

**Submitter :** Kent Zellner  
**Organization :** Zellner Pharmacy  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

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

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

**Submitter :** Mr. Marvin Cook Jr.  
**Organization :** Scott-Cook Pharmacy  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

[February 16, 2007]

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

[ Marvin Cook, Jr. RPH]

**Submitter :** Mrs. LINDA BEARDEN

**Date:** 02/16/2007

**Organization :** MURRAYVILLE PHARMACY

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

IF THE GOVERNMENT USES AMP, THEN THE DRUG COMPANIES SHOULD SALE THEIR PRODUCTS TO ALL PHARMACIES AT THE SAME PRICE. AS IT STANDS NOW, WE CANNOT BUY THE MEDICATIONS AT THE SAME DISCOUNTED RATE THAT THE MAIL ORDER PHARMACIES DO.

**Submitter :** Mr. Joseph Maslak  
**Organization :** Associated Wholesale Grocers / Valu Merchandisers  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-752-Attach-1.DOC



**General Merchandise    Health & Beauty    Specialty Foods**

**624 WESTPORT RD**

**KANSAS CITY, MISSOURI**

**64111**

February 16, 2007

**Via Electronic Mail**

Leslie Norwalk, Esq.  
Acting Administrator  
The Centers for Medicare & Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

**RE:    Proposed Rule To Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program; (Docket No. CMS--2238--    P)**

Dear Administrator Norwalk:

Associated Wholesale Grocers appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 22, 2006). We are very concerned about the projected impact of the proposed rule on our supermarket pharmacies.

Associated Wholesale Grocers (AWG) is a retailer owned grocery wholesale cooperative servicing over 1,900 independent grocery stores throughout 21 states. In addition to supplying grocery products, we also distribute health and beauty care, general merchandise and specialty foods through our wholly owned subsidiary, Valu Merchandisers Company. Our retailers own and operate grocery stores throughout a wide diversity of communities, providing needed products and services as well as jobs, tax revenue, and support of local charities. In addition, our retailers operate nearly 300 pharmacies throughout eight states.

AWG is a member of the Food Marketing Institute (FMI), and fully supports the comments filed by FMI and incorporates FMI's comments herein. In addition, we specifically wish to call your attention to the following issues.

As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Although we understand the challenge the dual use of AMP presents to CMS, we believe that several aspects of the proposed rule would unduly reduce AMP, thereby jeopardizing our company's ability to continue to serve Medicaid beneficiaries.

In this regard, we urge CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Supermarket pharmacy profit margins are in the range of approximately 2 to 3 percent of total revenues. Recent studies suggest that the Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.<sup>1</sup> In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our company will find it increasingly difficult to serve Medicaid

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<sup>1</sup> Government Accountability Office "Medicaid Outpatient Prescription Drugs: Estimated 2007 Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs", Letter to Rep. Joe Barton (R-TX) (December 22, 2006).

patients. This situation is exacerbated by dispensing fee amounts in the states in which we operate that are far below the costs we incur to dispense prescription drugs to Medicaid patients.

Accordingly, although we do not believe that this situation can be fully addressed through the regulatory process and we are joining with FMI and others to seek a change in the underlying law, we believe that CMS should take the steps discussed below to mitigate the problem in the interim.

First, CMS should revise the proposed AMP regulation so that it will align more closely with the underlying statute and provide a more realistic and accurate benchmark for pharmaceutical reimbursement to pharmacies. Specifically, the statute defines AMP as “the average price paid to the manufacturer for the drug in the United States by wholesales for drugs distributed to the retail pharmacy class of trade.” Accordingly, only those sales that are to entities that are truly within the “retail class of trade” should be included in the calculation. PBM’s, mail order pharmacies and other non-retail entities should be removed. Similarly, purchases by entities other than wholesalers should also be excluded. Likewise, the FUL should be based on the weighted average AMP of therapeutic alternatives, not the lowest cost alternative.

Second, CMS should delay publication of the AMP information to ensure that the consequences of publishing the data are fully understood. Publication of the AMP data will result in an immediate impact on the pricing of generic drugs that will create a floor on the price discounts that generic manufacturers are willing to offer, thereby reducing the level of competition between generic manufacturers with potentially significant negative effects on neighborhood pharmacists and the Medicaid program alike.

Third, state dispensing fees must be reviewed in light of the changes imposed by the federal drug reimbursement scheme. Accordingly, CMS should ensure that all pharmacy costs are included in the federal dispensing fee definition and require states to update their Medicaid dispensing fees to ensure appropriate utilization of generic drugs.

