L SMITH

Date: 02/20/2007

Submitter : Matthew Kiefer

Organization : Watson's City Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1156-Attach-1.TXT

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.*

Final Comments:

The rule, as currently written, would amount to gross negligence on the part of CMS if it ignores the GAO 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.

Independent pharmacies were the most responsive and helpful entities for CMS in signing up patients for Medicare part "D" plans, only to find the reimbursements were pitifully low and payments from PBM's were slow in coming.

As a new independent pharmacy owner I am quickly learning that CMS audits, reimbursemen turnaround times, payments for generics, and support make Medicare part "D" claims an unhealthy part of my business.

And now the proposed definition of AMP will make another government plan more trouble than it is worth. In this case I have a choice! If the Final Rule on CMS-2238-P is not more accurately defined to reflect *my true cost and include a reasonable fee for service I will not be taking Medicaid prescriptions after July 1st.*

#1157

VIA ELECTRONIC SUBMISSION

February 20, 2007

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

CMS File Code: CMS-2238

Ms. Norwalk:

American Pharmacy Services Corporation (APSC) is a cooperative buying group headquartered in Frankfort, Kentucky. It represents 380 independent pharmacies throughout Kentucky, Ohio and West Virginia. Many of these independent pharmacies are located in areas where the population is heavily dependent on Medicaid for health care services. It is on behalf of these pharmacies that I submit these comments to CMS today.

- The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail order pharmacies, hospital outpatient pharmacies and outpatient clinics. These pharmacies have access to rebates and price concessions that are not available to independent pharmacies. Despite this distinction, the acquisition costs for these entities are to be included in the calculation of AMP. As such, APSC is concerned AMP may be set at a rate lower than what independent pharmacies can purchase.

- The proposed change in reimbursement for multi-source prescription drugs is going to have a significant negative impact on independent pharmacies and, most importantly, the patients they serve. Using existing AMP data, GAO has estimated the new Federal Upper Limit (FUL) formula will cause retail pharmacies to be reimbursed, on average, 36% lower than actual cost for a large number of the most frequently prescribed multi-

American Pharmacy Services Corporation
102 Enterprise Drive
Frankfort, Kentucky 40601
Tel: (502) 695-8899 Fax: (502) 695-9912
www.apscnet.com Email: apsc@apscnet.com

source medications. Independent pharmacies derive the bulk of their revenues from prescription drug sales, and 60% of these sales are for multi-source drugs. If the current formula is not revised, they will no longer be in a position to continue to care for patients if doing so forces them to accept a loss on a significant number of the prescriptions they provide.

- The proposed rule does not address dispensing fees to be paid to pharmacy providers. CMS has asked states to amend their dispensing fees to counter this loss. However, as federal payment reductions to state Medicaid programs continue, the likelihood of this happening is small.

- Data and Market Delays

    - The proposed rule directs manufacturers to consider sales and associated price concessions extended to SCHIPs and SPAPs. Manufacturers do not have access to this information until they receive quarterly invoices from the states. The same is true for some Part D information. Instructions for addressing lagged data should be included in the final rule.

    - The current instructions for calculating AMP are silent as to whether chargebacks, rebates and other discounts to be paid at a later date should be treated as-paid or as-earned. The final rules should state with specificity which methodology should be used.

    - Upfront discounts on large purchases to be sold over an extended period of time can distort pricing available to retail pharmacies in the market. The final rule should adopt smoothing methodologies to handling price concessions of this nature.

- The proposed rule directs that AMP be calculated using a 9-digit NDC verses an II-digit NDC. If pharmacies purchase the most economical size, the return on investment decreases and the chance of outdating increases. Current regulations specify that FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. The final should continue using the II-digit methodology to support market efficiencies and eliminate waste.

Sincerely,

Trey Hieneman

Trey Hieneman, Director of Government Affairs

1158

ROYER PHARMACY

2 East Main Street, Ephrata, Pa. 17522-2799 717-733-6541
113 South Seventh Street, Akron, Pa. 17501-1332 717-859-4911
335 West Main Street, Leola, Pa. 17540-2107 717-656-3784
1021 Sharp Avenue, Ephrata, Pa. 17522-1135 717-733-1215
508 Hershey Avenue, Lancaster, Pa. 17603-5702 717-299-4737

02/15/2007

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

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

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

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

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

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

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

3. **Removal of Medicaid Data**

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

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

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

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

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

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

Sincerely,

Margret A. Sanbower, R.Ph.
Pharmacist Manager
Royer Pharmacy
335 W. Main St.
Leola, Pa. 17540
717-656-3784

cc. Members of Congress
Senator Arlen Specter
Senator Robert P. Casey, Jr.
Representative Joseph Pitts

Submitter : Dr. Sandra Lawson **Date:** 02/20/2007

Organization : Family Prescription Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1159-Attach-1.TXT

#1159

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of Family Prescription Center, a community retail pharmacy located at 129 Main St., Mountain City, TN. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Sandra K. Lawson
3418 Campbell Road
Mountain City, TN 37683

cc: Senator Lamar Alexander
Senator Bob Corker
Representative David Davis

Submitter : Mr. Craig Harvey **Date:** 02/20/2007

Organization : Regions Outpatient Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachement

CMS-2238-P-1160-Attach-1.DOC

#1160

Regions Hospital®

February 19, 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 Regions Hospital Pharmacy, 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. Regions Hospital is a 427 bed hospital located in St. Paul, Minnesota. **Regions Hospital is the 2nd largest provider of uncompensated care in the state of Minnesota. Regions 2006 uncompensated care write-offs will total approximately $34.5 million.** Since 2003, our write-offs have nearly doubled. Regions Hospital 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. In order to comply with these requirements if passed, Regions would need to create an electronic management system to report NDC data. At this time the NDC data requested does not currently exist in an accessible format. To comply using a manual process would be cumbersome and would consume people resources that currently provide direct patient care. The expense of creating an electronic process could easily exceed several hundred thousand dollars for Regions Hospital.

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. The projected impact on Regions could exceed $200,000 per year for this rule.

If the proposed rules changes are implemented as written, Regions Hospital Outpatient Pharmacy will need to evaluate participation in the 340B program as the cost to comply with the rules could easily exceed the annual savings currently realized and used to fund uncompensated care for the hospital as a whole. The ability of Regions Hospital to provide quality care at affordable prices for the underserved population we serve could be in jeopardy.

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,

Craig Harvey
Outpatient Pharmacy Manager
Regions Hospital
640 Jackson Street
St. Paul, MN 55101

651-254-9560

Submitter : Mr. MAHENDRA PATEL **Date:** 02/20/2007

Organization : FAMILY FARMACIA INC/AIPHA

Category : Pharmacist

Issue Areas/Comments

Background

Background

We are Medicaid provider in state of Illinois. Almost 80 % of our business is Medicaid.We would like to submit comments about proposed AMP base reimbursment for Medicaid to go into affecte on July 01, 2007.

Collection of Information Requirements

Collection of Information Requirements

A study done by Grand Thorton LLPon behalf of NCPA and NACS determine the cost of dispensing at $10.50 per prescription on average.This study was conducted on August 2006 thant included data from 24,400 pharmacies.The cost of doing business is increase every single day.

GENERAL

GENERAL

If AMP base reimbursment goes into effect,many independents pharmacies are forced out of Medicaid business, the quality of care will suffer in urban & rural area.This will increase the medival expenses of state as many medicaid recipients will end up with bigger health problem requiring hospitalization.If AMP base reimbursment should go in to effect, it should be reflect tha actual acquisiton cost of pharmacy with dispending fee should be increase at least $ 13.50 to reflect the increase cost fo filling prescriptions.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

The proposed rulling make AMP as basis for FUL (Federal Upper Limit) is in Medicaid program.According tThweo GAO (Goverment Accountabity) these FULs will be 36 % below average acquisition cost of most pharmacies.

Regulatory Impact Analysis

Regulatory Impact Analysis

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

Submitter : **Date: 02/20/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1163-Attach-1.RTF

#1163

February 15, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Down Home Pharmacy, a community retail pharmacy located at 1034 Main Street Bean Station, TN 37708. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

While the AMP data is not currently publicly available, so that retail pharmacies can actually

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Jimmy Collins
420 Derbyshire Court
Morristown, TN 37814

cc: Senator Lamar Alexander
Senator Bob Corker
U.S. Representative David Davis

Submitter : Virginia Tobiason **Date:** 02/20/2007

Organization : Abbott

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1164-Attach-1.DOC

#1164

Virginia Tobiason

100 Abbott Park Rd.
0391, Bldg. AP6D-2
Abbott Park, IL 60064-6008

t 847-937-8438
f 847-935-6613

February 20, 2007

VIA ELECTRONIC SUBMISSION AND HAND-DELIVERED
(http://www.cms.hhs.gov/eRulemaking)

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8015

Re: Comments on Proposed Rule Related to the Medicaid Drug Rebate Program, (CMS-2238-P)

Dear Administrator Norwalk:

Abbott is pleased to submit comments regarding several specific provisions of the Centers for Medicare & Medicaid Services' (CMS) proposed rule to implement the Medicaid prescription drug provisions of the Deficit Reduction Act of 2005 (DRA). Abbott is a broad-based health care company that discovers, develops, manufactures and markets products that span the continuum of care – from prevention to treatment and cure. Our product portfolio includes pharmaceuticals and medical devices as well as nutritional products for children and adults. Abbott is headquartered in north suburban Chicago, Illinois and employs 65,000 people worldwide.

We commend CMS for the thoughtful approach taken in the proposed rule. Abbott understands the difficulties faced by CMS in drafting a regulation that addresses the complexities and realities of today's pharmaceutical marketplace.

Our specific comments follow.

Determination of AMP (Section 447.504)

CMS has advanced a proposed rule that provides the much-needed clarity that has been recommended and requested by Congress, the GAO, OIG and stakeholders. In defining AMP with respect to the "retail pharmacy class of trade" we agree with CMS' interpretation that Congress intended to include multiple entities beyond the traditional walk-in retail pharmacy. Therefore, to reflect the reality of today's retail pharmaceutical marketplace, it is appropriate that CMS defines "retail class of trade" to include entities such as independent pharmacies, chain pharmacies, mail order pharmacies, and other arrangements that utilize retail class of trade for the dispensing of pharmaceuticals such as PBMs. Abbott also supports the inclusion of SCHIP, Medicare Part D, and SPAP sales, units and rebates in the calculation of AMP.

- PBM Payments – Abbott commends CMS' recognition that PBMs have assumed a significant role in retail drug distribution since the enactment of the --- Medicaid rebate law. We fully support CMS' proposal that AMP should be calculated to reflect the net price realized by the manufacturer inclusive of any "discounts, rebates, or other price concessions to PBMs associated with sales for drugs to the retail pharmacy class of trade." Abbott agrees that other arrangements with third party intermediaries, such as PBMs, which impact the amount realized by the manufacturer on drugs distributed to the retail class of trade should be included in the calculation of AMP.

  In the proposed rule, CMS seeks comment as to whether the inclusion of PBM rebates, discounts, and other price concessions in the AMP calculation is operationally feasible. As a manufacturer, Abbott would not have difficulty tracking rebates, discounts and other price concessions, as we are knowledgeable of such payments to the PBMs. Contracts with these entities generally provide that rebates, discounts, and other price concessions are payable to a PBM for prescriptions dispensed at retail and mail order pharmacies. Therefore, Abbott believes that manufacturers should be able to include all such rebates and other price concessions in the AMP calculation.

Abbott, however, is concerned about any approach that would impose on manufacturers an obligation to determine whether such price concessions are passed on to others, because we do not have access to that information. We ask that CMS clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning such downstream transactions.

- Coupons - The proposed rule would require manufacturers to include in their AMP and Best Price calculations the value of any patient coupons except those redeemed by a patient directly to the manufacturer. We ask CMS to reconsider this proposal for two reasons. First, patient coupons provide a benefit only to the individual and do not provide a benefit or truly impact any third party. And second, differential treatment of coupons based on method of redemption could have unintended consequences for patients who rely on coupons to help lower their drug prices. For example, patients could experience a delay in receiving the benefit of the coupon at point of purchase or some may never realize the offered benefit due to the additional steps that would be required to redeem the coupon directly with the manufacturer. We ask that CMS reconsider and permit manufacturers to exclude patient coupons from AMP and Best Price calculations.

- Single AMP- CMS should be aware that the Office of Pharmacy Affairs (OPA), within the Healthcare Systems Bureau of the Health Resources and Services Administration issued a letter dated January 30, 2007 advising pharmaceutical manufacturers that the DRA's statutory and regulatory changes to AMP will not impact the AMP used by the 340B program. If OPA's determination stands, pharmaceutical manufacturers will be required to calculate and maintain two separate AMPs.

  We believe that a single AMP is intended for use by both the Medicaid Rebate Program and the 340B program. We believe that Congress did not intend for two separate AMPs to be used – one for Medicaid rebates and the other for 340B pricing.

  We respectfully request that CMS work with OPA to ensure that pharmaceutical manufacturers are required to maintain only one AMP per 11-digit NDC.

Determination of Best Price (Section 447.505)

- Prompt Pay Discounts – While the DRA requires pharmaceutical manufacturers to exclude customary prompt pay discounts to wholesalers from AMP calculations, Congress was silent on the treatment of prompt pay discounts on Best Price determinations. A change in treatment of prompt pay discounts to exclude them from the calculation of AMP not only increases the basic rebate (15.1% of a now higher AMP) but also, in fact, establishes a new Best Price. We do not believe that it was Congress' intent to create a new level of Best Price and we urge CMS to reconsider its position. A more equitable treatment is to exclude the prompt pay discount not only from AMP but also from a manufacturer's Best Price determination.

- Bundled Sales – We recommend that CMS refrain from expanding the definition of bundled sales and instead adopt in the final rule the current definition contained in the Medicaid Rebate Agreement. The Medicaid Rebate Agreement defines a bundled sale as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately." We ask CMS to confirm that it is only in arrangements where a discount/rebate is offered on one drug contingent on the actual purchase of a separate drug, that a bundled sale exists. Also, in recognition of the fact that a given contract may describe multiple discounts, only some of which are bundled discounts, we ask CMS to confirm that the allocation required by the proposed rule need only be performed in connection with bundled discounts and the products whose sales create the bundle.

Authorized Generic Drugs (Section 447.506)

The DRA requires a manufacturer holding title to an original NDA of an authorized generic drug to include in the branded drug's Best Price calculation the sales of the authorized generic drug.

Abbott interprets the statute and proposed rule as imposing a new requirement on an NDA holder to include in its Best Price determination sales of the authorized generic drug by the authorized generic company/secondary manufacturer. The statute and proposed rule do not appear to require the NDA holder to include in its Best Price determination the transfer price from the NDA holder to the authorized generic company/secondary manufacturer. The proposed rule's preamble language reads in pertinent part, "We propose to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and Best Price." This language indicates that it is the downstream sales of the authorized generic company or secondary manufacturer that the statute requires to be included in the brand manufacturer's Best Price determination. This interpretation is consistent with the manner in which CMS has historically treated Best Price, intending to capture in the calculation all downstream sales into the commercial marketplace. Although the proposed rule provides some guidance, Abbott encourages CMS to explicitly confirm in the final rule that the statute does not require an NDA holder to include in its AMP and Best Price calculations the transfer price of the authorized generic drug from the NDA holder to the secondary manufacturer.

