Submitter : Mr. FRED CARRUTHERS **Date:** 02/20/2007

Organization : CARRUTHERS PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

02-20-2007]

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,
FRED CARRUTHERS R.PH.

Submitter : Mr. TRUSHAR SHETH **Date:** 02/20/2007

Organization : GIANNOTTO'S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED FILE FOR COMMENTS FROM GIANNOTTO'S PHARMACY

CMS-2238-P-1202-Attach-1.TXT

CMS-2238-P-1202-Attach-2.TXT

#1202

Giannotto's Pharmacy
195 First Avenue
Newark, NJ 07107
973-482-8220
FAX:973-482-0615
Trushar A. Sheth, RPh
PRESIDENT

VIA ELECTRONIC SUBMISSION

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

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

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

Submitter : Steve LaFrance **Date:** 02/20/2007

Organization : USA Drug

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1203-Attach-1.PDF

USA Drug
Super D Drug Store · IKE'S Deep Discount Drugs · mays Drug Stores · Drug Warehouse · MED-X · DRUG MART

February 19, 2007

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

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

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

Our Corporation operates 155 pharmacies in five states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

3017 North Midland Drive • P.O. Box 939 • Pine Bluff, AR 71603 • (Office) 870.535.2411 • (Fax) 870.535.5601

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

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

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

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

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

Sincerely,

Steve LaFrance
Chairman

Submitter : Mr. TRUSHAR SHETH **Date:** 02/20/2007

Organization : GIANNOTTO'S PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHED COMMENTS FROM GIANNOTTO'S PHARMACY

CMS-2238-P-1204-Attach-1.TXT

#1204

Giannotto's Pharmacy
195 First Avenue
Newark, NJ 07107
973-482-8220
FAX:973-482-0615
Trushar A. Sheth, RPh
PRESIDENT

VIA ELECTRONIC SUBMISSION

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

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

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.
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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.
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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,

Trushar Sheth, R.Ph., CCP,
PRESIDENT,
GIANNOTTO'S PHARMACY
973-482-8220

Submitter : Bettie Wilson **Date:** 02/20/2007

Organization : Mountain States Health Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

My comment is attached.

CMS-2238-P-1205-Attach-1.DOC

#1205

Johnson City Medical Center
400 N. State of Franklin Road
Johnson City, Tennessee 37601

Mountain States Health Alliance

February 20, 2007

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

Dear Sir or Madam:

I am replying with comments to your proposal in the proposed rule dated December 22, 2006 on file code CMS-2238-P. This is the proposed rule in the Federal Register to implement certain provisions in the Deficit Reduction Act of 2005 which would require hospitals to provide an 11-digit unique NDC number on the billing submission to State Medicaid agencies for outpatient drug administration to enable the state to bill manufacturers for rebates.

This requirement would create a massive and expensive undue hardship on our 11 hospital system. We have no electronic mechanism to provide this information at the current time and do not foresee development of one in the future, so this would be a manual process. This manual process would add many steps to our already complex medication ordering, dispensing, and administering process. Addition of this proposed process could impact patient safety in a negative manner as our workflow would be disrupted resulting in (possible) slow down of pharmacist order review/verification and entry. Also, we do not currently have the financial and staffing resources to implement workflow changes that would be required to carry out this as a manual process.

We do not have separate billing systems for outpatients and inpatients. We have an integrated inpatient and outpatient pharmacy billing system and pharmacy dispensing system. This system relies on the same drug product inventories and may include multiple generic supplies (each with a separate NDC number) of the same medication.

At any one time any of our pharmacies could have several generic products as well as the brand NDC of the same generic entity product on the shelf and/or in our automated dispensing system cabinets. Order entry pharmacists do not know what NDC number of the product the specific patient will actually receive (from the pharmacy or adc). When we order drug products from our wholesaler and that product is out of stock at the wholesaler, the distributor automatically substitutes another NDC item for that product. This also results in different/more NDC numbers in our stock. We do "dose by dose" dispensing and billing. We do not dispense by prescription in multiple quantities as does a retail pharmacy.

Our current pharmacy information system has no way of sending the NDC number to patient accounting to be placed on the bill. Our current financial system and charge master have no place to enter the NDC number associated with the drug charge on the financial side. We have no room in adcs or on the pharmacy shelves to divide products up by NDC number.