We appreciate the opportunity to provide you with our concerns and respectfully request that you address them on the record. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to contact me at (816) 360-8350 or by email at [jmaslak@awginc.com](mailto:jmaslak@awginc.com)

Sincerely,

Joseph Maslak  
Executive Director, Pharmacy  
Valu Merchandisers Company  
624 Westport Rd.  
Kansas City, MO 64111

**Submitter :** Vi Do  
**Organization :** NCAP  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-2238-P-753-Attach-1.DOC

March 12, 2007

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

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

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

- 1. Remove PBM and Mail Order from Retail Class of Trade**
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
  
- 2. Implement a Trigger Mechanism**
  - (i) Addresses severe price fluctuations
  - (ii) Reduces risk of Market Manipulation
  - (iii) Mitigates Risk of Pricing Lag
  
- 3. Use of 11-Digit NDC versus 9-Digit NDC**
  - (i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely,

Vi Do

cc. Members of Congress (David Price, Richard Burr, Elizabeth Dole)

**Submitter :** Jerry Eledge  
**Organization :** LaVergne Drug Store  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**Background**

**Background**

I am the owner of an independent pharmacy.

**Collection of Information**

**Requirements**

**Collection of Information Requirements**

The switch of medicaid pharmacy reimbursement to AMP instead of the current AWP.

**Provisions of the Proposed**

**Regulations**

**Provisions of the Proposed Regulations**

Don't know what to put in this field.

**Response to Comments**

**Response to Comments**

If pharmacy reimbursement is changed from AWP to AMP it will cause me to stop accepting medicaid prescriptions as I may lose up to 50% of the cost of the prescriptions. This change could cause me to close my business. The changes will permeate throughout my industry closing many small businesses.

CMS-2238-P-754-Attach-1.DOC

February 16, 2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

Jerry P. Eledge  
LaVergne Drug Store

**Submitter :** Ms. Jennifer Morris  
**Organization :** Manning Pharmacy  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**Background**

**Background**

This is regarding the use of AMP pricing for the reimbursement for drugs.

**Collection of Information Requirements**

**Collection of Information Requirements**

The provision of the proposed regulations would use manufacturer price as the basis of cost for pricing in community pharmacy practice. Currently we do not have the information we do not have the information regarding what those costs would be. AWP (Average Wholesale Price) is the published price used by all wholesalers, PBMS and pharmacies. Currently a percentage is taken off of the wholesale price when the final retail price of a prescription is figured.

**GENERAL**

**GENERAL**

With AMP structure as it is currently proposed, the average pharmacy would be left struggling to find revenue streams to replace the 8-15% margin that would be below the level at which we currently purchase at. In short, we would be reimbursed by Medicare Part D at least 10% below what we can even buy any product for. If AMP is going to be the standard, then substantial increases need to be incorporated into the reimbursement structure to accommodate these shortfalls. This proposed structure also has shortfalls in that constant cost increases by the manufacturer are not addressed in a timely manner.

**Regulatory Impact Analysis**

**Regulatory Impact Analysis**

The actual 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, we propose a "trigger mechanism" whereby price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

**Submitter :** Mrs. Sophia De Monte

**Date:** 02/16/2007

**Organization :** APHA

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

I urge you to reconsider the new reimbursement criteria for prescriptions under the Medicaid program.

The practice of pharmacy is a service. Providing the product is but 1 step in a process. How does one cure an illness? Is it by trust and faith that the cure will work or is it by the dollar sign?

The bottom line is: You get what you pay for.

How can our nation be a world leader, when our healthcare system is so out of control. Our people need to be educated about prevention, disease management and proper use of medications. What do you call it when you financially strangle the profession that has been the most accessible to the people? There are better options to rein in healthcare costs.

Thank you,  
Sophia De Monte

**Submitter :** Mr. J. Michael Morton

**Date:** 02/16/2007

**Organization :** Vanceboro Pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-2238-P-757-Attach-1.TXT

February 18, 2007

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

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

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

**1. Remove PBM and Mail Order from Retail Class of Trade**

- (i) Creates consistency in the Regulation
- (ii) Conforms definition with market reality

**2. Implement a Trigger Mechanism**

- (i) Addresses severe price fluctuations
- (ii) Reduces risk of Market Manipulation
- (iii) Mitigates Risk of Pricing Lag

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

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

**If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disasterous to my Medicaid patients, which represent approximately 61% of my business.**

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

Sincerely,

J. Michael Morton  
Vanceboro Pharmacy  
421 Farm Life Avenue  
P. O. Box 218  
Vanceboro, NC 28586

(252) 244-1086

cc. Rep. Walter B. Jones, Jr.  
Sen. Elizabeth Dole  
Sen. Richard Burr

**Submitter :** Dr. Rick Sain

**Date:** 02/16/2007

**Organization :** Reeves Sain Drug Store

**Category :** Pharmacist

**Issue Areas/Comments**

**Background**

Background

I know that The Deficit Reduction Act of 2005 has required some changes to Medicaid reimbursement.