Also, CMS should provide assurances that the primary manufacturer is permitted to rely on the accuracy of the pricing information provided by the authorized generic company.

Requirements for Manufacturers (Section 447.510)

- 12-month Rolling Average Methodology – We appreciate CMS' willingness to entertain comments from manufacturers about applying a 12-month rolling average methodology to the calculation of monthly and quarterly AMPs. This methodology is particularly helpful for the monthly calculation,

payer for a drug for which the Medicaid program pays only a small co-payment.

We believe this to be the intent of the statutory language, which is bolstered by then Senate Finance Chairman Grassley in his August 14, 2006 letter to CMS in which he advised that it was not Congress' intent to require manufacturers to pay rebates at a level above the percentage paid for the drug by a state Medicaid program. Applicable statutory language further supports this point. As a prerequisite to receiving federal Medicaid matching funds, Section 1927(a)(7)(A) of the Social Security Act, as amended by Section 6002 of the DRA requires states to collect and submit utilization and to secure Medicaid rebates for single source physician-administered drugs. The statutory language reads in pertinent part, "to secure rebates *under this section* for drugs administered for which payment is made *under this title*." This language clearly refers to payments under the Medicaid program. The statutory language does not give states the authority to collect rebates based on expenditures through the Medicare program.

Abbott appreciates the opportunity to comment on the proposed rule, as well as the effort that CMS has put into the development of the proposed rule. We look forward to further dialogue with CMS on the many important topics addressed in this rulemaking and hope our comments are helpful. Please feel free to contact us if we can be of further assistance.

Sincerely,

Virginia Tobiason
Senior Director, Corporate Reimbursement
Government Affairs
Phone: 847-937-8438
virginia.tobiason@abbott.com

because the DRA does not permit manufacturers to restate monthly AMPs. In general, a rolling average methodology benefits virtually all stakeholders by providing stability in pricing and avoiding significant fluctuations in monthly and quarterly AMPs caused by lagged sales and rebate data.

- Recalculation of Base Date AMP - Abbott applauds CMS for recognizing that manufacturers should have the opportunity to adjust base date AMP to account for the changes set forth in the DRA and the final rule. However, we request that pharmaceutical manufacturers be given the opportunity to restate earlier 2007 AMPs to account for the CPI impact caused by implementation of the DRA's Prompt Pay and authorized generic provisions and also be able to re-establish the base date AMP for the new calculation metric created by the CMS final rule. Senator Grassley stated in his May 12, 2006 letter to CMS in pertinent part, "... your recommendations should suggest a means for adjusting rebate computations so that no manufacturer is subject to increased inflation adjustment rebates by function of the changing definition." The Senator's statement is consistent with the two-step approach advocated by Abbott above.

- Certification of Pricing Reports - CMS proposes to adopt the certification requirements established by the Medicare Part B Program for average sales price (ASP). While we applaud the goal of consistency with ASP procedures, we respectfully remind the agency that ASP is calculated on a quarterly basis, not every month. The timeliness of our monthly AMP reports will be undermined if we are required to provide certification as outlined in the proposed rule. The Medicaid Rebate statute contains a civil monetary penalty provision for knowingly submitting false information. As there is no statutory requirement in the DRA for such a certification we ask that CMS eliminate the certification process for the monthly AMP reports.

Physician-Administered Drugs (Section 447.520)

Concerning rebates for physician-administered drugs, we respectfully request that CMS provide clarification in the final rule that the states should collect a Medicaid rebate only for that portion of the payment made by a state Medicaid program. If CMS does not clarify this provision, manufacturers could be required to remit full rebate payments to states where Medicare is the primary

Submitter : Mrs. Colleen Cox **Date:** 02/20/2007

Organization : ClearSpring Pharmacy

Category : Individual

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

Submitter : Ms. Nancy Mosher **Date:** 02/20/2007

Organization : Planned Parenthood of Northern New England

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1166-Attach-1.DOC

CMS-2238-P-1166-Attach-2.DOC

#1166

COMMENT FROM
PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND HEALTH CENTERS

February 16th , 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the President and CEO of Planned Parenthood of Northern New England (PPNNE), which includes a network of 26 non-profit outpatient health centers in Vermont, New Hampshire, and Vermont that provides critical reproductive health services to uninsured and underinsured women, men and teens. PPNNE serves over 60,000 patients each year. Over 70% of these patients are under 200% of the Federal Poverty Level and can not afford the health services -- particularly oral contraceptives -- that PPNNE provides without discounted prices and our sliding fee scale.

For over 40 years, PPNNE has been committed to ensuring access to quality reproductive health services to women and men in Vermont, New Hampshire and Maine regardless of their ability to pay. In addition to providing deeply discounted oral contraceptive medications to women, we provide pregnancy tests, screening for cervical, breast and testicular cancer; testing and treatment for sexually transmitted infections, and immunizations for women, men and teens. Our ability to provide this range of services to the underprivileged members of our communities rests in large part with our ability to purchase oral contraceptive drugs from drug manufacturers willing to provide them at nominal prices

We are writing with great concern that the Centers for Medicare and Medicaid Services ("CMS") did not define "other safety net providers" as authorized by section 6001(d)(IV) of the Deficit Reduction Act of 2005 ("DRA"). PPNNE is a safety net provider, but it is critical that we are defined as such to ensure access to nominal prices for contraceptives.

At this time all but one of PPNNE's health care centers are considered 340B covered entities (as defined in DRA section 6001(d)(I)) through either Title X federal family planning program or the section 318 STD prevention program. While the 340B program currently keeps our health centers eligible for nominal drug pricing, 340B is simply not our golden ticket to sustained business. Given state and federal financial constraints, we simply cannot rely on the continued

funding from Title X and section 318, thus our eligibility as a 340B program is under constant threat. Thus, It is crucial to the continued operation of PPNNE's health centers that the Department of Health and Human Services (HHS) immediately defines "other safety net providers."

Quite simply, Title X and section 318 provide us with only a thin layer of eligibility for favorable drug pricing, but this protection is easily upset. This tenuous nature of our participation in the TX and 318 programs is real. Therefore, this issue is of great concern to us. The continuation and fiscal viability of PPNNE lies in our ability to purchase oral contraceptives at less than 10% of the average retail price. Should we lose our Title X or section 318 at any of our health centers, our ability to continue to serve our patients would be greatly compromised.

If we lose our Title X or section 318 status, we also lose our 340B status. While losing our 340B status would not change our commitment to providing poor women with affordable contraception, we would have no statutory access to the nominal drug pricing program. For this reason, we strongly urge CMS to include in its definition of safety net providers non profit health care facilities like ours.

If we are not defined as a safety net provider and lose eligibility under 340B, our ability to serve our clients would be crippled – not only in the areas of offering low cost contraception, but in all areas of reproductive health care. In effect we would no longer be able to provide the high quality services for poor women and men that they desperately need. This gap in services would have a particularly devastating impact to over 40,000 clients who are under 200% of the Federal Poverty Level that we serve in Vermont, New Hampshire and Maine each year.

Planned Parenthood of Northern New England urges CMS very strongly to reconsider its position and exercise the authority granted it by Congress to define "other safety net providers" in the final rule.

Respectfully Submitted,

Nancy Mosher
President and CEO
Planned Parenthood of Northern New England
Vermont, New Hampshire and Maine

Submitter : Ms. Michelle Featheringill **Date:** 02/20/2007

Organization : Planned Parenthood of New Mexico

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1167-Attach-1.DOC

#1167

February 20, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I submit these comments as President and CEO of Planned Parenthood of New Mexico, Inc. – a non-profit organization that has been providing reproductive health care in New Mexico since 1964. Each year we serve over 26,000 individuals in our five outpatient health centers located in Albuquerque, Rio Rancho and Santa Fe. More than 22 percent of New Mexicans lack health insurance so many women in the state count on us for low-cost, high quality health care.

In a recent survey, we determined that more two-thirds of our patients at Planned Parenthood of New Mexico (PPNM) have incomes below 150 percent of the federal poverty level. On the state level, twenty-three percent of women aged 15-44 have incomes below the federal poverty level, and 31 percent of all women in this age group are uninsured (i.e. do not have private health insurance or Medicaid coverage). Fifteen percent of women aged 15-44 are enrolled in Medicaid. However, according to the Guttmacher Institute, public family planning clinics in New Mexico only serve 54 percent of all women in need of publicly supported contraceptive services and 52 percent of the teenagers in need.

Many women and teens choose to come to PPNM because we've been providing services for over 40 years in the state, while other health care organizations have come and gone. They know who we are and where we are. Students and women who work appreciate our convenient walk-in and same-day appointments, and our evening and weekend hours.

Our patients know that Planned Parenthood is committed to keeping costs for services and supplies affordable and accessible. We've developed programs like PILLS NOW, PAY LATER a plan that allows a patient to take home a years worth of contraceptives, which she can pay for via debit card or bank draft each month. This is especially appealing for women who may have to travel some distance every month to reach a pharmacy in a state as large as New Mexico. However, our recent increase in pill prices has caused some patients to reconsider entering the program since they're not certain they'll have enough money in their account each month. Others are struggling to cover the monthly cost of their oral contraceptives now – we've had patients pay with a pile of bills and change.

PPNM has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. Like most Planned Parenthood providers, we strive to keep all of our prices for services, as well as contraceptive methods, as low as possible. When we were hit with the direct impact of the "Deficit Reduction Act," we were unable to fully absorb the increased costs that we experienced, and subsequently were forced to pass on the substantial increase to our patients. Without nominal pricing availability, we fear that the negative impact and inability of our patients to pay the necessary increases will make it extremely difficult for us to sustain our clinics financially. If PPNM were forced to close our clinic doors, the negative impact in our very poor State would be immense.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Many of our Planned Parenthood sister health centers across the country are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. Planned Parenthood of New Mexico, however, is not federally funded. Therefore, we do not qualify as a 340B covered entity.

At the same time, PPNM serves as a key safety net provider to many women in our state. Our ability to continue to do so rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, we do not qualify for the three categories above.

We sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will reconsider and exercise its authority to name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. PPNM is a clearly safety net provider and we strongly urge CMS to include in its definition of safety net providers nonprofit, outpatient clinics like ours.

Over 26,000 women rely on PPNM every year for their family planning and contraceptive needs; we are an integral resource for New Mexicans. It is imperative for us to maintain our ability to purchase contraceptives through a nominal pricing purchasing contract. Please strongly consider our request.

We appreciate your time and the opportunity to present our comments

Respectfully submitted by,

Michelle Lynn Featheringill
President/CEO
Planned Parenthood of New Mexico
Albuquerque, NM

Submitter : **Date: 02/20/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule could have a devastating impact on the financial viability of retail pharmacies and pharmacy practice. Community pharmacies cannot purchase multi-source generics at the prices obtained by PBM owned pharmacies and mail order pharmacies. Major mail order pharmacies and PBM's buying power allows them to leverage manufacturers for substantial rebates which are not available to retail pharmacies. This rule will give mail order pharmacies an unfair competivie advantage over retail pharmacy. PBM's are currently already forcing the majority of patients to use their own mail order pharmacies in order to save money on their copays. If you ever speak with those patients forced either financially or otherwise to use mail-order you will find the majority are disatisfied with the care they receive. They continue to go to their neighborhood retail pharmacy for conseling and other services. If you pass legislation that continually only affects the little guy then where will YOU go to fill your anitbiotic prescription or pain pills when all the neighborhood pharmacies are out of business. Who will fill prescriptions in the rural areas? If you want to control the cost of medications, taget those ultimately responsible, the drug manufacturers and physicians that are prescribing brand name medications when there are generics that would work just as well 80% of the time. It is not the retail pharmacies that are profiting. If you find that hard to believe then look at the reported profits of the major drug companies and PBM's versus independent retail pharmacies. I guess every legislative effort in this great country of ours is only aimed at helping the rich get richer and the poor get poorer. Im glad my tax dollars are spent on helping compaines like Merck who own the manufacturers, mail order pharmacies and insurance companies get richer. What next? I know let Merck own physicians too. Then they alone can tell patients and CMS what the patient can take, where they can purchase it and what physician they are required to go to. Maybe then companies like Merck can take over CMS or wait maybe in certain ways they already have.

Submitter : **Dr. Thad Schumacher** **Date: 02/20/2007**

Organization : **Dr. Thad Schumacher**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Ms. Norwalk:

I am writing to you to express my concerns with regard to the current proposed medicare prescription drug pricing suggested under CMS 2238 P. It is my opinion and that of the majority of my profession that using the proposed rules to calculate AMP will have a dramatic reduction of Medicare patients access to their pharmacists and disastrous effects on the small businesses of independent retail pharmacies across the nation.

As a manager of a new independent pharmacy in a metropolitan area, I see and experience retail pharmacies struggle to provide personalized patient care such as compliance assistance, patient education, and home delivery while seeing reimbursements continue to be reduced. Everyday, I help Medicare patients choose the right medication to compliment their therapy while simultaneously choosing the most cost-effective therapy for them. It costs about $9.00 according to the National Association of Chain Drugstores to fill the average prescription. This number at my pharmacy would be higher as I make it a point to spend quality time with each of my patients.

Not only does it more expensive to fill prescriptions for the Medicare population, the profit made per prescription is also less, leading to significantly reduced margins that are not sustainable in a successful business. The average gross profit on a Medicare prescription at my pharmacy currently is $10. This profit can be compared to my overall gross profit per prescription (Medicare and all other third parties) of $14.32 showing that Medicare is already failing to provide adequate reimbursement for the services that I provide my Medicare patients. The National Community Pharmacists Association has reported that the current proposed rules will lead to a reimbursement 36% less than pharmacy acquisition costs. These numbers lead me to one conclusion. If AMP in its current form were to be implemented, this pharmacy would be forced to stop accepting Medicare patients prescriptions. In my opinion, this would be the fate of many Medicare recipients with regard to accessing their current pharmacist. This huge decrease in pharmacy providers especially in rural areas will be detrimental to public health.

What can be done to change this detrimental outcome? Do not base Federal Upper Limits (FULs) on AMP because this does not account for the acquisition cost of multisource generic medications. Do not use AMP as a basis for reimbursement, for it was never intended to represent the acquisition costs of medications by pharmacies. For AMP to be considered an appropriate benchmark, it must be redefined to reflect the actual costs to retail pharmacies. This could be attained by excluding all rebates and price concessions made by pharmaceutical manufacturers that are not available to retail pharmacies. You should exclude all mail order facility and PBM pricing formats from AMP calculations as mail order and PBM pharmacies receive special pricing from manufacturers and they are not as accessible to the public as a pharmacy located in a patient s neighborhood. Making these special price compensations and rebated programs transparent to the public would also bring light to the unlevel playing field in acquisition costs of retail pharmacies and mail order and PBM facilities. It would also be important to report AMP at the 11-digit NDC level to ensure accuracy.

Thanks you for your time with regard to this matter. If you have any questions or wish for clarification please do not hesitate to call me 623-221-6630 or email me at thad67@msn.com. This decision effects future access of Medicare patients to their pharmacists. Please do not let them down.

