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.

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,

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.

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,

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

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,

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.)

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 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,

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.**

---

[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.

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.

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.

---

[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".

---

[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.

---

[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

13 East Washington Ave.
Washington, NJ 07882

Phone : 908-689-0036
Fax : 908-835-0633

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 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.

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,

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

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.

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,

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.)

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 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,

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

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.)

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 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,

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

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 Smethport, 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 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,

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.

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,

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

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

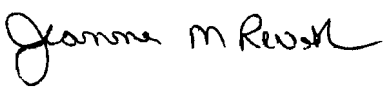
The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to 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,



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.

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,

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.

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,

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