**GENERAL**

GENERAL

I want to comment on the definition of AMP. As a pharmacy owner, and as President of the Tennessee Pharmacist Association, I am truly concerned that the pharmacy reimbursement for generics under Medicaid will be less than our acquisition costs on a very large number of drugs. I know there is need for change, and I do not mind change, but it seems to keep coming on the backs of the pharmacies. We need to really study this to be sure that it is done in a more fair manner. I understand that a GAO study has been done, and I hope this will be taken into consideration. The pharmacists' time and many costs associated with filling a prescription are tied to the mark up on a prescription. If we are not going to be paid for counseling, delivering, etc. then we have to be paid on what it costs to fill a prescription, and this has been shown to average around \$ 10.50 per Rx. Again, I hope this will be taken into consideration. I am not for the current definition as it stands on AMP. Thank you.

**Submitter :** Dr. Elliott Sogol  
**Organization :** Dr. Elliott Sogol  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

February 16, 2007

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

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

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

1. Remove PBM and Mail Order from Retail Class of Trade
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
2. Implement a Trigger Mechanism
  - (i) Addresses severe price fluctuations
  - (ii) Reduces risk of Market Manipulation
  - (iii) Mitigates Risk of Pricing Lag
3. Use of 11-Digit NDC versus 9-Digit NDC
  - (i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely,

Elliott M. Sogol, PhD, R.Ph

cc. Members of Congress (Price, Dole )

Submitter : Mr. John Bahlman

Date: 02/16/2007

Organization : Pharmacy Plus

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 18, 2007

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

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

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

1. Remove PBM and Mail Order from Retail Class of Trade

- (i) Creates consistency in the Regulation
- (ii) Conforms definition with market reality

2. Implement a Trigger Mechanism

- (i) Addresses severe price fluctuations
- (ii) Reduces risk of Market Manipulation
- (iii) Mitigates Risk of Pricing Lag

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

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

If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disastrous to my Medicaid patients, which represent approximately 42% of my business.

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

Sincerely,

John H. Bahlman, Jr.  
Pharmacy Plus, Inc.  
2029 Boulevard  
Colonial Heights, VA 23834  
(804) 520-2400

cc. Sen. John W. Warner  
Sen. James Webb  
Rep. Randy Forbes

**Submitter :** Mr. Richard Savner  
**Organization :** Pathmark Stores, Inc.  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment.

CMS-2238-P-761-Attach-1.DOC

February 20, 2007

**Via Electronic Mail**

Leslie Norwalk, Esq.  
Acting Administrator  
The Centers for Medicare & Medicaid Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, DC 20201

**RE: Proposed Rule To Implement Provisions of DRA Relating to Prescription Drugs under the Medicaid Program; (Document No. CMS--2238-- P)**

Dear Administrator Norwalk:

Pathmark Stores, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid program. 71 Fed. Reg. 77174 (Dec. 27, 2006) as discussed more fully below, we are very concerned about the impact of the proposed rule on our supermarket pharmacies.

By way of background, Pathmark operates 141 stores in the New York-New Jersey and Philadelphia metropolitan areas. We achieve \$4 billion dollars in annual revenue, 10% of which is derived from our 129 pharmacies. One of our more noteworthy attributes is our commitment to operating stores in lower income, urban neighborhoods. Not surprising is the fact that many of our customers, and in particular pharmacy patrons, are Medicaid beneficiaries. Quite often, Pathmark is one of the few retail outlets available for these residents to fill their prescription needs. We are proud of our long-standing commitment to serving the needs of people in low-income communities.

Pathmark is also a member of the Food Marketing Institute (FMI), and fully supports the comments filed by FMI and incorporates FMI's comments herein. In addition, we specifically wish to call your attention to the following issues.