Thad Schumacher, PharmD
Cactus & 35th Ave Family Pharmacy
12450 N 35th Ave #25
Phoenix, AZ 85029
602-298-1460

Submitter : Dr. Connie Bolte **Date:** 02/20/2007

Organization : Moore Compounding 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 reimbursement for the remaining Medicaid recipients to a level where as a business 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 specialty pharmacy in a 40 mile radius that offers compounded prescriptions to the Medicaid clients in our area. The health needs of those 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. 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 : Mr. Michael J Ruggiero **Date:** 02/20/2007

Organization : Astellas Pharma US

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-1171-Attach-1.PDF

CMS-2238-P-1171-Attach-2.PDF

1171-1

astellas
Leading Light for Life

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8015

VIA ELECTRONIC SUBMISSION AND EXPRESS MAIL
(http://www.cms.hhs.gov/eRulemaking)

Re: Comments on Proposed Rule related to the Medicaid Rebate Program, CMS-2238-P

Dear Ms. Norwalk:

Astellas Pharma US appreciates this opportunity to comment on the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) on December 22, 2006 implementing certain provisions of the Deficit Reduction Act of 2005 (DRA) relating to the Medicaid program.[1] Astellas is a global, research-based pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products that treat unmet medical needs. Our North American product lines focus on the therapeutic areas of immunology, cardiology, infectious disease, dermatology, and urology.

We appreciate the challenges involved in implementing the DRA, and commend CMS on its efforts in this area. We generally agree with the comments being submitted by the Pharmaceutical Research and Manufacturers of America, and we urge CMS to give careful consideration of the recommendations set forth in those comments. In our comments, we wish to focus in particular on the need to ensure adequate access to oral immunosuppressives at the pharmacy level for Medicaid transplant patients.

The DRA changed the federal upper limit (FUL) for multiple source drugs to 250% of the average manufacturer price (AMP) for the least costly drug in each multiple-source group.[2] CMS has proposed to use its rulemaking authority to establish safeguards to ensure that the FUL is set at a price that is "adequate . . . to ensure that a drug is available for sale nationally as presently provided in our regulations."[3] Specifically, CMS has proposed not to include in a FUL calculation: (1) the AMP of an NDC that has been terminated; or (2) an AMP that is less than 30 percent of the next highest AMP in the relevant multiple source drug group.[4]

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[1] Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

[2] Social Security Act (SSA) § 1927(e)(5).

[3] 71 Fed. Reg. 77174, 77187 (Dec. 22, 2006).

[4] Id. at 77188. CMS proposed that the 30% outlier policy not apply when calculating the FUL for a multiple-source group that includes only the innovator and the first generic to enter the market.

We support CMS' proposal to establish these safeguards in the FUL methodology, and we believe an additional safeguard is warranted to ensure adequate access to anti-rejection immunosuppressives for Medicaid beneficiaries who have had organ transplants. Transplant patients must take immunosuppressives to prevent rejection of the transplanted organ, and access to these medications is critical. Missing even a few days of an anti-rejection immunosuppressive regimen can cause graft failure, resulting in loss of the organ and catastrophic consequences for the patient.

The special importance of access to immunosuppressives has prompted CMS to use its regulatory authority to establish safeguards for these therapies under Part D. CMS did this "because it was necessary . . . to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[5] This rationale applies equally in the Medicaid context, particularly in light of a recent report by the Government Accountability Office indicating that AMP-based FULs would result in Medicaid payment for many drugs that is substantially below pharmacy acquisition costs.[6]

We therefore urge CMS to establish an additional safeguard in the FUL methodology for immunosuppressives. Specifically, we propose that CMS base the FUL for immunosuppressive multiple-source drug groups on the lowest AMP that is not less than 70% of the next-highest AMP in the multiple-source drug group. In addition, we urge CMS to apply this safeguard to all anti-rejection immunosuppressive FULs, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor.

* * *

Astellas appreciates your consideration of these comments, and would be pleased to provide any additional information that might be helpful to CMS as it prepares the final rule. Please contact me at 847-405-1640, or via email Michael.Ruggiero@us.astellas.com, if we can be of any assistance.

Sincerely,

Michael J. Ruggiero
Senior Director, Government Policy & External Affairs

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[5] Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines -- Formularies,* at 7.

[6] GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs (Dec. 22, 2006).

1171-2

astellas
Leading Light for Life

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8015

VIA ELECTRONIC SUBMISSION AND EXPRESS MAIL
(http://www.cms.hhs.gov/eRulemaking)

Re: Comments on Proposed Rule related to the Medicaid Rebate Program, CMS-2238-P

Dear Ms. Norwalk:

Astellas Pharma US appreciates this opportunity to comment on the proposed rule published by the Centers for Medicare and Medicaid Services (CMS) on December 22, 2006 implementing certain provisions of the Deficit Reduction Act of 2005 (DRA) relating to the Medicaid program.[1] Astellas is a global, research-based pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products that treat unmet medical needs. Our North American product lines focus on the therapeutic areas of immunology, cardiology, infectious disease, dermatology, and urology.

We appreciate the challenges involved in implementing the DRA, and commend CMS on its efforts in this area. We generally agree with the comments being submitted by the Pharmaceutical Research and Manufacturers of America, and we urge CMS to give careful consideration of the recommendations set forth in those comments. In our comments, we wish to focus in particular on the need to ensure adequate access to oral immunosuppressives at the pharmacy level for Medicaid transplant patients.

The DRA changed the federal upper limit (FUL) for multiple source drugs to 250% of the average manufacturer price (AMP) for the least costly drug in each multiple-source group.[2] CMS has proposed to use its rulemaking authority to establish safeguards to ensure that the FUL is set at a price that is "adequate . . . to ensure that a drug is available for sale nationally as presently provided in our regulations."[3] Specifically, CMS has proposed not to include in a FUL calculation: (1) the AMP of an NDC that has been terminated; or (2) an AMP that is less than 30 percent of the next highest AMP in the relevant multiple source drug group.[4]

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[1] Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

[2] Social Security Act (SSA) § 1927(e)(5).

[3] 71 Fed. Reg. 77174, 77187 (Dec. 22, 2006).

[4] Id. at 77188. CMS proposed that the 30% outlier policy not apply when calculating the FUL for a multiple-source group that includes only the innovator and the first generic to enter the market.

We support CMS' proposal to establish these safeguards in the FUL methodology, and we believe an additional safeguard is warranted to ensure adequate access to anti-rejection immunosuppressives for Medicaid beneficiaries who have had organ transplants. Transplant patients must take immunosuppressives to prevent rejection of the transplanted organ, and access to these medications is critical. Missing even a few days of an anti-rejection immunosuppressive regimen can cause graft failure, resulting in loss of the organ and catastrophic consequences for the patient.

The special importance of access to immunosuppressives has prompted CMS to use its regulatory authority to establish safeguards for these therapies under Part D. CMS did this "because it was necessary . . . to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[5] This rationale applies equally in the Medicaid context, particularly in light of a recent report by the Government Accountability Office indicating that AMP-based FULs would result in Medicaid payment for many drugs that is substantially below pharmacy acquisition costs.[6]

We therefore urge CMS to establish an additional safeguard in the FUL methodology for immunosuppressives. Specifically, we propose that CMS base the FUL for immunosuppressive multiple-source drug groups on the lowest AMP that is not less than 70% of the next-highest AMP in the multiple-source drug group. In addition, we urge CMS to apply this safeguard to all anti-rejection immunosuppressive FULs, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor.

* * *

Astellas appreciates your consideration of these comments, and would be pleased to provide any additional information that might be helpful to CMS as it prepares the final rule. Please contact me at 847-405-1640, or via email Michael.Ruggiero@us.astellas.com, if we can be of any assistance.

Sincerely,

Michael J. Ruggiero
Senior Director, Government Policy & External Affairs

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[5] Centers for Medicare & Medicaid Services, *Medicare Modernization Act 2007 Final Guidelines -- Formularies*, at 7.

[6] GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs (Dec. 22, 2006).

Submitter : **Rod Reinhardt** **Date: 02/20/2007**

Organization : **First Choice Pharmacy of Henderson**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

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

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

Sincerely,

Rod Reinhardt, Owner

Submitter : Alan Layton **Date:** 02/20/2007

Organization : Mountain West Medical Center/Wal-mart

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

It appears that the proposed rule assumes a level playing field both in purchasing and in patient counselling. This is a huge disadvantage to community pharmacies who will be expected to compete with PBM owned mail order facilities which are able to contract for lower manufacturer pricing and bigger rebates. These types of rules and decisions continue to increase the required number of prescriptions per pharmacist hour needed to maintain viabililty let alone profitability for community pharmacies. As the workload increases it has a direct negative effect on patient safety. The time available to counsel patients has continually eroded away as the required workload has increased. Mail order facilities continue to dispense prescriptions with "counseling available" allowing them to avoid the costs of pharmacies true benefit, educating and protecting the patient.

Please revisit the differences between mail-order and retail pharmacy, both in the purchasing and the service expectations before passing this rule

Submitter : Dr. Tracy Hart **Date:** 02/20/2007

Organization : Family Prescription Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1174-Attach-1.TXT

1174

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of Family Prescription Center, a community retail pharmacy located at 129 Main St., Mountain City, TN. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Tracy D. Hart
PO Box 105
Mountain City, TN 37683

cc: Senator Lamar Alexander
Senator Bob Corker

Representative David Davis

Submitter : Mr. Jerry Friedman **Date:** 02/20/2007

Organization : American Public Human Services Association

Category : State Government

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

See attachment

GENERAL

GENERAL

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1175-Attach-1.DOC

#1175

APHSA
American Public Human Services Association

NASMD
National Association of State Medicaid Directors
an affiliate of the American Public Human Services Association

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: **CMS–2238-P**

Re: Proposed Rule: Medicaid Program; Prescription Drugs

Dear Ms. Norwalk:

The American Public Human Services Association (APHSA) and its affiliate, the National Association of State Medicaid Directors (NASMD), respectfully submits this comment letter on the Medicaid prescription drug benefit. APHSA and NASMD are commenting on the proposed rule published in the December 22, 2006 Federal Register (71 FR 77174) for the Centers for Medicare and Medicaid Services (CMS). Please be assured that the state Medicaid agencies are fully committed to implementing the prescription drug related provisions of the Deficit Reduction Act of 2005 (DRA) and to their respective initiatives that seek to improve the efficiency of the Medicaid pharmacy benefit.

APHSA and NASMD believe that the DRA included important provisions that could facilitate increased transparency in prescription drug pricing in the Medicaid program and provide states with the tools they need to improve the accuracy of their reimbursement methodologies. States also recognize that these are essential steps in providing quality, affordable care to Medicaid consumers.

Medicaid's fundamental federal-state partnership necessarily means that states have a vested interest in ensuring the policy on drugs ensures ease of implementation. Further, states have an interest in assuring that the Congressional intent with respect to the DRA provisions can be implemented. As CMS continues to evaluate the best course of action to achieve these goals, we are submitting comments in the following areas:

- Ensuring the accuracy of average manufacture price (AMP) data for use in validating states' reimbursement methodologies and establishing AMP-based federal upper limits (FULs);
- Providing states with the flexibility to respond to market forces in a timely fashion; and
- Minimizing procedural challenges and recommending steps to improve the efficiency of collection of rebates on physician administered drugs.

Definitions – Section 447.502

Definition of Dispensing Fee
The proposed dispensing fee definition infers a specific methodology – that is a cost-based calculation not reflective of economies and competition in the marketplace. This is inconsistent with the intent of Congress and the administration to provide states' with the flexibility to set their own dispensing fee levels. In addition, it may result in Medicaid rates that are not representative of a marketplace in which other insurers consistently pay lower rates for ingredient costs and dispensing fees together than most Medicaid programs.

States also have noted that the proposed definition allows payment of a dispensing fee each time a drug is dispensed, regardless of whether such dispensing is consistent with economical practices. States have identified situations where some pharmacies, sometimes colluding with prescribers, fraudulently split maintenance drug prescriptions to obtain additional dispensing fee payments. States request that CMS clarify the proposed definition so that it does not preclude states from preventing such behaviors.

Determination of AMP – Section 447.508

In its proposed rule CMS requested input on its definition of AMP. With regard to mail order pharmacies, states note that mail order pharmacies are able to capitalize on their economies of scale by purchasing in bulk and dispensing in large quantities. Additionally, mail order and other large scale purchasers have access to discounts that are not available to rural or sole proprietorship pharmacies. Based on this disparity, CMS should consider excluding mail order pharmacies in the AMP calculation.

CMS also requested comments on the new AMP calculation for setting FULs on generic drugs and whether there could be possible impacts on utilization and reimbursement for brand name drugs under Medicaid. States have conducted initial evaluations of the AMP data and will need additional time to conduct more comprehensive assessments and fully evaluate the new AMP-based FULs. Further, states believe it may be premature to evaluate the changes and impact of AMP pricing in the marketplace that may occur over time.

At this time, states note that there could be a challenge in achieving the most accurate reimbursement while not indirectly creating a disincentive to dispense generic prescription drugs. Some states have raised concerns that the proposed AMP-based reimbursement could discourage generic dispensing and have the unintended effect of increasing brand utilization and Medicaid costs. That is, if the aggregate impact of the AMP-based FULs results in a shift to brand name drugs and/or increase in dispensing fees, this could cause inefficiencies in the Medicaid prescription drug benefit. In addition, states recognize that provisions of the proposed rule may directly or indirectly impact their provider network, particularly in communities with small providers and/or those dependent on one provider.

For these reasons, states urge CMS to examine the range of factors – in addition to the ingredient costs – impacting states' reimbursement methodologies and preserve states flexibility to maintain a reasonable, market-based threshold for reimbursement. States ask that CMS consider the variations in prices and availability across states. We wish to offer for CMS' consideration the

possibility of creating an appeals process to allow pharmacies, drug wholesalers, and states to report situations whereby prescription drugs are not available or not available at the prices listed under the AMP-based FUL. For example, rural pharmacies may not have access to the same pricing available to larger markets or mail order pharmacies. Confirmed reports could result in CMS raising or suspending a FUL.

States also offer for your consideration that the appropriate definition of fair market value can only be truly determined by measuring the prices wholesalers charge all pharmacies in the aggregate on a real-time basis. In general, the wholesaler effect needs to be considered an essential component of this equation to accurately and equitably determine "fair market value."

Requirements for Manufacturers – Section 447.510

States believe that the DRA and this proposed rule begin to elaborate on the important steps that will help to increase access to and transparency of AMP data and a more appropriate reimbursement system, including by defining AMP in statute and regulation. However, states have identified several challenges and concerns with the proposed rule related to AMP.

AMP Data

States strongly encourage CMS to ensure that the AMP data is of a level of quality that will permit states to validate their current reimbursement methodology and improve the efficiency of the Medicaid pharmacy benefit. At a minimum, standard AMP data should reflect only those products currently available and be based on a specified supply time period, specifically:

1) CMS began providing states with sample or "non-standard" AMP data in July of 2006, and, based on this information, most states have conducted preliminary analysis of the AMP data. States have reported that there are a significant number of terminated products or products that were not available in every state that were included in the manufacturers' lists. The result is that states are presented with new challenges and questions as to why manufacturers would be reporting such data, even if this were a "sample" AMP file.