We feel that implementation and management of this process would result in increased financial costs to our facilities. As a rough estimate, we believe it could cost as much as 25¢ per dose dispensed to implement. This would translate to millions of dollars per year for our alliance and hospitals. Our Johnson City Medical Center facility alone dispensed about 4 million doses during the last year. The financial burden on this one facility could be around $1,000,000 per year (at 25¢ per dose). The impact on workflow, staffing and financial resources of our hospitals would be dramatic and not justifiable given current fiscal and workforce constraints. We therefore ask you to reconsider this proposal. Thank you for your time and consideration in this matter.

Mountain States Health Alliance is a multiple hospital entity which includes hospitals in Northeast Tennessee and Southwest Virginia. The hospitals include Johnson City Medical Center, North Side Hospital, Johnson City Specialty Hospital, Johnson County Community Health Center, Indian Path Medical Center, Sycamore Shoals Hospital, Smyth County Community Hospital, Dickenson County Hospital, Norton Community Hospital, Woodridge Hospital, and Quillen Rehabilitation Hospital.

Sincerely,

Bettie K. Wilson, D.Ph.
Systems Director, Pharmacy Services
Mountain States Health Alliance
400 N. State of Franklin Road
Johnson City, TN 37604
1-423-431-6734
wilsonbk@msha.com

Submitter : DANIEL ST.CLAIR **Date:** 02/20/2007

Organization : DOWNEY DRUG

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

02/20/07

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

DANIEL ST.CLAIR
PHARMACIST/OWNER
DOWNEY DRUG ANNISTON, AL

Submitter : Mrs. Mindy Rasmussen **Date:** 02/20/2007

Organization : Arizona Pharmacy Alliance

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1207-Attach-1.PDF

1207

1845 E. Southern Avenue, Tempe, AZ 85282 (480) 838-3385

February 16, 2007

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

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

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

Summary

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

Specifically we will comment on two sections of the proposed regulation, §447.504 and §447.510. §447.504 which address the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology set forth in §447.504 creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts, rebates, and price concessions. §447.510 of the proposed regulation addresses how manufacturers are to provide CMS with AMP data, defines the timing of the reporting and outlines the record keeping requirements. The methodology employed in §447.510 creates five areas of concern: (i) there is a potential for market manipulation inherent in the reporting process; (ii) the ability or in-ability of agencies to 'claw-back' in an effort to correct improperly reported AMP data is not defined; (iii) the reporting system itself creates an artificial price lag in the reimbursement basis; (iv) a provision to account and adjust for severe isolated price shifts is noticeably absent from the section; and (v) the suggested time for record retention is overly burdensome. Additionally AzPA offers comments in response to the CMS request for comment regarding the use of the 11-Digit NDC rather than the 9-Digit NDC code. The following comments are meant to address the above-mentioned nine (9) concerns.

§447.504 Determination of AMP

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

The following comments address these three areas of concern.

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

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

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

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless the state mandates utilizing mail order pharmacy. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments. AzPA contends that PBMs do not "purchase prescription drugs from a manufacturer or wholesaler" or "[dispense] drugs to the general public". In order to do so, PBMs would need to be licensed as pharmacies under the applicable states laws. AzPA is unaware of any state that licenses PBMs, as pharmacies, to purchase, receive or dispense drugs to the general public. As such, we believe section 447.504(e) should be amended to eliminate all pharmacy benefit managers (PBMs).

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

As with the nursing home pharmacies, mail order pharmacies that operate as a closed door operation should not be included in the retail class of trade. As such, we believe section 447.504(e) should be

amended to exclude any closed door mail order pharmacy and any mail order pharmacy whose rebate or discount arrangements are not available to other pharmacies in the retail pharmacy class of trade.