As CMS notes in the proposed rule, the use of Average Manufacturer Price (AMP) as a benchmark for pharmacy reimbursement represents a departure from the previous role of AMP in the Medicaid rebate calculation. Although we understand the challenge the dual use of AMP presents to CMS, we believe that several aspects of the proposed rule would unduly reduce AMP, thereby jeopardizing our company's ability to continue to serve Medicaid beneficiaries.

In this regard, we urge CMS to take the steps necessary to ensure that pharmacies are adequately reimbursed for serving Medicaid patients. Supermarket pharmacy profit margins are in the range of approximately 2 to 3 percent of total revenues. Recent studies suggest that the Federal Upper Limits (FULs) based on AMP may result in ingredient cost reimbursement that is below pharmacy acquisition cost.<sup>1</sup> In this context, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. To the extent that FULs are below pharmacy acquisition costs for generic drugs, our company will find it increasingly difficult to serve Medicaid patients. This situation is exacerbated by dispensing fee amounts in the states in which we operate that are far below the costs we incur to dispense prescription drugs to Medicaid patients.

Accordingly, although we do not believe that this situation can be fully addressed through the regulatory process and we are joining with FRO 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. Single 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.

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<sup>1</sup> Government Accountability Office “Medicaid Outpatient Prescription Drugs: Estimated 2007 Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs”, Letter to Rep. Joe Barton (R-TX) (December 22, 2006).

We appreciate the opportunity to provide you with our concerns and respectfully request that you address them on the record. If you have any questions regarding our comments or if we may be of assistance in any way, please do not hesitate to contact me at 732-499-3000, X-3105 or email [RSAVNER@PATHMARK.COM](mailto:RSAVNER@PATHMARK.COM).

Sincerely,  
Richard Savner  
Director of Public Affairs  
Pathmark Stores, Inc.  
200 Milik St.  
Carteret, NJ 07008

**DRAFT**

**Submitter :**

**Date:** 02/16/2007

**Organization :**

**Category :** Critical Access Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-762-Attach-1.DOC

# Baystate Medical Center

Submitted Electronically: <http://www.cms.hhs.gov/eRulemaking>.

February 16, 2007

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

Re: File Code CMS-2238-P  
Deficit Reduction Act/prescription drugs  
71 Fed. Reg. 77174, 77188 (Dec. 22, 2006)

To Whom It May Concern:

On behalf of Baystate Medical Center (Baystate), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005, published in the Federal Register on December 22, 2006 (*71 Fed. Reg. 77174, 77188*). Baystate is a six hundred fifty three (653) bed hospital located in Springfield, MA and is a disproportionate share hospital (DSH) under the Medicare program. As a DSH hospital we have utilized the 340B program to assist us in our mission to improve the health of the people in our communities. We fear that if these proposed revisions to the 340B rules are adopted it will hinder our ability to utilize the 340B program in fulfilling our mission.

The most significant issue with the proposed revision is that it appears to violate federal law; hospital clinic administered drugs are exempt from rebate requirements under the Medicaid statute. However, the explicit purpose of the NDC collection rule for "physician administered drugs" is to facilitate rebate collections by the States. CMS needs to review these proposed revisions in light of the pre-existing statutory exemption from rebates and explicitly exempt hospital outpatient clinic drugs from the new NDC collection rule. We are confident that CMS will realize that there no reason for states to collect NDC information on drugs the states are explicitly exempted from collecting rebates on in the first place.

Assuming that these proposed rules are not found to be inconsistent with federal law, additional issues need further examination and clarification by CMS.

In section 447.520 of the proposed rule (*FFP: Conditions relating to Physician Administered Drugs, 71 fed. Reg., 77188*), CMS states that the impact on hospitals will be "small" or "insignificant." This is absolutely not the case for Baystate's billing system as it is not configured to have the capacity to substitute NDC numbers as identifiers for clinic administered drugs (as distinguished from the HCPCS codes known as "J-codes" that are currently used for Medicaid billing purposes). For Baystate to be able to perform this feat it will be necessary to revamp our billing system - - no small task given that this will involve the acquisition or development of an entirely new billing system. This new system will be

expensive, not only in terms of acquiring the system, but also in logistical terms such as employee training and system troubleshooting issues experienced with any new application. CMS suggests that as an alternative to an electronic billing system, covered entities could manually enter these codes in only 15 seconds per claim, a claim that is unsupported and quite at odds with our knowledge of administering outpatient drugs. A sizeable portion of our outpatient drugs are administered to our patients in a tailored method best described as a "cocktail." These cocktails are compounds of multiple drugs, and therefore each drug's NDC number must be identified. There is simply no possible way a person could manually identify the NDC number for each compound in a multi-drug cocktail for each visit in 15 seconds or less.