2) Some states have reported that there is significant fluctuation in AMP and that this inconsistency could result in inaccurate estimates of the acquisition costs that providers pay. This also could result in fluctuating FULs, thereby making it difficult for states to make timely and reasonable adjustments to their reimbursement methodologies to reflect such fluctuations. At the onset of implementation of the DRA provisions, states believe that it would be appropriate to provide additional time to allow states to monitor the fluctuations of the complete AMP data before they could make adjustments in reimbursement.

3) We encourage CMS to provide additional guidance on FUL pricing for prescription drugs that is not based on a different supply schedule, that is, by the actual package size of the drug. A FUL set on a weighted AMP by package price may not cover the actual acquisition costs of pharmacies purchasing smaller package sizes – while other pharmacies purchasing larger package sizes would be over paid.

Accountability for Accurate Data

We respectfully request that CMS assist in verifying the accuracy of the data by implementing accountability measures for manufacturers. States understand from the CMS call held on January 4, 2007, that the agency believes that the transparency of AMP information should help to reduce the erroneous data problem. However, states remain concerned by the lack of controls and accountability measures for manufacturers. In addition, the historical experience of states indicates that existing CMS processes have been insufficient in monitoring and managing the prescription drug files. The lack of updated data can reasonably be expected to result in inappropriate FUL calculations and impose an unforeseen burden on states to identify and subsequently report any inaccuracies to CMS.

As a result, states urge CMS to implement systems checks and measures to hold manufacturers accountable for the quality of data they provide, including reporting or not reporting accurate data. States request that in developing this system of checks and accountability measures, CMS include representation from state Medicaid agencies in addition to CMS representatives.

Implementation Timeline

States are concerned that the final regulation may not be published until July 1, 2007 and that many questions essential to implementation of the proposed rule will remain unanswered until this time. We understand that this is the date specified in the DRA. However, we urge CMS to consider and account for the steps states' will need to take in order to operationalize the final rule and meet this deadline.

States are unlikely to have the processes and systems in place for a number of reasons, including:

1) States must wait for CMS to finalize the provisions of this rule before they can develop the systems and processes to implement it, otherwise, states will have to undertake a second implementation initiative to reflect the changes and additional information CMS is expected to provide in the final rule.

2) Although states received AMP data in 2006, this was sample data, so they will have had insufficient time to evaluate the monthly fluctuations in AMP and any impacts on various facets of their Medicaid program. As noted above, the sample data was inaccurate and insufficient to make firm policy decisions. Any changes that states will need to make to their state Medicaid plan or dispensing fees are likely to require state legislation and/or submission of a state plan amendment and this will take considerable time.

3) The implementation timeframe is short and some states are unlikely to have the staff and funding resources to meet the deadline.

Transfer of AMP Files

Finally, with regard to AMP, the proposed rule states that CMS will distribute the monthly AMP file to states. States are concerned that the monthly file that CMS intends to send will contain only the drug name. In turn, states will have to translate the drug descriptions in the file that will enable them to easily analyze the impacts of the FUL with their processed claims. In addition, providing the file to states in such a fashion may lead to misinterpretations and lack of identification of applicable products with their National Drug Codes (NDCs) that are necessary to

process claims. In essence, this will require many states to invest new resources to manage this information.

States believe CMS can and should assist in making this process more efficient. We believe there would be a significant strain on states' resources if they were required to manage all of the new AMP data, including pricing updates, manually without some assistance. Therefore states request that CMS consider alternative mechanisms to facilitate states' utilization of workable data in a timely fashion. Specifically, a mechanism is needed that applies the rate to the new NDC that meet those criteria listed in the proposed rule. One possibility is to provide the file on at least a monthly basis to the nationally recognized pricing compendia that, in turn, could provide descriptive drug information, unique identifiers and pricing data, including updated NDC codes, within the file that would be distributed to states.

New FUL Calculation and Impact on Preferred Drug Lists

States also urge CMS to consider the adverse impact that the new AMP-based FUL could have on state prescription drug lists (PDLs) that have otherwise been effective in helping to appropriately contain costs in the Medicaid prescription drug benefit. For example, every month states could be required to consider the new AMP-based FUL for their respective PDLs. States have noted that in addition to procedural difficulties with this process, there may be challenges and unintended consequences on the level of savings expected to accrue from the new FUL if the net cost to the federal government and a particular state is less than the costs of generic. Specifically, this could compromise supplemental rebate agreements that states have in place in situations where the federal rebate and supplemental rebate together produce greater savings than the new FUL.

Access to Data for Territories

APHSA and NASMD also respectfully request that CMS provide the U.S. territories with access to the new AMP data so they may leverage the information in their calculations for reimbursement on brand-name and generic drugs, as well as on rebates negotiations with the drug companies. Access to the proposed new AMP data will provide a benchmark in the rebate negotiation process, maximizing the utilization of available Medicaid funds.

Drugs: Aggregate Upper Limits of Payment – Section 447.512

The proposed rule includes an exception to allow providers to indicate when a specific brand drug is medically necessary for a particular recipient. However, CMS has indicated that this exception is permitted only in instances when the physician "certifies in his or her own handwriting" that the drug is necessary. States request that CMS reconsider this requirement as it is contradictory to state and federal efforts to transition to e-prescribing and other health information technology innovations.

Upper Limits for Multiple Source Drugs – Section 447.514

In the proposed rule, CMS notes that Congress did not intend that AMP should be restructured to collect it by 11-digit National Drug Codes (NDCs) and that this would create a new burden for manufacturers. We respectfully disagree with CMS' decision not to restructure the information collection method. Rather, the 11-digit NDC methodology will more accurately reflect the prices

paid by the majority of rural and sole proprietorship pharmacies. Specifically, states note that in some areas there is a lack of availability of all package sizes. This is particularly the case with rural or sole proprietorship pharmacies. Thus, the 9-digit NDC favors large scale purchasers and mail order pharmacies who capitalize on economies of scale by purchasing pharmaceuticals in the largest package size or those available in bulk where this methodology is not financially feasible or available to our rural pharmacies. States also recommend that AMP-based FUL pricing should be calculated on standardized package sizes.

FFP: Conditions Relating to Physician Administered Drugs – Section 447.520

The DRA called for a number of changes to improve the efficiency of billing methodologies for physician administered drugs. States are prepared to work with CMS to develop the appropriate measures and guidance that will be needed to ensure these provisions are implemented effectively.

Provider education
States are concerned that the proposed rule does not take into account the extensive education and systems updates that will be required to ensure that providers can comply with the new physician administered drug billing methodologies. A "standardized rebatable labeler list" would help to avert states having to deny claims several months later. States expect the change in the billing system and practices to be an especially acute problem in situations of small provider groups or among providers that utilize separate contractors for their billing systems.

As such, states respectfully request that CMS inform providers of the Healthcare Common Procedure Coding System (HCPCS) codes will require a National Drug Code (NDC) that they can bill the state. As stated above, without this information, providers may not know who is and is not a rebating labeler.

In addition, we believe that it would be an onerous requirement to mandate states – without any assistance from CMS – to work with providers to ensure that these codes are collected for rebatable drugs. States believe that since this is a national issue impacting all states and providers in the same way, it is reasonable to request that CMS develop standardized literature to educate providers rather than requiring each Medicaid agency to develop its own materials.

States also believe that CMS has significantly underestimated the burden of this provision on states if it is implemented as proposed. At a minimum, CMS should revise its burden estimate to account for the extensive education and outreach that states will ultimately be required to undertake.

Aligning Medicare and Medicaid rules
States also request that CMS provide clarification and guidance on the rule's impact and interaction with Medicare. There are a significant number of providers that will be impacted because of Medicaid's role in providing coverage for individuals dually eligible for Medicare and Medicaid. States are concerned that the proposed rule does not address the impact on Medicare carriers and, in turn, this will create obstacles in Medicaid agencies' ability to efficiently comply with these provisions. In fact, based on previous experience working with Medicare providers, states believe that Medicare carriers are not prepared to provide detailed NDC information that is

necessary to ensure that Medicaid can obtain the rebate, when applicable. Without this information, there could be a significant number of denied claims that may not be able to be resolved. In turn, beneficiaries could receive bills for denied claims or be refused treatment.

States urge CMS to use its authority to ensure that the Medicare and Medicaid rules align so that state Medicaid agencies can comply in a timely, efficient manner. That is, CMS should require Medicare to do a "crosswalk" and address Medicare's responsibility in providing rebate information for certain prescription drugs provided to a dually eligible beneficiary.

Impact on DMERC

Many states currently do not receive an NDC from a DMERC. However, states believe that the standardization of physician administered drugs necessarily should impact DMERCs and that there may be a multitude of requirements for DMERCs. As such, states also request that CMS provide clarification and guidance on the role and responsibilities of DMERCs with regard to the provisions of the proposed rule.

NDC requirement for HCPCS drugs

In addition, states note that there will be operational challenges associated with the NDC requirements for HCPCS prescription drugs. There are two paper forms, the CMS 1500 and the UB04 that are in use. The electronic 837 format for both the CMS 1500 and UB04 can accommodate the NDC, including the NDC quantity. However, the paper version of the UB04 does not have a space for this information. CMS has indicated that each state should develop its own unique form.

States urge CMS to reconsider this issue, particularly given the limited timeframe available to adopt a new form. Due to the administrative procedures and existing demands on state staff, states face great challenges in meeting this requirement. Instead, states respectfully request that CMS develop a standard UB04 form that provides for a way to indicate the NDC. This will guarantee uniformity across states and ensure that states are not subject to lose any rebates or revenues.

Hardship waiver

CMS in the proposed rule and in its verbal communication with states indicated that the agency does not expect that states will need a hardship waiver to meet these requirements. For the reasons stated above and other factors impacting state Medicaid programs, such as the concurrent implementation of the National Provider Identification number (NPI) and ongoing systems upgrades that cannot accommodate the change in the specified timeframe, states respectfully request that CMS be amenable to the possibility that a hardship waiver may be needed in some states and be prepared with a hardship waiver process.

Retail Price Survey

Although this proposed rule does not specifically address Section 6001(e) of the DRA which provided for a survey of retail prices and state performance rankings, states wish to offer comments that we believe impact this proposed rule and CMS' related work on the retail price survey. As it finalizes this process, states request that CMS consider various factors and unique state situations that will impact this information. Specifically, pharmacies are required to bill

Medicaid their usual and customary price that is supposed to reflect what the pharmacy charges a "regular" customer. However, although states are diligent in ensuring that pharmacies are compliant with Medicaid policies, due to misunderstandings associated with this requirement, there may be some pharmacies that increase the rate they charge to Medicaid programs because they do not think they have to charge the same to both types of customers. This could skew the data used in the retail price survey. In addition, in the state reimbursement price ranking, the state supplemental rebates are excluded in the best price determination. However, for gross payments made to pharmacies this does not reflect the true price a state Medicaid agency may be paying. In turn this will skew the ranking and could result in over reporting. As such, states strongly encourage CMS to make note in its report of these and any other factors that clarify the results.

Regulatory Impact

States respectfully request that CMS reconsider or clarify the level of administrative costs associated with this regulation. Specifically, CMS should provide estimates of the federal and state administrative costs. This estimate should reflect the fact that AMP-based FUL pricing is not currently in effect. Although the rule has not yet been finalized, states already have invested significant time and resources assessing the impact of AMP and the proposed rule.

We would be pleased to meet with you at any time or provide any additional information that may helpful to you on these matters. Thank you for considering our comments. If you have any questions, please do not hesitate to contact me or Martha Roherty at (202) 682-0100, ext. 299.

Sincerely,

Jerry W. Friedman
Executive Director

Nancy Atkins
Chair, NASMD Executive Committee

Cc:
Dennis Smith
Director
Center for Medicaid State Operations, CMS

Matt Salo
Director of Health Legislation
National Governors Association

Joy Wilson
Director, Health Policy
National Conference of State Legislatures

NASMD Executive Committee

ubmitter : **Ms. Cristal Thomas** **Date: 02/20/2007**

Organization : **Ohio Medicaid**

Category : **State Government**

ssue Areas/Comments

Background

Background

See Attachment

Collection of Information Requirements

Collection of Information Requirements

See Attachment

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1176-Attach-1.PDF

CMS-2238-P-1176-Attach-2.PDF

1176-1

Ted Strickland
Governor

Helen E. Jones-Kelley
Director

30 East Broad Street Columbus, Ohio 43215-3414
jfs.ohio.gov

February 15, 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, MD 21244-8015

Comments on the Proposed Rule Concerning the Medicaid Program: Prescription Drugs CMS-2238-P

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposed rules regarding the Medicaid prescription drug program changes outlined in sections 6001 (a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA). Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid and the Medicare Premium Assistance Program. These programs cover 1.7 million Ohioans each month.

Preserving access to prescription drugs for Medicaid recipients should be a priority for the Centers for Medicare and Medicaid Services (CMS). The Ohio Medicaid program is concerned that several provisions contained in the Notice of Proposed Rule Making (NPRM) in the December 22, 2006, Federal Register may limit access to prescription drugs, both at the pharmacy and in the physician's office.

Ohio Medicaid has three main concerns. First and foremost, we are concerned that the requirement that physicians bill using National Drug Code (NDC) in addition to Healthcare Common Procedure Coding System (HCPCS) code for physician-administered drugs will create a new billing procedure that is used only for Medicaid, creating an administrative burden that many physicians may not be able to carry. This causes Medicaid patients to be treated differently than other patients in the practice, and as a result physicians may choose to not accept Medicaid patients. We believe that this will create a barrier to access.

Second, we are concerned that CMS has indicated that it does not expect any states to submit a hardship waiver to accommodate a delay in collecting NDCs on claims for physician-

administered drugs. In addition to the concern that physicians will not be able to accommodate this new billing procedure, we will be unable to make system updates in time to meet the January 1, 2008, deadline.

Third, we are concerned about the variability that will occur in the proposed calculation of Average Manufacturer Price (AMP), leading to wide variations in the Federal Upper Limit (FUL). These variations will create an unfair burden on pharmacies, as they will not be able to predict reimbursement for future months to plan for inventory. This provision will also be administratively burdensome for states to implement if the FUL changes on a monthly basis.

More information about each of these concerns appears below, along with additional comments. Please carefully consider these comments as CMS prepares to publish the final rule.

Section II: Provisions of the Proposed Regulations

Basis and Purpose of Subpart I – Section 447.500

The definition of "dispensing fee" outlined in this section indicates that CMS does not intend to mandate a dispensing fee methodology to which states must adhere. Ohio Medicaid agrees with this point. However, CMS goes on to indicate that states should evaluate the relationship between AMP and pharmacy acquisition cost to determine a dispensing fee that is adequate to cover a pharmacy's cost. We are concerned that the AMP changes will result in a FUL that is too low for pharmacies to be able to acquire the drugs. In response, many states have already increased the dispensing fee, and other states have this under consideration. In fact, CMS staff have encouraged states to increase dispensing fees. We are concerned that states' increases in dispensing fee will negate any savings from changes to the FUL.

Recommendation:

* CMS should examine whether increases in dispensing fees will negate any savings anticipated from the AMP changes proposed in this NPRM.

Determination of Average Manufacturer Price – Section 447.504

Ohio Medicaid agrees with the proposed definition of "retail pharmacy class of trade" as it relates to the calculation of AMP. The exclusion of long-term care (LTC) pharmacies is consistent with a policy that the retail class of trade exclude special populations. We also agree that mail order pharmacies should be included in the retail class of trade due to their availability to most consumers. Pharmacy benefit manager (PBM) discounts should also be included in the calculation of AMP since most Americans, including dual eligibles enrolled in the Medicare prescription drug program, benefit from these discounts.

Recommendations:

* CMS should use the definition of "retail pharmacy class of trade" that is proposed in the NPRM.
* CMS should require manufacturers to include PBM discounts in the calculation of AMP.

Requirements for Manufacturers – Section 447.510

Ohio Medicaid believes that it is imperative that AMP pricing must be fairly stable, due to its use in calculating the FUL. If AMP changes substantially from one month to the next, the FUL may also be changed on a monthly basis. This is an administrative infeasibility for Medicaid programs and for pharmacy providers. Pharmacies must be assured that they are able to purchase drugs at or below the FUL, and that any stock previously purchased at a higher price will not be reimbursed in the next month by the state at a new, unfairly low, FUL. States must be assured that the FUL will not change monthly for each drug, due to the administrative time in updating pricing each time a new FUL is released.

Our analysis of the AMP data provided to states by CMS since July 2006 revealed wide variations between the lowest AMP for many drug/strength combinations (FUL group). For example, one FUL group examined in the months July through November 2006 showed that in the five-month period, three different manufacturers provided the lowest AMP in at least one month. The lowest AMP, and resulting FUL, is shown below, along with the percent change from the previous month:

	Lowest Reported AMP	FUL (250% AMP)	Percent Change from Previous Month
July	0.021014	0.052535	
August	0.021014	0.052535	0.00%
September	0.008659	0.021648	-58.79%
October	0.008659	0.021648	0.00%
November	0.011646	0.029115	34.50%

The same FUL group shows one manufacturer's AMP changing from 0.025796 to 0.108960, and back down to 0.013098 within the same five-month period. If this amount of volatility is seen in a FUL group that has a limited number of generic products available, the FUL could vary wildly.

The Government Accountability Office (GAO) report presented to Rep. Joe Barton on December 22, 2006 [1], confirmed the volatility in AMP. GAO found that the majority of FUL groups had a median increase or decrease in AMP of 33 percent from one quarter to the next. While both our analysis and GAO's used AMPs reported under previous guidelines, the new calculations proposed in this NPRM would not change the variability from month to month. Changes this great are unacceptable for pharmacies and state Medicaid programs.

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

CMS has offered suggestions for reducing the volatility of AMP from month to month. One suggestion is that manufacturers be allowed to rely on estimates of their quarterly price concessions when submitting monthly AMP data. CMS has also requested comments on allowing manufacturers to use a twelve-month rolling average estimate of discounts. We believe that CMS should mandate, not simply allow, manufacturers to use a twelve-month rolling estimate of price discounts in reporting monthly AMP. This will reduce the volatility in the FUL, giving states and pharmacy providers assurance that access will not be denied to Medicaid recipients due to pharmacies being unable to purchase drugs within the FUL. This will also reduce the administrative burden on states of updating FUL pricing for each drug on a monthly basis.

By mandating manufacturers to use a rolling average of price concessions for AMP calculations, CMS will reduce volatility in FUL pricing. However, we believe that best price calculations should be made using only actual price concessions realized by the manufacturer in the quarter. In this way, states will be assured that the rebate per unit amount will be accurate.

Recommendation:

* CMS should mandate manufacturers to use a rolling twelve-month estimate of price concessions while reporting the monthly AMP, but require actual discounts be used in reporting the quarterly best price.

Upper Limits for Multiple Source Drugs – Section 447.514

As noted in the previous section, Requirements for Manufacturers, Ohio Medicaid is concerned that updating the FUL on a monthly basis based on monthly reported AMP will result in great variation. This situation will cause hardship for both state Medicaid agencies and pharmacies. State Medicaid agencies will be required to spend large amounts of administrative time to comply with the FUL, and pharmacies will not be able to plan inventory levels if the reimbursement can change at any time. Again, Ohio requests that CMS mandate that manufacturers use a rolling twelve-month average discount in reporting AMP. We do agree that CMS should not use the new formula for calculation of AMP until it is apparent that manufacturers are correctly reporting AMP, and that the volatility from month to month has been resolved.

Ohio Medicaid also asks CMS to clarify whether states will be responsible for using the AMP published on the CMS web site to calculate the FUL, or whether CMS will continue to send FUL updates as it has done in the past. We request that CMS continue to calculate the FUL and send periodic updates to the states.

We agree with CMS's proposal to set the FUL based on the lowest AMP that is not less than thirty percent of the next highest AMP, except in the case of the first generic product available. This is a reasonable way to ensure that an outlier is not used as the basis for the FUL, and that pharmacies will be able to purchase the product at a price below the FUL.

Recommendations:

* CMS should mandate manufacturers to use a rolling twelve-month estimate of price concessions while reporting the monthly AMP.
* CMS should continue to publish FUL updates.
* CMS should proceed with its proposal to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP.

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

We are concerned about the requirements for physicians to bill multiple-source drugs using NDC in addition to HCPCS code. Ohio Medicaid has five major concerns related to this provision.

First, the requirement that physicians bill using both HCPCS and NDC creates a billing system for Medicaid that is different from other payers, including Medicare, which may result in physicians choosing not to serve Medicaid patients. For most physician offices, Medicaid clients are the exception rather than the rule. We believe that many physicians and other providers affected by this provision will find that recording the NDC for Medicaid patients is administratively burdensome, and not worth the effort. Medicaid reimbursement for many physician services is already below cost, and this will add an additional incentive for providers to limit or even eliminate Medicaid patients from their practice. This will result in a reduction in access to care for our recipients.

It is important to note that the clinical professionals who administer care do not generally look at a patient's insurance plan when treating the patient. Clinicians are more concerned with care than with payment, and let their billing staff worry about reimbursement. However, it will be the clinicians that incur the burden of recording NDCs when drugs are administered in the office. This may result in Medicaid patients being treated differently than privately-insured patients or those covered by Medicare. In addition, Medicaid is a secondary insurance for many patients. As noted in the Regulatory Impact Analysis of this NPRM, CMS believes "most of the Medicaid beneficiaries who receive physician-administered drugs are also in Medicare." While Ohio Medicaid does not agree with this statement about the scope of physician-administered drugs, it illustrates that even if clinicians were to look at the patient's insurer when administering a drug during an office visit, it is Medicare rather than Medicaid that would be noted. Medicare does not require reporting of NDC on claims, so this obligation would be overlooked.

Ohio Medicaid is also concerned that clinicians may not know where to obtain the NDC from a package label, and how to correctly record an eleven-digit code. For billing purposes, an eleven-digit code is required. Many drug packages list a ten-digit NDC, and there are conventions to determine where a zero must be added. It is unlikely that the administering clinician will know how to turn the ten-digit number into an eleven-digit NDC.

Second, we are concerned that the requirement for an NDC to be included on a claim will apply to Medicare Part B crossover claims, and that at this time Medicare does not require NDC to be included on claims for a non-miscellaneous HCPCS code. Without this information, states will

be forced to deny claims that Medicare has already paid. We have communicated with the Medicare Part B carrier that serves our region, and they have indicated that NDC numbers may be included in the electronic documentation record, which is the 2400-NTE, 02 field of the electronic claim. This is a notes field that is difficult to use for claims adjudication because it is a text field that may be used for many purposes. The presence of an eleven-digit number in this field may or may not signify an NDC. Unless and until Medicare requires NDC numbers to be reported in an easily identifiable field on the claim, Medicaid programs will be unable to use an NDC reported on the claim.

A third concern is that CMS staff have indicated that physicians will need to bill for products that are included in the rebate program, or the state will be required to deny the claim. While pharmacy claims are generally billed through a point-of-sale system in real time, physicians often do not bill until several weeks after the service was rendered. Physicians would not know ahead of time which products are part of the rebate program, and which are not. This creates a potential for medically appropriate claims to be denied.

Fourth, HCPCS codes are billed by units that may be different from the unit identified by the rebate program for a particular NDC. CMS has provided a list of the twenty most frequently-billed multiple source drugs[2]. Of the drugs included on this list, the difference between billing and rebate units is an issue for at least two drugs. First is HCPCS J2550, promethazine hydrochloride injection. The billable unit for this HCPCS code is each 50 milligrams. The rebate unit for the NDC is per milliliter, with the product packaged 25 mg/ml. A second example from this list is J7644, ipratropium bromide inhalation solution, unit dose. The billable unit for this HCPCS code is each one milligram. The rebate unit for corresponding NDCs is per milliliter, with the product packaged 0.2mg/ml in 2.5ml units (0.5mg per dose). Unless these drugs are always billed in the correct multiples of units, an unlikely scenario from a clinical standpoint, states will have to bill manufacturers for partial units, and manufacturers will have to respond. These are just two examples from the "top 20" list that has been published by CMS. Another example is J1815, insulin, per 5 units. The rebate unit for insulin under most NDC numbers would be each milliliter. There are 100 units per milliliter of insulin.

Fifth, Ohio's Medicaid Management Information System (MMIS) is outdated, having become operational in 1986, and it will be virtually impossible to implement the inclusion of the NDC in the current claims payment system. We are in process of contracting for a new Medicaid Information Technology System (MITS) and plan to include this functionality in the new system. However, this system will not be operational until at least 2009. We therefore request that CMS reconsider its position that it will not accept hardship waiver requests from any state. Ohio plans to submit a hardship waiver request.

Recommendations:

* CMS should examine whether this requirement will result in reduced access to care for Medicaid recipients due to a non-standard billing procedure for these patients versus patients insured under other programs, including Medicare.

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[2] Posted at http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Top20PhysicianAdministered.pdf

- CMS should mandate that Medicare Part B carriers require NDCs on claims that will be crossed to Medicaid, and that the NDC must be included on the crossover claim from the carrier. The NDC must be in an easily identifiable field, not in a "notes" field that may also be used for other purposes.
- CMS should reconsider the implementation of the provision that states require NDC in addition to HCPCS on provider-administered claims, and that states deny claims for NDCs of products not included in the rebate program.
- CMS should reconsider its position that all drugs billed by HCPCS codes must be a product from a manufacturer participating in the rebate program.
- CMS should resolve discrepancies between rebate units and HCPCS billing units before implementing this provision.
- CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance to the change.

Section III: Collection of Information Requirements *Note: the comments in this section have also been submitted to the Office of Strategic Operations and Regulatory Affairs.*

FFP: Conditions Relating to Physician-Administered Drugs. (447.520)

Ohio Medicaid disagrees with the estimates that CMS has proposed for the time for physician office staff, hospital outpatient departments, and other entities to bill using both NDC and HCPCS. The estimate of 15 seconds, or nine cents per claim, significantly understates the time and funds that will be required for these providers to learn the requirements, train staff, and implement the procedures. In addition to the individual administering the drug, the entire billing staff will need to be trained to include NDC on the claim. While the ongoing effort may be small, the initial training will be intensive for both providers and for Medicaid programs.

We are also concerned with CMS's position that no state will need to apply for a hardship waiver for this provision. As previously stated, Ohio's Medicaid Management Information System (MMIS) became operational in 1986, and it will be virtually impossible to implement the inclusion of the NDC in the existing claims payment system. We are in process of contracting for a new Medicaid Information Technology System (MITS) and plan to include this functionality in the new system. However, this system will not be operational until at least 2009. Ohio Medicaid asks that CMS reconsider its position that it will not accept hardship waiver requests from any state. We also believe that the estimate for the time that it would take a state agency to apply for a hardship waiver is not accurate. Five hours is not enough time for a state to gather the information, synthesize it into the format required by CMS, and gain approval of the request from all stakeholders that would need to be involved.

Recommendations:

- CMS should reconsider the financial impact on providers that bill for drugs administered in the provider setting.

* CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance to the change.

Section V: Regulatory Impact Analysis

A. Overall Impact

The impact statement indicates that the savings estimates do not include federal or state administrative costs, because CMS believes that the costs would be small. Ohio Medicaid strongly disagrees with this statement. Administrative costs include state staff training for new processes, state staff time to perform new tasks, the time and resources needed for training stakeholders, and significant technology updates. Administrative costs related to implementing the FUL changes include planning staff time to analyze and implement the FUL for a much larger number of drugs than have been included in the past, as well as the anticipated increased frequency of FUL updates. Administrative costs related to requiring NDCs on claims for physician-administered drugs will likely outweigh the increased revenue from rebates related to these claims. As previously mentioned, Ohio's MMIS is twenty years old, and in the process of being replaced. Enhancing the system to accept NDCs on claims for physician-administered drugs will be a huge undertaking that will be obsolete in only two years when the new MITS application is installed. In addition to the technology updates, state staff, providers, and billing entities will need to be trained on the new procedures. Due to the high cost of implementing these provisions, CMS should accept and approve hardship waiver requests from states.

Ohio Medicaid also disagrees with CMS's estimate of the impact of compliance on physician practices, hospitals, and non-profit providers. As previously mentioned, each employee in these settings will need to be trained on new billing procedures for physician-administered drugs, and will need to adjust their administrative processes accordingly. While an estimate of less than nine cents per claim may be accurate at some time in the future, the initial costs of implementing this provision will be significantly higher and should be included in the total impact on billing providers.

Recommendations:

* CMS should include state and federal administrative costs in the impact analysis.
* CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance.
* CMS should include the cost of implementing NDC billing on providers that bill for drugs administered in the provider setting.

B. Anticipated Effects

2. Effects on State Medicaid Programs

CMS has underestimated the costs related to implementing the provisions included in this NPRM. As previously noted, states will need to allocate resources to implement FUL pricing for a much larger number of drugs, and likely at more frequent intervals. States will also need to allocate resources to train state staff and providers about the requirement for NDCs to be included on claims for physician-administered drugs. Finally, states will be required to expend resources to update the technology required to process claims that include NDCs. Ohio Medicaid believes that these costs will far outweigh any savings due to increased rebate revenue or decreased reimbursement to pharmacies for FUL drugs. In addition, many states have indicated, and CMS has encouraged, a need to increase dispensing fees for pharmacies. These costs may also negate any proposed savings due to decreased reimbursement.

Recommendation:

* CMS should reduce savings estimates to account for increased administrative burden on state Medicaid agencies.

Conclusions

Ohio Medicaid looks forward to working with CMS on the implementation of the Deficit Reduction Act changes to the Medicaid pharmacy program. Preserving access to prescription drugs for Medicaid consumers is a priority. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,

Cristal A. Thomas
State Medicaid Director

1176-2

Ted Strickland
Governor

Helen E. Jones-Kelley
Director

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February 15, 2007

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Comments on the Collection of Information Requirements
For the Proposed Rule Concerning the Medicaid Program: Prescription Drugs
CMS-2238-P

Dear Ms. Musotto and Ms. Astrich:

Thank you for the opportunity to comment on collection of information requirements reported in the proposed rules regarding the Medicaid prescription drug program changes outlined in sections 6001 (a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA). Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid and the Medicare Premium Assistance Program. These programs cover 1.7 million Ohioans each month.

Preserving access to prescription drugs for Medicaid recipients should be a priority for the Centers for Medicare and Medicaid Services (CMS). The Ohio Medicaid program is concerned that the information collection requirements outlined in this Notice of Proposed Rulemaking (NPRM) are understated.