With respect to calculations of Average Manufacturer Price (AMP), the proposed rule relating to the treatment of prompt pay discounts will likely increase the prices Baystate pays for our outpatient drugs by adversely affecting the formula for calculating 340B prices. It is our experience that the greatest difficulty in AMP assessment is the lack of transparency in the system, something which the General Accounting Office (GAO) reported just several days ago (*PRESCRIPTION DRUGS Oversight of Drug Pricing in Federal Programs*, GAO-07-481T, Feb. 9, 2007). While we agree that AMP calculation should be solidified, we feel a more transparent method should be developed.

Ultimately, we fear that if the 340B program is revised as proposed the burdens will increase while the benefits will be removed, and we will be forced to reassess our participation in the program. Should the Commonwealth of Massachusetts ever wish to impose rebate obligations on these 340B outpatient drugs it would short-change our operating budget by seriously reducing our drug discounts. These revisions would seriously jeopardize a program that has accounted for nearly \$5.25 million in annual savings for our hospital.

Thank you for listening to our concerns. We trust that you will review and revise these proposed regulations in light of the issues and concerns we have raised.

Sincerely,

Gary Kerr, M.B.A., Pharm.D.  
Director of Pharmacy Services  
Baystate Medical Center  
759 Chestnut Street  
Springfield, MA 01119

**Submitter :** Mr. C. Stroud Tilley  
**Organization :** Pharmacy Plus of New Bern, Inc.  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

February 18, 2007

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

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

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

1. Remove PBM and Mail Order from Retail Class of Trade
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
2. Implement a Trigger Mechanism
  - (i) Addresses severe price fluctuations
  - (ii) Reduces risk of Market Manipulation
  - (iii) Mitigates Risk of Pricing Lag
3. Use of 11-Digit NDC versus 9-Digit NDC
  - (i) Represents the most common package size dispensed by retail pharmacies

If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disastrous to my Medicaid patients, which represent approximately 39% of my business.

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

Sincerely,

C. Stroud Tilley, III  
Pharmacy Plus of New Bern, Inc.  
1204 S. Glenburnie Road  
New Bern, NC 28562  
(252) 636-3322

cc. Sen. Elizabeth Dole  
Sen. Richard Burr  
Rep. G.K. Butterfield

**Submitter :** Mr. David Godbee  
**Organization :** ADDISON DISCOUNT PHARMACY  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-2238-P-764-Attach-1.WPD

CMS-2238-P-764-Attach-2.WPD

CMS-2238-P-764-Attach-3.WPD

CMS-2238-P-764-Attach-4.PDF

CMS-2238-P-764-Attach-5.PDF

CMS-2238-P-764-Attach-6.PDF

2/16/07

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

David Godbee  
Addison discount pharmacy

**Submitter :** Mr. J. Michael Morton  
**Organization :** H&H Drug Company  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

February 18, 2007

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

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

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

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

2. Implement a Trigger Mechanism  
(i) Addresses severe price fluctuations  
(ii) Reduces risk of Market Manipulation  
(iii) Mitigates Risk of Pricing Lag

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

If AMP does not cover my actual acquisition cost, the impact on my pharmacy will be disastrous to my Medicaid patients, which represent approximately 69% of my business.

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

Sincerely,

J. Michael Morton  
H&H Drug Company  
512 Queen Street  
PO Box 309  
Grifton, NC 28530  
(252) 524-4101

cc. Sen. Elizabeth Dole  
Sen. Richard Burr  
Rep. G.K. Butterfield  
Rep. Walter B. Jones, Jr.

**Submitter :** Mr. RAY ROBERTSON  
**Organization :** PROFESSIONAL PHARMACY  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

WE WILL NOT BE ABLE TO SERVICE MEDICAID RECIPIENTS UNDER THE SCENARIO THAT YOU ESTABLISH AN EXTREMELY LOW (BELOW OUR ACQUISITION COST) AMP WITHOUT ESTABLISHING A MINIMUM DISPENSING FEE.  
SEE ATTACHMENT

CMS-2238-P-766-Attach-1.DOC

[date]

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

[ Name]

**Submitter :** Mr. Ron Fitzwater  
**Organization :** Missouri Pharmacy Association  
**Category :** Health Care Professional or Association

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-767-Attach-1.PDF



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211 E. Capitol Ave. ♦ Jefferson City, MO 65101 ♦ 573-636-7522 ♦ Fax 573-636-7485 ♦ www.morx.com

February 16, 2007

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

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

The Missouri Pharmacy Association (MPA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP, as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

### **Summary**

MPA continues to support federal efforts that are designed to positively affect the affordability of and access to prescription drugs and health care professionals. While we are supportive of these efforts, we are compelled to offer the following comments on CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP, as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. Specifically, we will comment on two sections of the proposed regulation – §447.504 and §447.510.