Ohio Medicaid is particularly concerned that the requirement that physicians bill using National Drug Code (NDC) in addition to Healthcare Common Procedure Coding System (HCPCS) code for physician-administered drugs will create a new billing procedure that is used only for Medicaid, creating an administrative burden that many physicians may not be able to carry. This causes Medicaid patients to be treated differently than other patients in the practice, and physicians may choose to not accept Medicaid patients. We believe that this will create a barrier to access.

Section III: Collection of Information Requirements

FFP: Conditions Relating to Physician-Administered Drugs. (447.520)

Ohio Medicaid disagrees with the estimates that CMS has proposed for the time for physician office staff, hospital outpatient departments, and other entities to bill using both NDC and HCPCS. The estimate of 15 seconds, or nine cents per claim, significantly discounts the time and funds that will be required for these providers to learn the requirements, train staff, and implement the procedures. In addition to the individual administering the drug, the entire billing staff will need to be trained to include NDC on the claim. While the ongoing effort may be small, the initial training will be intensive for both providers and for Medicaid programs.

We are also concerned with CMS's position that no state will need to apply for a hardship waiver for this provision. Ohio's Medicaid Management Information System (MMIS) became operational in 1986, and it will be virtually impossible to implement the inclusion of the NDC in the existing claims payment system. We are in process of contracting for a new Medicaid Information Technology System (MITS) and plan to include this functionality in the new system. However, this system will not be operational until at least 2009. Ohio Medicaid asks that CMS reconsider its position that it will not accept hardship waiver requests from any state. We also believe that the estimate for the time that it would take a state agency to apply for a hardship waiver is not accurate. Five hours is not enough time for a state to gather the information, synthesize it into the format required by CMS, and gain approval of the request from all stakeholders that would need to be involved.

Recommendations:

* CMS should reconsider the financial impact on providers that bill for drugs administered in the provider setting.
* CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance to the change.

Ohio Medicaid looks forward to working with CMS on the implementation of the Deficit Reduction Act changes to the Medicaid pharmacy program. Preserving access to prescription drugs for Medicaid consumers is a priority. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,

Cristal A. Thomas
State Medicaid Director

Submitter : Mr. Harry Rieck **Date:** 02/20/2007

Organization : Merck & Co., Inc.

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See REVISED attachments from Merck & Co., Inc.

CMS-2238-P-1177-Attach-1.PDF

CMS-2238-P-1177-Attach-2.DOC

1177-1

Merck & Co., Inc.
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February 20, 2007

VIA EXPRESS MAIL AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
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7500 Security Boulevard
Baltimore, MD 21244–8015.

Re: **Comments on Proposed Rule Related to the Deficit Reduction Act and the Medicaid Drug Rebate Program, MS-2238-P**

Dear Acting Administrator Norwalk:

Merck & Co, Inc. (Merck) is pleased to submit the following comments regarding the Proposed Rule to implement provisions of the Deficit Reduction Act of 2005 (DRA) that was published by the Centers for Medicare and Medicaid Services (CMS) in the *Federal Register* on December 22, 2006 (Proposed Rule).[1]

Merck has long been involved in the Medicaid rebate program, not only through its participation, but also by its recommendation of policies to further the successful implementation of the program. Prior to the enactment of the rebate program, Merck had implemented its own voluntary "Equal Access to Medicines Program," which represented the first initiative by a major pharmaceutical manufacturer to provide voluntary rebates to state Medicaid programs. Subsequently, Merck played a constructive role in both providing technical comments on the statutory language adopted in the Omnibus Budget Reconciliation Act of 1990 that established the Medicaid rebate program and on regulatory guidance adopted by the then-Health Care Financing Administration. More recently, in April and August 2006 respectively, Merck provided input to both the United States Department of Health and Human Services Office of Inspector General (OIG) and

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[1] Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

to CMS concerning implementation of the DRA. In September 2006, Merck provided data in response to CMS's request for "Sample AMP" calculations.

Merck appreciates the opportunity to submit the following comments on the Proposed Rule regarding the calculation and reporting of Average Manufacturer Price (AMP) and Best Price. Merck joins in the comments submitted today by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Biotechnology Industry Organization (BIO). Merck submits these comments to supplement the PhRMA and BIO comment letters on matters that Merck believes are of particular importance and on which Merck believes modifications from the Proposed Rule are required to achieve greater efficiency, to increase the likelihood of consistency in price reporting, and to reduce the complexity of price calculations. Merck hopes that these comments are helpful to CMS as it formulates its Final Rule and remains willing to assist CMS in any manner that CMS believes would be beneficial to this process.

A. Definitions Section (447.502)

1. Bona Fide Service Fees

The Proposed Rule would exclude "bona fide service fees" from AMP and Best Price, and would define a bona fide service fee as: "a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not an entity takes title to the drug."[2] As the Proposed Rule notes, this is the same definition of bona fide service fee that CMS recently adopted in the context of Average Sales Price (ASP) calculations.

In the ASP context, CMS has announced several important principles relating to the fair market value component of the bona fide service fee definition that Merck believes should apply to AMP and Best Price calculations as well.[3] To address concerns expressed by commenters in the ASP context that the fair market value criterion might

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[2] 71 Fed. Reg. 77174 at 77176, 77180.

[3] These interpretations were announced in the Medicare final physician fee schedule rule for 2007, published in the Federal Register on December 1, 2006.

not encompass fees for services "that can only be performed by the entity to which the fee is paid," CMS clarified that bona fide service fees mean expenses that a manufacturer "generally would have . . . paid for . . . at the same rate had these services been performed by other or similarly situated entities."[4] CMS further clarified that it was not necessary for manufacturers to calculate a fair market value for each individual service purchased from an entity; instead, "it may be appropriate to calculate fair market value for a set of itemized services, rather than fair market value for each individual itemized service, when the nature of the itemized services warrants such treatment."[5] In addition, CMS made clear that the appropriate methods for determining whether a fee represents fair market value "may depend on the specifics of the contracting terms, such as the agreed-upon mechanism for establishing the payment (for example, percentage of goods purchased)." CMS also emphasized that, because "manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value," CMS was "not mandating the specific method manufacturers must use to determine whether a fee represents fair market value."[6] Because a standard methodology for determining fair market value will simplify price reporting calculations, Merck believes that CMS should explicitly confirm that these particular principles also apply to determining whether a fee constitutes fair market value in the Medicaid context.

In addition to the fair market value component, the bona fide service fee definition as proposed also requires that such fees must not be "passed in whole or in part to a client or customer of an entity [that receives the fee]." As CMS is aware, manufacturers such as Merck generally do not know whether certain of their customers, such as PBMs, pass through or retain fees that are paid to them. Accordingly, to address this uncertainty, Merck believes that CMS should establish in the Final Rule that, unless a manufacturer and its customer agree by contract that part or all of a particular fee that would otherwise qualify as a bona fide service fee should be passed on to another party, the manufacturer may presume that the fee is not passed through to a third party and therefore can treat the fee as a bona fide service fee. This approach would be easy to apply and would offer certainty to manufacturers, thus increasing the likelihood of accurate and consistent AMP calculations and Best Price determinations.

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4 Id.

5 Id.

6 Id.

The rule that we have proposed for addressing this issue also would be consistent with the suggestion previously made by the Health Industry Group Purchasing Association (the trade association for GPOs) concerning GPO fees, for which, as with fees to PBMs, the ultimate recipient is unknown to the manufacturer. In its letter to CMS, HIGPA recommended that fees to GPOs should not be treated as price concessions "unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization."[7] In our view, this would be a sensible, easily-applied standard for distinguishing fees, both to GPOs and to other customers, that are intended as price concessions on the manufacturer's products from those that are not.

With respect to GPO fees in particular, CMS may also want to clarify that such fees do not affect AMP calculations when the GPO negotiates purchase prices for member hospitals for drugs used in the inpatient setting, since the underlying sales to hospitals would be excluded from AMP in this circumstance.

2. Bundled Sales

CMS proposes the following new definition of "bundled sale":

> Bundled sale means an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug[8] or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or, where the resulting discounts or other price concessions are greater than those which would have

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[7] January 2, 2007 Health Industry Group Purchasing Association letter to CMS, at 2.

[8] Merck's understanding is that the use of the term "drug" in the Proposed Rule refers to the term "covered outpatient drug" as defined in the Medicaid Rebate Act. As noted below, Merck believes that this point should be clarified in the Final Rule.

> been available had the bundled drugs been purchased separately or outside the bundled arrangement.[9]

The new definition would replace and expand the definition in the existing Medicaid Rebate Agreement, which provides:

> Bundled Sale refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

The new definition that CMS has proposed significantly changes and expands the existing definition, for example:

- Under the proposed definition, contracts involving the "purchase of the same drug" apparently can result in a "bundled sale," whereas under the current contractual definition a "bundled sale" requires "the packaging of drugs of different types."

- Under the proposed definition, "drugs of different types" refers to drugs that have different nine-digit National Drug Codes (NDC-9), whereas previously the definition of "bundled sale" did not refer to "drugs of different types" at the NDC-9 level.

- The proposed definition expands the scope of "bundled sales" to include contracts under which the only condition for a discount or other price concession on a drug is the inclusion of the drug on a formulary, the achievement of market share, or some other unspecified "performance requirement." Under the current definition, a bundled sale exists only if a price concession on a drug is contingent on a "purchase requirement" for a drug of a different type. The proposed rule's apparent focus on "performance requirements," as opposed to "purchase requirements,"

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[9] CMS, "Medicaid Program; Prescription Drugs; Proposed Rule," 71 Fed. Reg. 77174, 77195 (Dec. 22, 2006) (to be codified at 42 C.F.R. § 447.502); see also id. at 77176.

could mean that a bundled sale would exist even if a particular arrangement does not require a customer to purchase any drugs, much less more than one drug type.

- The phrase "some other performance requirement" as used in the proposed definition is undefined and open-ended, and could raise questions about whether virtually any contract should be treated as a "bundled sale."

The proposed definition of "bundled sale" is overbroad, and the method by which discounts would be allocated appropriately among drugs within the new definition is unclear. The broad scope of the new proposed definition could create both unnecessary disruption to the marketplace and confusion and complexity from a price reporting perspective. The purpose of requiring manufacturers to reallocate discounts among drugs constituting a "bundled sale" is to ensure that the AMP and Best Price reported for each drug within the bundle accurately reflects the value of the discounts offered on each product. The Proposed Rule never explains how (or if) its proposed changes would improve the accuracy of AMP or Best Price calculations in any respect. We are not aware of any improvement in accuracy of either AMP or Best Price calculations that would result from the proposed expansion of the definition of "bundled sale" in the Proposed Rule. CMS should not require manufacturers to reallocate the discounts that customers actually paid unless there is a compelling reason why the reallocation would improve the accuracy of AMP and Best Price.

The consequence of CMS's proposed expansion of the definition of "bundled sale" is that manufacturers would be required to reallocate discounts across products (or even across different dosage forms or strengths of a drug or across sales of the same drug during different months or quarters), for a wider variety of arrangements. Thus, AMP and Best Price calculations would become even more complex, and the risk of error and the burdens imposed on manufacturers would substantially increase. In turn, this complexity could result in inconsistencies among the methodologies that manufacturers use to apportion bundled discounts in their AMP and Best Price calculations.

Now that AMP is potentially a reimbursement metric that will be calculated and reported on a monthly basis (and will have to be certified as accurate), the heightened risks of error and inconsistency among manufacturers are of even greater concern. CMS recognized these risks when addressing "bundled sales" in the context of ASP calculations -- which, unlike AMP, is reported quarterly. There, CMS concluded that: (a)

it did not have sufficient information concerning the types of arrangements that manufacturers had with various customers and could not predict how those arrangements might evolve over time; (b) it was premature to issue specific guidance on bundled sales; and (c) in the absence of specific guidance, manufacturers could make reasonable assumptions regarding how discounts under bundled sales are allocated, so long as the methodology chosen resulted in an accurate ASP calculation and did not create inappropriate financial incentives.[10]

Merck believes that CMS should take a similar approach to bundled sales in the Medicaid program. With AMP as a reimbursement metric, the objective in the Medicaid program should be the same as the objective in the Medicare Part B program -- to ensure accurate calculations and not to create inappropriate financial incentives. Merck does not believe that any facts have changed since the promulgation of the Physician Fee Schedule Rule that warrant a different treatment of bundled sales for AMP and Best Price purposes than for ASP purposes. Indeed, the fact that AMP will be reported monthly and certified by manufacturers amplify the need for simplicity in the calculation process. Moreover, Merck believes that CMS should continue to take caution to avoid changes in a manufacturer's price calculations that increase their complexity and that are not required

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[10] Specifically, CMS noted as follows: "Since we do not yet fully understand the variety of bundling arrangements that exist in the marketplace and how they are likely to evolve over time, we believe it is important to be cautious in establishing a specific methodology that all manufacturers must follow for ASP purposes. Consequently, we are not establishing a specific methodology that manufacturers must use for the treatment of bundled price concessions for the purposes of the ASP calculation at this time. In the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculations of ASP, consistent with the general requirements and the intent of the Act, federal regulations, and its customary business practices. Our intent in not being prescriptive in this area at this time is to allow manufacturers the flexibility to adopt a methodology with regard to the treatment of bundled price concessions in the ASP calculations that, based on their particular circumstances, will best ensure the accuracy of the ASP calculation and not create inappropriate financial incentives."

See CMS, "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007; Final Rule," 71 Fed. Reg. 69624, 69675 (Dec. 1, 2006) (emphasis added).

by statute, unless such changes are necessary to improve the accuracy and consistency of AMP and/or Best Price calculations. In this regard, we note that neither the Medicaid Rebate Act nor the DRA directs CMS to make changes via rulemaking to the contractual definition of "bundled sales."

Merck's Recommendations Concerning "Bundled Sale" Arrangements

Based on the foregoing, Merck respectfully requests that CMS take the following actions in the Final Rule:

- CMS should retain the definition of "bundled sale" that is set forth in the Medicaid Rebate Agreement.

- In the alternative, if CMS decides that a definition of "bundled sale" that goes beyond the Medicaid Rebate Agreement's current definition of a "bundled sale" is necessary, CMS should: (1) explain specifically why the expansions in the definition of a "bundled sale" are needed to improve the accuracy and consistency of AMP and/or Best Price calculations, and exactly how the new, broader definition would produce more accurate figures and would warrant the additional burdens imposed on manufacturers; (2) delete the phrase "other performance requirements" from the proposed definition, or provide additional specificity regarding the meaning of that phrase; (3) provide specific examples of each type of arrangement that would be encompassed by the new "bundled sale" definition; and (4) avoid unnecessary marketplace disruption by allowing manufacturers to apply the new definition of "bundled sale" only to agreements entered into subsequent to the effective date of the Final Rule.

- CMS should also confirm that "bundled sale" arrangements are limited to arrangements that involve covered outpatient drugs. That is, the Final Rule should reiterate the guidance now contained in the Medicaid Drug Rebate Operational Training Guide (p. F11d) on arrangements that include products other than covered outpatient drugs: "Valid bundled sales only include drug products that meet the definition of a covered outpatient drug as defined in the drug rebate agreement and statute. If a non-drug product . . . is included in the bundled sale, it is not eligible for inclusion in the Medicaid Drug Rebate Program."