§447.504 addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (1) the proposed definition of the retail pharmacy class of trade; (2) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (3) the treatment of discounts, rebates and price concessions.

§447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record-keeping requirements. The methodology employed in §447.510 creates five areas of concern: (1) there is a potential for market manipulation inherent in the reporting process; (2) the ability or inability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (3) the reporting system itself creates an artificial price lag in the reimbursement basis; (4) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (5) the suggested time for record retention is overly burdensome.

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

#### **§447.504 Determination of AMP**

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (1) the proposed definition of the retail pharmacy class of trade; (2) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (3) the treatment of discounts, rebates and price concessions. The following comments address these three areas of concern.

##### Defining Retail Pharmacy Class of Trade

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

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

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

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption

that mail order pharmacies' and PBMs' discounts, rebates and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs. In Missouri, Medicaid recipients obtain their medications from their community retail pharmacy. Most states bill for and receive rebates or other price concessions directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies, we address the unique contractual arrangements in detail later in these comments.

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

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

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

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

likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

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

#### Inclusion of Medicaid Sales

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

#### Discounts, Rebates and Price Concessions

MPA contends that certain discounts, rebates and price concessions found in §447.504(g)(6) and (9) should not be included in the AMP calculation. Price concessions provided by drug companies to PBM and mail order pharmacies in the form of rebates, charge-backs or other contractual arrangements by their very relationship are not available to out-of-pocket customers or third party private sector parties. The proposed regulation concedes that the benefits of these rebates, price concessions, charge-backs and other contractual arrangements may not be – and MPA asserts that they are not – shared with the community retail pharmacy networks, out-of-pocket customers and third party payors, and, thus, they are not available to the “general public.” Since PBM and mail order pharmacies (1) now often are vertically integrated with manufacturers and others in the supply chain, (2) have contractual arrangements in many states that are not transparent in the health care system and (3) have purchasing power and drug substitution/distribution control greater than the other entities included in the retail class of trade, they are clearly distinguishable from the community retail pharmacies from which the Medicaid clients obtain their medications. For these reasons, we strongly urge CMS to reconsider the inclusion of mail order pharmacy rebates, charge-backs and other price concessions. AMP should reflect the prices paid by retail pharmacies; however, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions manufacturers

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

On balance, we are concerned that including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."<sup>1</sup> 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."<sup>2</sup> The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to health care in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

#### **§447.510 Requirements for Manufacturers**

This section of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record-keeping requirements. The methodology employed to set forth the above tasks creates five areas of concern: (1) there is a potential for market manipulation inherent in the reporting process; (2) the ability or inability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (3) the reporting system itself presents an artificial price lag in the reimbursement basis; (4) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (5) the suggested time for record retention is overly burdensome. The following comments address each of these areas of concern.

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<sup>1</sup> Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.

<sup>2</sup> GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

## Market Manipulation

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

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

## ‘Claw-back’

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

## Pricing Lag

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

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<sup>3</sup> §447.510(d)(2)

### Severe Price Shifts

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

In its simplest form, the trigger mechanism could accomplish the following: (1) limit the affects of price posting lag; (2) mitigate potential market manipulation; (3) mitigate a possible disincentive to fill generics by the retail pharmacies; (4) limit incorrect public data; and (5) provide CMS with the most up-to-date calculation of AMP.

The ability to adjust the posted AMP between reporting periods will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address and mitigate the issues surrounding pricing lag.

The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the OIG will act as a damper to market manipulation. The longstanding intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate, there is a market disincentive to increase the drug's utilization. The trigger mechanism's ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real-time posting of the generic's AMP. Clearly, the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have the most up-to-date AMP data.