- With respect to the allocation methodology, CMS should adopt the same approach that it took in the ASP context, where CMS decided that it was premature to establish a specific allocation methodology. Instead, CMS concluded that manufacturers "may make reasonable assumptions" in their ASP calculations, "consistent with the general requirements and the intent of the Act, federal regulations, and its customary business practices." Merck believes that CMS should adopt a similar approach with respect to AMP and Best Price. In the alternative, if CMS does propose an allocation methodology, Merck requests that CMS develop methodologies specific to each type of transaction that CMS identifies as a "bundled sale" and that CMS give manufacturers and other interested parties an opportunity to comment on those methodologies.

B. Retail Pharmacy Class of Trade (447.504)

1. Closed Mail Order Pharmacies

AMP is defined by statute as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade" (excluding prompt pay discounts starting in 2007).[11] The Proposed Rule would define the "retail pharmacy class of trade" as "any independent pharmacy, chain pharmacy, mail order pharmacy, [PBM], or other outlet that purchases, or arranges for the purchase of drugs from a manufacturer . . . and subsequently sells or provides the drugs to the general public."[12] Similarly, the Proposed Rule describes the retail pharmacy class of trade as "that sector of the drug marketplace . . . which dispenses drugs to the general public . . . ."[13]

Merck agrees with the approach of identifying entities within the retail pharmacy class of trade as those that dispense drugs to the "general public" and believes that this approach is consistent with Congressional intent. We note, however, that mail order pharmacies will not always fall into this class, because some mail order pharmacies are "closed" pharmacies that only serve individuals covered by certain payors or health

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[11] 42 U.S.C. 1396r-8(k)(1)(A).

[12] Fed. Reg. at 77196 (proposed) 42 C.F.R. § 447.504(e)).

[13] Id. at 77178.

plans. Consequently, CMS should clarify in the Final Rule that the retail pharmacy class of trade includes those mail order pharmacies that "sell[ ] or provide[ ] drugs to the general public," but not closed mail order pharmacies. Prices to closed mail order pharmacies should thus be excluded from AMP calculations.

2. Third Party Rebates

The Proposed Rule provides that "to the extent manufacturers are offering . . . price concessions to [a] PBM that are not bona fide service fees, we propose that these lower prices be included in AMP."[14] Consistent with this treatment of PBM rebates, the Proposed Rule would also include in AMP rebates paid to third-party payors such as Medicare Part D plans, qualified retiree prescription drug plans, and State Pharmaceutical Assistance Programs.[15]

Merck supports the general approach CMS has proposed of including rebates to PBMs and third-party payors in AMP calculations. However, this approach could reduce AMP, which will shortly become a reimbursement metric. Federal upper limits for multiple source drugs will be 250% of AMP starting this year, and some States might decide to use AMP in their Medicaid reimbursement formulas for other drugs once AMPs become public. As noted in our August 2, 2006 letter to CMS, Merck believes it is critically important for pharmacy reimbursement to correlate to pharmacy acquisition cost. Because AMP as defined in the Proposed Rule would include rebates that are not necessarily offered to retail pharmacies, it will be important for CMS to caution the States about the need to evaluate the relationship between AMP and pharmacy acquisition costs carefully before adopting any type of AMP-based reimbursement formula.

To help ensure that AMP-based Medicaid reimbursement formulas have a percentage markup over AMP that preserves Medicaid beneficiaries' access to medicines, CMS should re-emphasize in the Final Rule that it "encourage[s] States to analyze the

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[14] Id. at 77179.

[15] Id. at 77180. It is unclear whether the Proposed Rule would require manufacturers to include supplemental Medicaid rebates in AMP. CMS should clarify this point in the Final Rule.

relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs."[16]

3. *Price Concessions to PBMs*

As noted above, the Proposed Rule provides that "to the extent manufacturers are offering . . . price concessions to [a] PBM that are not bona fide service fees, we propose that these lower prices be included in AMP."[17] The proposed regulatory text would similarly provide that "[d]iscounts, rebates or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade" are included in AMP.[18] However, the Proposed Rule also includes language that could create confusion about the treatment of price concessions to PBMs in AMP calculations; in particular, the Proposed Rule notes that AMP includes price concessions to PBMs "that affect the net price recognized by the manufacturer" for drugs provided to the retail pharmacy class of trade.[19] To promote greater uniformity in AMP calculations and preclude the possibility of confusion regarding the treatment of PBM price concessions, CMS should state clearly in the Final Rule that any price concessions to PBMs should be included in AMP calculations.[20]

4. *Non-Purchasing HMOs*

Like the Medicaid Rebate Agreement, the Proposed Rule would expressly exclude sales to health maintenance organizations (HMOs) from AMP calculations.[21] However, the Proposed Rule does not distinguish between HMOs that actually purchase drugs and distribute them to members through the HMO's own closed pharmacies, and

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[16] Id. at 77176.

[17] Id. at 77179.

[18] Id. at 77196 (proposed 42 C.F.R. § 447.504(g)(3)).

[19] Id. at 77179.

[20] We agree with CMS that bona fide service fees paid to PBMs (or others) should be excluded from AMP and Best Price. CMS should make clear that these fees are not properly considered price concessions, rather than use language suggesting inaccurately that bona fide service fees are price concessions but nonetheless are excluded from AMP and Best Price.

[21] 71 Fed. Reg. at 77179.

those HMOs that do not purchase drugs but instead reimburse retail pharmacies for drugs dispensed to HMO members. The latter category of HMOs act as third-party payors. Thus, as with other retail pharmacy sales that are reimbursed by third-party payors,[22] sales of drugs that are dispensed by retail pharmacies and reimbursed by those HMOs (and the amount of any concessions associated with those sales) should be included in AMP. To enhance consistency, CMS should clarify in the Final Rule that sales of (and price concessions associated with) drugs dispensed at retail pharmacies that are reimbursed by non-purchasing HMOs also are included in AMP.

C. Coupon Programs (447.504(g)(11) and 447.505(c)(12))

Among the types of programs that Merck utilizes to assist patients are coupon programs and voucher programs. Merck uses the terms "coupons" and "vouchers" to describe two distinct types of programs which may fall under the rubric of "manufacturer coupons" as used by CMS in the Proposed Rule. Although "coupon" and "voucher" programs may appear similar, they are different in purpose and function. Merck believes that an understanding of this distinction is essential for CMS to regulate their impact on AMP and Best Price calculations.

As Merck uses the term, "coupons" are certificates provided to patients that entitle them to discounts on their prescription drug purchases, either at the point-of-sale (through a reduction in the amount the consumer is required to pay the dispensing pharmacy) or subsequent to the purchase (by sending the coupon to the manufacturer or a clearinghouse with proof-of-purchase in order to receive a cash reimbursement from the manufacturer). In either case, the amount of the discount provides a dollar-for-dollar reduction in the amount paid out-of-pocket by the patient. Whether the coupons are redeemed by the dispensing pharmacy or directly by the patient, the entire discount represented by the coupon goes to the patient. In point-of-sale coupons, the dispensing pharmacy receives reimbursement for the discount passed on to the patient plus a small handling fee for administering the transaction. The impact of the handling fee on Merck's AMP and Best Price should be evaluated under the rules that CMS establishes for determining bona fide service fees. However, with respect to the drugs dispensed subject to the discount conferred by the coupon, the pharmacy receives no part of the

[22] The Proposed Rule provides that drugs reimbursed by Medicaid, Medicare Part D plans, and State Pharmaceutical Assistance Programs are included in AMP when the drugs are dispensed by retail pharmacies. Id. at 77180.

discount and is prohibited from charging more than its usual and customary price less the discount. If the patient is a member of a managed care plan, the discount on the product is limited to the amount of the patient's copayment or coinsurance.

"Vouchers," by contrast, are certificates provided to patients that entitle the patient to receive a specified number of units of a drug free-of-charge. In this respect, vouchers function similarly to product samples. The manufacturer in a voucher program contracts with a vendor, which in turn contracts with the pharmacy. The pharmacy dispenses the drug free-of-charge to the patient and is then reimbursed by the vendor according to a formula negotiated between the vendor and the pharmacy, plus a dispensing fee. The vendor bills the manufacturer for this reimbursement expense (which is designed to be revenue neutral to the retail pharmacy), plus a service fee. Again, the service fee to the vendor should be evaluated under the definition of "bona fide service fee" adopted in the final rule. Since the manufacturer indirectly reimburses the dispensing pharmacy through the negotiated formula, the dispensing pharmacy does not submit a reimbursement claim for those units to any public or private insurance program of which the consumer may be a beneficiary. Although vouchers are submitted for redemption through a pharmacy, the discount has no effect on the acquisition price paid by the pharmacy for the prescription drug dispensed upon the presentation of a voucher.[23]

CMS proposes to require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP," but "to include coupons redeemed by any entity other than the consumer in the calculation of AMP."[24] Similarly, CMS proposes to require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price," but "to include coupons redeemed by any entity other than the consumer in the calculation of best price."[25] In the context of Best Price calculations, CMS premises its proposed disparate treatment of manufacturer coupons on its belief that "the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose

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[23] The mechanics of how coupons and vouchers are processed and redeemed are outlined in more detail in Exhibit A.

[24] 71 Fed. Reg. 77174, 77181 (Dec. 22, 2006); see also id. at 77197 (to be codified at 42 C.F.R. §§ 447.504(g)(11) & (h)(9)).

[25] Id. at 77183; see also id. at 77197 (to be codified at 42 C.F.R. §§ 447.505(c)(12) & (d)(8)).

sales are included in best price," but that "the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy)."[26] Although CMS does not state so explicitly, this rationale presumably underlies CMS's proposed treatment of manufacturer coupons in AMP calculations as well.

Although CMS does not propose a definition of "manufacturer coupon," we assume that this term encompasses "coupons" as described above. In addition, we are concerned that "vouchers" may also be included in potential interpretations of "manufacturer coupon," whether or not this was CMS's intent. We respectfully submit that CMS's proposed treatment of coupons (and possibly vouchers) in AMP and Best Price calculations is not appropriate. In our view, coupons redeemed directly by patients to the manufacturer should not be treated any differently from coupons redeemed to the manufacturer through other parties. CMS suggests that coupons redeemed "by entities other than consumers" somehow affect the prices those entities pay for drugs dispensed subject to those coupons. CMS thus appears to believe that, by honoring coupons presented by patients, which the entities then submit to manufacturers for redemption, the redeeming entities receive a price concession. This belief is contrary to Merck's experience, in which coupons (and vouchers) are intended solely for the financial benefit of patients, regardless of the means by which they are redeemed.

When a patient presents a coupon to a pharmacy that dispenses prescription drugs, the pharmacy provides the patient with a discount equal to the coupon's face value. When a patient presents a voucher, the pharmacy provides the drug to the patient for free. Upon "redeeming" the coupon or voucher to the manufacturer, the pharmacy receives a reimbursement that correlates to the coupon or voucher's value. Consequently, the value of the coupon or voucher "passes through" the redeeming entity to the patient and has no effect on the acquisition price paid by the redeeming entity to purchase the units of the drug dispensed subject to the coupon or voucher. The transaction that establishes the price the redeeming entity paid to acquire the drug occurs well before the patient ever presents the coupon or voucher to the redeeming entity. Indeed, the transaction in which the drug is acquired often involves only a wholesaler and a retail pharmacy; the

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[26] Id. at 77183.

manufacturer may not even be a party.[27] Because the redeeming entity in the case of both coupons and vouchers does not retain any portion of the discount conferred to the patient, the coupon or voucher has no effect on the price the entity paid for the prescription drugs it dispenses to the patient. The coupon/voucher, accordingly, is not a cost-saving program offered to an entity other than the patient, and the value of the coupon or voucher should not be included in manufacturers' calculations of either AMP or Best Price.

Moreover, CMS's proposed approach could have unintended adverse consequences on both coupon and voucher programs, which offer substantial financial benefits to patients. This is especially true with regard to voucher programs, if CMS considers vouchers under the umbrella of "manufacturer coupons." Although vouchers function similarly to product samples (like samples, vouchers allow a patient to try a drug without cost for a limited time to enable the patient's physician to determine the safety and efficacy of the drug for the particular patient), they have many advantages over product samples. From the physician's standpoint, vouchers are easier to safeguard, store and distribute to patients; indeed, an increasing number of physician practices will not accept samples and will only accept vouchers. Also unlike samples, vouchers offer advantages because they require a prescription before they can be used and a pharmacist must fill the prescription. For the patient, vouchers allow the dispensing pharmacy an additional opportunity to track prescription drug use and thereby monitor for adverse drug interactions. Thus, they provide another opportunity for the patient to ask questions of a healthcare practitioner. Manufacturers should not be penalized from a pricing standpoint for offering vouchers that are redeemable at the point of sale.

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[27] If coupon or voucher programs were "relevant" to AMP or Best Price, it is not clear how the manufacturer should account for the value of such a program in its price calculations. If the pharmacy buys the drugs from a wholesaler, the manufacturer would not: (a) know the acquisition price for the drug that the pharmacy paid (because it is not a party to the agreement between the distributor and the pharmacy); or (b) have the ability to trace the units dispensed to the patient using a coupon or voucher to a sale from the manufacturer to a wholesaler. Moreover, if the Proposed Rule were to become effective, would the net price for AMP or Best Price purposes require the manufacturer to subtract from the acquisition price: (a) the dispensing fee paid to the redeeming entity, (b) the discount paid to the consumer, (c) the reimbursement amount paid to the redeeming entity; or (d) some combination of these elements?

With regard to coupon programs, CMS's proposed approach could also result in manufacturers requiring patients to redeem coupons directly to them. This would burden patients by requiring them to put forth the full out-of-pocket cost of the prescription and to wait 6-8 weeks for reimbursement after mailing proof-of-purchase forms to the manufacturer. It also potentially could require manufacturers to pay for additional infrastructure to administer such coupon programs. Merck does not believe that such additional steps are necessary or warranted. Coupons serve the valuable purpose of encouraging patients to obtain the medications their physicians have prescribed by reducing the cost of such medications to the patients, and we are concerned that CMS's proposal could reduce or unduly burden patient participation in those programs.

Based on the foregoing, Merck respectfully requests that CMS take the following actions in the Final Rule:

Coupons

- Adopt a definition of "manufacturer coupon" that encompasses cost-saving programs offered to patients but that recognizes the different means by which coupons may be redeemed. Merck proposes that CMS adopt the following definition:

  > "Manufacturer coupon" means "any certificate provided to a consumer that provides by its terms that the consumer is entitled to a discount on his or her purchase of drugs, either: (A) at the point-of-purchase, through a reduction equal to the face value of the coupon up to the amount the consumer is required to pay the entity that dispenses the drugs, or (B) subsequent to the purchase, through receipt of a cash reimbursement from the manufacturer (or a vendor under contract to the manufacturer to administer the coupon program) where the reimbursement amount is equal to the lesser of the amount the consumer paid to the dispensing entity or the face value of the coupon."

- Require manufacturers to exclude from their AMP and Best Price calculations:

- Any manufacturer coupon redeemed by a consumer either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the coupon program; and

- Any manufacturer coupon redeemed by an entity other than a consumer (after being presented to and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program.

➢ Specify that manufacturers should also exclude from their AMP and Best Price calculations: (A) the reimbursement amount paid to the redeeming entity for the manufacturer coupon; and (B) any fees paid to an entity other than a consumer that redeems a manufacturer coupon where the fee satisfies the definition of "bona fide service fee" adopted by CMS in the Final Rule.

Vouchers

CMS does not expressly address in the Proposed Rule how manufacturers should treat in their AMP and Best Price calculations drugs that are ultimately dispensed to patients upon presentation of vouchers. Merck believes that CMS should confirm that manufacturer vouchers are not subject to CMS's guidance regarding "manufacturer coupons." If CMS does decide to treat manufacturer vouchers explicitly in the Final Rule, Merck respectfully requests that CMS take the following actions with regard to vouchers:

➢ Adopt a definition of "manufacturer voucher" that encompasses cost-saving programs offered to patients but that recognizes the different means by which vouchers may be redeemed. Merck proposes that CMS adopt the following definition:

> "Manufacturer voucher" means "any certificate provided to a consumer that provides by its terms that the consumer is entitled to a specified number of units of a drug free-of-charge, without (A) any co-payment from the consumer, or (B) reimbursement to the entity that dispenses the drug from any insurance program of which the consumer may be a beneficiary."

- Require manufacturers to exclude from their AMP and Best Price calculations:

  - Any manufacturer voucher redeemed by a consumer either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the voucher program; and

  - Any manufacturer voucher redeemed by an entity other than a consumer (after being presented to and honored by such entity) either directly to the manufacturer or to a vendor under contract with the manufacturer to administer the voucher program.

- Specify that manufacturers should also exclude from their AMP and Best Price calculations: (A) the reimbursement amount paid for any manufacturer vouchers; and (B) any fees paid to an entity other than a consumer that redeems a manufacturer voucher where the fee satisfies the definition of "bona fide service fee" adopted by CMS in the Final Rule.

The approach that we have suggested is the most practical and fair method for all parties because the relevant price of a covered outpatient drug for AMP and Best Price purposes is the price that the manufacturer charges to the wholesaler or retail pharmacy (if the manufacturer sells directly to the retail pharmacy) for the drug, not the reimbursement amount paid to the entity at which a voucher is redeemed or the financial value of a voucher to the patient.

If CMS does not adopt the approach that we have suggested above, Merck respectfully requests clear guidance from CMS as to how manufacturers should account

for coupons and vouchers in their calculations of AMP and Best Price.[28]

D. Authorized Generic Agreements (447.506)

Section 6003 of the DRA directed innovator manufacturers, effective January 1, 2007, to take sales of authorized generic products into account in the calculation of the innovator manufacturer's AMP and Best Price. With respect to AMP, the DRA required that, "in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [FFDCA],"[29] the innovator manufacturer's AMP "shall be inclusive of the average price paid for such drugs by wholesalers for the drugs distributed to the retail pharmacy class of trade."[30] With respect to Best Price, the DRA provides that the innovator manufacturer's Best Price "shall be inclusive of the lowest price for such authorized [generic] drug available from

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[28] The Medicaid Rebate Act defines Best Price as the lowest price charged "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C)(i). Accordingly, Merck is concerned with the Proposed Rule's discussion of Best Price, which provides: "[w]e propose to consider any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as 'other arrangements'. . . that . . . should be included in the calculation of Best Price." 71 Fed. Reg. at 77182. To avoid any confusion, CMS should confirm explicitly in the Final Rule that Best Price is the lowest price realized by the manufacturer net of all price concessions to a specific Best Price-eligible customer. This clarification would recognize the Medicaid Rebate Act's requirement that Best Price must be determined by reference to customer-specific prices, rather than prices derived by aggregating price concessions to different customers.

[29] DRA section 6003(a)(2)(B)(iii). Section 505(c) of the FFDCA addresses new drug applications (NDAs) that the FDA must approve as a prerequisite for a company to market drugs and certain biologics (such as human growth hormone and insulin).[29] By contrast, FDA approves abbreviated new drug applications (ANDAs) under 505(j) (for certain generic products) and biologics license applications (BLAs) (for certain biologics) under section 351 of the Public Health Service Act (PHSA). Therefore, Section 6003 by its terms, including the reference to Section 505(c) of the FFDCA, applies to authorized versions of products marketed under NDAs, but does not apply to products marketed under ANDAs or BLAs.

[30] Id.

the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, [HMO], nonprofit entity or governmental entity."[31]

The DRA is silent concerning how manufacturers should blend sales of an authorized generic version of their drugs with their own sales of the drug for purposes of the AMP calculation. It also does not expressly address whether the Best Price determination takes into account the transfer price of the authorized drug from the innovator manufacturer to the authorized generic manufacturer, or the lowest price of the authorized drug from the authorized generic manufacturer to its Best Price-eligible customers, or both.

Section 447.506 of the Proposed Rule suggests a definition of the term "authorized generic" and proposes to require manufacturers to include "the direct and indirect sales of [an authorized generic] drug in its AMP" and "the price of [an authorized generic] drug in the computation of best price for the single source or innovator multiple source drug . . . to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States." However, like the DRA, the Proposed Rule neither specifies a procedure for blending sales by the authorized generic manufacturer in the innovator company's AMP nor identifies the prices that must be taken into account in determining Best Price. In the preamble to the Proposed Rule, CMS appears to conclude that the only relevant price for Best Price purposes is the price from the authorized generic manufacturer to its customers:

> we would require that sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs be included by the primary manufacturer in the sales used to determine the best price for the single source or innovator multiple source drug approved under Section 505(c) of the FFDCA during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity or governmental entity within the United States. The primary manufacturer must include in its calculation of best price all sales of the authorized generic drug which have been sold or marketed by a secondary

[31] DRA section 6003(a)(2)(B)(iii).

> manufacturer or by a subsidiary of the brand manufacturer.[32]

Merck agrees that, for Best Price purposes, the relevant price for a drug that is the subject of an authorized generic agreement should be the lower of: (a) the lowest price charged by the innovator manufacturer in a Best Price-eligible sale; or (b) the lowest price charged by the authorized generic manufacturer in a Best Price-eligible sale. We also agree that the transfer price -- that is, the price at which the innovator manufacturer sells the drug to the authorized generic manufacturer -- should not be taken into account in Best Price, even if the transfer price would otherwise be the lowest price at which the drug is sold. Transfer prices may involve complex royalty or profit-sharing arrangements that would be difficult for the innovator manufacturer to incorporate into its Best Price and for CMS to evaluate. In such situations, the amount of the royalty or profit share likely will not be known until long after the reporting period has ended. Therefore, Merck supports the approach that CMS has suggested in the preamble to the Proposed Rule. To avoid any confusion, we request that the wording of the regulation be clarified so that the Final Rule will more closely track this approach, making it clear that the transfer price is not a Best Price-eligible sale for the innovator manufacturer.

With respect to both AMP and Best Price, as Merck explained in its August 2, 2006 letter to CMS, we recommend that CMS adopt a specific methodology for blending authorized generic sales with sales by the innovator manufacturer. We believe that there are two potential blending methodologies available to CMS:

1. CMS could require manufacturers of innovator drugs and manufacturers of authorized generic version(s) of those innovator drugs to calculate AMPs and to determine Best Prices for their own products, using only the sales data specific to those products (as identified by their National Drug Code (NDC) numbers), and to include in their AMP reports the number of units sold during the rebate period. CMS could also require innovator drug manufacturers to identify the NDC(s) associated with authorized generic versions of their innovator drugs marketed under their NDAs. CMS would be responsible for using this information to calculate weighted AMPs and to determine Best Prices for the innovator drugs and then for reporting this information to innovator drug manufacturers.

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[32] 71 Fed. Reg. 77174, 77184 (Dec. 22, 2006).

2. CMS could require manufacturers of innovator drugs to obtain information from manufacturers of authorized generic version(s) of their innovator drugs, either the AMPs or Best Prices themselves or the underlying sales data. Manufacturers of innovator drugs then would use this information, in combination with sales data for their innovator drugs, to calculate AMPs and to determine Best Prices for their innovator drugs. If this approach were taken, CMS should allow the innovator manufacturer to rely on a certification from the authorized generic manufacturer as to the accuracy of the information provided.

Merck recommends that CMS adopt the first option in the Final Rule.[33] Merck's concern with the second option is that the thirty days available to manufacturers to calculate AMP and to determine Best Price would make it difficult for innovator drug manufacturers to obtain information from the manufacturers of authorized generic versions of their innovator drugs, to take any steps they may consider appropriate to verify the accuracy of that information, and then to calculate AMPs and determine Best Prices for their innovator drugs. With a short time period to complete these tasks, innovator drug manufacturers could have reduced confidence in the accuracy of their AMPs and Best Prices.

The first blending option would avoid this concern by making manufacturers responsible only for the accuracy of their own price information, while also enabling CMS to exercise effective oversight with respect to the information being submitted by both the innovator and the authorized generic manufacturer. Additionally, Merck

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[33] If CMS does adopt a manufacturer blending procedure, we urge CMS also to specify that the innovator manufacturer need not begin applying the blending procedure until the quarter following the launch of the authorized generic product. If an authorized generic agreement is effective in the middle of a quarter, our view is that, for ease of administration, CMS should permit innovator manufacturers to defer accounting for authorized generic sales in its AMP or Best Price until the quarter following the launch of the authorized generic drug. Additionally, CMS should take steps to avoid the need for disclosure of potentially business sensitive information, such as transaction-level data, from authorized generic manufacturers to innovator manufacturers.

believes that the first option would avoid risks associated with requiring a private company to obtain pricing and utilization information from a competitor.[34]

Merck's Recommendations Regarding Authorized Generic Arrangements

- With respect to AMP and Best Price, CMS should include a provision in the Final Rule that would expressly require manufacturers of innovator drugs and manufacturers of authorized generic version(s) of those innovator drugs to calculate AMPs and to determine Best Prices for their own products, using only the sales data specific to those products (as identified by their NDC numbers), and to include in their AMP reports the number of units sold during the rebate period. CMS should also require innovator drug manufacturers to identify the NDC(s) associated with authorized generic versions of their innovator drugs marketed under their NDAs. CMS should be responsible for using the information provided to calculate weighted AMPs and to determine Best Prices for the innovator drugs and then for reporting this information to innovator drug manufacturers. For authorized generic agreements that are effective in the middle of a quarter, CMS should not begin to apply this blending procedure until the following quarter.

- CMS should confirm that the Best Price of a drug that is the subject of an authorized generic agreement is the lower of: (a) the lowest price charged for the drug by the innovator manufacturer in a Best Price-eligible sale; and (b) the lowest price charged for the drug by the authorized generic manufacturer in a Best Price-eligible sale. CMS should also confirm in the language of the Final Rule the principle expressed in the preamble to the Proposed Rule: that Best Price does not include the transfer price at which the innovator manufacturer sells the drug to the authorized generic manufacturer.

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[34] See Statement 6, "Provider Participation in Exchanges of Price and Cost Information," of the Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care, which is available at http://www.ftc.gov/reports/hlth3s.htm#6).

E. Rolling Average Methodology (447.510)

CMS proposes to require manufacturers to calculate monthly AMP using the same methodology as for quarterly AMP, except that: (a) the monthly AMP would cover one month instead of one quarter; (b) the monthly AMP would not be subject to revision; and (c) manufacturers would be permitted to estimate end-of-quarter rebates or price concessions in monthly AMP calculations.[35] CMS requests comments on whether it should adopt a 12-month rolling average methodology to apply to lagged price concessions in both the monthly and quarterly AMP calculations. Under the approach adopted by CMS, manufacturers would continue to report revisions to AMP that result from information learned after the quarterly reporting date.

As noted in Merck's August 2, 2006 letter, Merck believes that, because of the role that AMP may play in product reimbursement, an important objective of the Medicaid program going forward should be to minimize unnecessary instability and volatility in AMP calculations. To accomplish this goal, Merck continues to believe that CMS should revise the AMP calculation to eliminate the need to adjust AMPs after they have been reported. In this regard, we applaud CMS's decision to preclude routine restatements of monthly AMP.

However, Merck does not believe that the three-month rolling average methodology proposed by CMS covers a sufficient amount of time to ensure accurate and stable reported AMPs. Instead, Merck would urge CMS to adopt a "twelve-month rolling average methodology" for monthly (and quarterly) AMPs similar to the methodology used to estimate the value of lagged discounts when calculating ASP, another reimbursement metric.[36] Adoption of the twelve-month rolling average methodology, allowing smoothing of all lagged pricing information (including chargebacks), not only would have the benefit of consistency across the Medicaid and Medicare programs, but also would enable companies to use a sufficient period of time in the rolling average

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[35] 71 Fed. Reg. 77174, 77185-86 (Dec. 22, 2006).

[36] See 42 C.F.R. § 414.804(a)(3). In this regard, Merck applauds CMS's proposal that manufacturers exclude product returns from the AMP calculation. This proposal will align AMP reporting with ASP reporting and also will remove a potential source of volatility from the AMP calculation.

calculation to improve the accuracy of the monthly (or quarterly) AMPs that may be used to determine pharmacy reimbursement.

In the event that CMS implements this change to the AMP calculation, Merck also recommends that CMS describe in the Final Rule the (presumably limited) circumstances in which CMS would either expect or permit manufacturers to recalculate AMPs. In particular, CMS should provide guidance to manufacturers regarding whether, in light of the need to maximize stability in reimbursement metrics, restatements remain an appropriate means for correcting subsequently discovered AMP calculation errors.

F. Effective Date

The DRA requires CMS to promulgate rules concerning AMP by no later than July 1, 2007. Many of the changes that would result from promulgation of the Final Rule will require time for manufacturers to implement. For example, the issues raised concerning coupon and voucher programs could affect millions of coupons and vouchers that are currently on the market. Similarly, the changes to the definition of retail pharmacy class of trade, and to AMP and Best Price generally, will require companies to revise their price reporting processes and to re-program and test their information technology systems. Whatever decisions that CMS ultimately makes in the Final Rule concerning these and other issues, manufacturers will need time to implement them. The reprogramming and testing of systems will take considerable time and effort and cannot be started until manufacturers know what the Final Rule requires.

Accordingly, to allow for reprogramming and testing of systems to occur and for manufacturers otherwise to come into compliance with the requirements of the Final Rule, Merck recommends that CMS give manufacturers a period of not less than four quarters from the date that the Final Rule is issued before the changes made in the Final Rule that are not required by the DRA become effective. This window, through at least July 1, 2008, would afford both manufacturers and CMS time to prepare their processing systems for the changes that the Final Rule will require. If such a "ramp up" period is not granted, not only would there be a heightened risk of error and inconsistency in the periods immediately following the issuance of the Final Rule, but also reimbursement to retail pharmacies could be adversely affected because AMPs are not reported accurately. For these reasons, Merck strongly urges CMS to allow manufacturers a period of time of not less than twelve months to make the necessary system modifications

and to put procedures in place to mitigate the risk that AMP (and Best Price) are not calculated and reported accurately.

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Merck appreciates the opportunity to comment on the Proposed Rule. Merck also recognizes and appreciates the considerable effort that CMS put into the development of the Proposed Rule, and we hope that our comments will be useful to CMS as it develops the Final Rule. Merck would be pleased to provide any additional information upon request.

Sincerely,

Harry J. Rieck

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