### Record Keeping

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

## **Additional Comments**

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

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

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

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

Sincerely,



Ron L. Fitzwater, CAE  
Chief Executive Officer

cc Senator Christopher S. "Kit" Bond  
Congressman William "Lacy" Clay, Jr.  
Congressman Russ Carnahan  
Congressman Emanuel Cleaver  
Congressman Roy Blunt  
Congressman Kenny Hulshof

Senator Claire McCaskill  
Congressman Todd Akin  
Congressman Ike Skelton  
Congressman Sam Graves  
Congresswoman Jo Ann Emerson

**Submitter :** Mr. Mark Pawlowski  
**Organization :** Planned Parenthood of South Central Michigan  
**Category :** Health Care Professional or Association

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-2238-P-768-Attach-1.RTF

**Submitter :**

**Date: 02/16/2007**

**Organization :**

**Category : Pharmacist**

**Issue Areas/Comments**

**Background**

**Background**

I am a pharmacist by profession. I want to comment on the Formula for AMP.

**GENERAL**

**GENERAL**

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

This rule can really impact pharmacist owned community pharmacy. If this rule is implemented the way it is now can force small pharmacy out of business and can also effect the service provided by small pharmacies to community on whom people rely on advise for the medications.Closing of pharmacies can also hurt local economy and employment also.

I sincerely hope that this should be counted in decision before implementing and I also hope this rule also dosenot intend to hurt small community pharmacy.

**Submitter :** Dr. Dusty Pruett

**Date:** 02/16/2007

**Organization :** APCI

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

I would like to express my concerns with the proposed rule changes to pharmacist reimbursement. I feel that the proposed changes fail to recognize the impact that pharmacists have on patients. If we are not properly paid for our services we will no longer be able to provide these services to Medicaid customers. Please reconsider the proposed changes and the impact they will have on the community.

**Submitter :** Mr. Charles Campbell

**Date:** 02/16/2007

**Organization :** LaBrenz Pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

**Background**

**Background**

I am a registered pharmacist/pharmacy owner in the state of Michigan. I have been practicing in Michigan for 19 years.

**GENERAL**

**GENERAL**

2 points:

1. It is unfair to include mail-order pharmacy in determining AMP. Mail Order Pharmacies pay less for the cost of the drug from the manufacturer than retail pharmacies do. They also receive additional rebates from manufacturers that retail pharmacies do not.
2. In addition to providing a product, retail pharmacies also provide a service. Pharmacies should be appropriately re-imbursed for this service. Michigan is thinking of taxing this service!!

**Response to Comments**

**Response to Comments**

If AMP falls below our acquisition cost, we may be forced to stop accepting medicaid. This will deny access to care for our most vulnerable citizens.

Submitter : Mr. Harold Harmon

Date: 02/16/2007

Organization : H & M Drugs

Category : Pharmacist

Issue Areas/Comments

**GENERAL**

GENERAL

February 16, 2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

John Harold Harmon

Submitter : Dr. Christy Bolt

Date: 02/16/2007

Organization : H & M Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 16, 2007

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Sincerely,

Christy Bolt

**Submitter :** Dr. Ashley Johnson  
**Organization :** H & M Drug  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

February 16, 2007

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Sincerely,

Ashley Johnson

**Submitter :** Mr. sharad gandhi

**Date:** 02/16/2007

**Organization :** auburn pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Propose regulation cms-2238-p for rx drugs should not be supported.

this change will force small independent pharmacies like mine to colse down.I am located in predominanty medicaid patient area and I will not even be able to buy medications at the rate cms is proposing to reimburse back to me.this will force me to close this pharmacy and this will deprive poor people of badly needed medications.I have been serving these poor people since 20 years.They depend on me to take care of their family rx needs.Please vote against this proposition and help poor people of your constituency.

Thank you,  
Sharad Gandhi Rph

**Submitter :** Mr. Robert Roppel

**Date:** 02/16/2007

**Organization :** Prescription Shoppe

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Dear Sirs, I am pharmacy owner located in Crookston, MN. We are a major supplier of pharmacy services in our rural community. The CMS's proposal to reduce reimbursement rates to AMP will have a devastating effect on our business (and our patients). The AMP as used by CMS has to ignore sales to PBMs and Mail Order. Manufactures sell drugs to them at a rate no retail pharmacy can buy them for. The AMP has to ignore rebates and concessions that drug companies give to PBMs and Mail Order pharmacies----I don't get them!!! When CMS sets the AMP they can't use Medicaid data since those sales are regulated by the government and the inclusion of Medicaid data would create a circular loop negating the validity of AMP. The AMP should also be updated weekly because manufactures raise prices consistantly and pharmacies could get caught in the lag time.

Sincerely,

Robert. D Roppel R.Ph.  
211 N Main  
Crookston, MN  
56716

**Submitter :** Mr. David O'Brien  
**Organization :** Cordova Drug Co., Inc.  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Cordova Drug Co., Inc.  
Box 220  
516 First Street  
Cordova, Alaska 99574  
(907) 424-3246 Fax (907) 424-3245  
email cordovadrug@ctcak.net  
February 16, 2007

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

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

1. Remove PBM and Mail Order from Retail Class of Trade
  - (i) Creates consistency in the Regulation
  - (ii) Conforms definition with market reality
  
2. Implement a Trigger Mechanism
  - (i) Addresses severe price fluctuations
  - (ii) Reduces risk of Market Manipulation
  - (iii) Mitigates Risk of Pricing Lag
  
3. Use of 11-Digit NDC versus 9-Digit NDC
  - (i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely, David A. O'Brien RPh, Owner

**Submitter :** Mr. Richard Dreiling

**Date:** 02/16/2007

**Organization :** Duane Reade

**Category :** Drug Industry

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

CMS-2238-P-778-Attach-1.DOC

**Submitter :** Mr. chris decker

**Date:** 02/16/2007

**Organization :** pharmacy society of wisconsin

**Category :** Pharmacist

**Issue Areas/Comments**

**Background**

Background

comment on calculation of AMP for use in determining the federal upper limit of prescription drugs in the Medicaid program.

**Collection of Information**

**Requirements**

Collection of Information Requirements

447.504 and 447.510

**GENERAL**

GENERAL

see attached

CMS-2238-P-779-Attach-1.PDF

**Submitter :** Dr. curtis rising  
**Organization :** the medicine shoppe  
**Category :** Drug Industry

**Date:** 02/16/2007

**Issue Areas/Comments**

**Background**

**Background**

I am a pharmacist and come from a small town of 1000 people. I have been practicing in rapid city sd a town of 50000 people.

**Collection of Information**

**Requirements**

**Collection of Information Requirements**

i am concerned and outraged about the future amp pricing upon drugs. I do not know where the offices that are doing the pricing of these drugs. The OAC's study showed that the price would be 36 percent below the cost of medications to my pharmacy. What is not understood is that if this goes through and is enacted then there will be very few pharmacies that will accept medicaid. My home town pharmacy closed down because of medicare part d and the cut backs that they imposed. That will be nothing compared to the fall out of the amp pricing. Not only will there be no pharmacies that will not take medicaid payments but there will be no pharmacies in any town under 10000 population. And worst of all there will be no pharmacy coverage for those who need it most ie. the medicaid population. As a pharmacist i am out raged that no one sees pharmacist as professional citizens that provide an invaluable service. I save lives every day. People ask me questions about their health all day long and i don't get paid for that now. If you expect pharmacy to cure the high cost of medications by cutting our services then you are not seeing the big picture. Why have there been no cuts to the manufactures that charge such a high price on the medication that cost them pennies to produce. Example, zocor was 120 dollar per 30 tabs 6 months ago and now they are being produced at 60 dollars per thousand. Congress and CMS needs to attack the high cost of prescriptions at the root, the manufactures. It is not right to put the whole cost on pharmacy. If things aren't done right what will happen is that there will be no pharmacy that will take medication insurance of anykind and then where the nation bc.

curtis rising

**Response to Comments**

**Response to Comments**

Pharmacies have been the target of many regulations and cutbacks in the drug industry.

**Submitter :** Mrs. Catina Griffith  
**Organization :** Professional Pharmacy  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

If cms cannot set an AMP cost basis that covers actual drug costs or legislates a fee that results in a profit, then it becomes impossible for an independent pharmacy to fill these prescriptions.

CMS-2238-P-781-Attach-1.DOC

**Submitter :** Mr. Les Gwyn-Williams  
**Organization :** Terry's Family Pharmacy,inc  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-2238-P-782-Attach-1.DOC

**Submitter :** Mr. Mel Rauton  
**Organization :** Prescription Center, Inc.  
**Category :** Pharmacist

**Date:** 02/16/2007

**Issue Areas/Comments**

**GENERAL**

GENERAL

February 16, 2007

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

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

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

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

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

3. Removal of Medicaid Data

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

4. Manufacturer Data Reporting for Price Determination Address Market Lag

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

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

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

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

Sincerely,

Mel Rauton, Jr., R.Ph.  
Owner  
Prescription Center, Inc.

107 Rutledge Avenue  
Charleston, SC 29401