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

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

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

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

Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

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

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

The inherent market volatility, associated with pharmaceutical manufacturing, occasionally results in dramatic shifts in price structure. The proposed regulation is noticeably silent in offering any mechanism to account for this fact. Severe price shifts and the significant issues associated with pricing lag can be effectively addressed with the implementation of trigger mechanisms. CMS should identify a reasonable and appropriate percentage shift in real time price that would trigger a review and recommendation by the Office of the Inspector General (IG). It is recommended that CMS clearly define the stakeholders empowered to alert CMS of significant price shifts. Once alerted the IG would research and then recommended an updated AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means. In its simplest form the trigger mechanism could accomplish the following: (i) limit the effects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to date calculation of AMP. The ability to adjust the posted AMP, between reporting periods, will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag. The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the IG will act as a damper to market manipulation. The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanisms ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP. Clearly the ability of CMS to efficiently respond to and adjust for market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

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

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

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

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

Sincerely,

Mindy Rasmussen, R.Ph.
Executive Director/CEO

cc. Members of Congress in state

Submitter : JAMES DOWNEY **Date:** 02/20/2007

Organization : DOWNEY DRUG ANNISTON/ALEXANDRIA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

02/20/07

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

JAMES DOWNEY
PHARMACIST/OWNER
DOWNEY DRUG ANNISTON, AL

Submitter : Mr. mukesh patel **Date:** 02/20/2007

Organization : lapuja pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

rph

Collection of Information Requirements

Collection of Information Requirements

roughly about $11.58 in usa. by cutting the the price that even we dont get form manufacturer will even put almost every one on the list of bankrupcy or close the door for those underserved populatin of the country. which i terms will cause more emergency visits, more hospitalisation & frantic office visits from the receipents. which in terms cost billions more then the cutting/saving that is porposed.please help us understand how in the world this kind of language has been written in the congress. may be we should rethink again. lets not invole the politics. if the government realy wants to reduce the deficit there are ways where we can all help. this is just not the right way of doing it. the medicare prescription plan-d (mapd)
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the government has the responsibilty of the society to curtail the cost of any thing thay may be irational. here the cost is to close the doors of communty pharmacies. so that the big manufacuters can do what ever they have to maintain their hafty margins.

GENERAL

GENERAL

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Submitter : Dr. Lelan Stice **Date:** 02/20/2007

Organization : Jefferson Regional Medical Center

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1210-Attach-1.DOC

1210

1/20/2007

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

To Whom It May Concern:

On behalf of Jefferson Regional Medical Center, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Jefferson Regional Medical Center is a 471 bed hospital located in Pine Bluff, Arkansas, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. This task has been recognized in the past as near impossible to maintain. Current billing systems do not have methodologies or capabilities to capture the NDC number at the time of administration, nor do they have a method to verify that a generic or substituted brand was used at the time of administration.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. Loss of 340B discounts on clinic medications would cost our hospital approximately $300,000 per year.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. Our hospital participates in several nominal pricing agreements, that would add many thousands of dollars per year to the cost of caring for indigent patients in Southeast Arkansas. Currently, Jefferson Regional Medical Center is managing approximately $48,000,000 per year in indigent care and bad debt. This burden cannot be increased, as the rise in indigent care has driven our margin to less than 2% on many years.

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

Sincerely,

Lelan Stice, PD
Administrative Director of Pharmaceutical and Materials Management
Jefferson Regional Medical Center

Submitter : **Dr. Albert Sanderson** **Date: 02/20/2007**

Organization : **Tennessee Pharmacists**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a pharmacist with K-Mart Pharmacy, 560 South Jefferson Avenue, Cookeville, TN 38501. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

Collection of Information Requirements

Collection of Information Requirements

1. Definition of "Retail Class of Trade"
2. Calculation of AMP
3. Removal of Medicaid Data
4. Manufacturer Data Reporting for Price Determination
5. use of 11-Digit NDC verses 9-Digit NDC

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1211-Attach-1.TXT

#1211

February 20, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of K-Mart Pharmacy, a community retail pharmacy located at 560 South Jefferson Ave, Cookeville, TN 38501. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

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

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Albert Sanderson RPh, PD
1505 Overcreek Drive
Nashville, TN 37217

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Jim Cooper

Submitter : Mr. James Gronski **Date:** 02/20/2007

Organization : Medical Center Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Proceeding with the current AMP reimbursement rate means that my pharmacy will no longer be able to provide services to Medicaid patients in this rural, southeast Missouri county. We have a large number of Medicaid patients. If we cannot provide services to them we will also have to terminate about half of our 12 employees as our prescription volume will drop substantially. Comments from CMS about negotiating lower prices from drug companies and distributors are farcical. As a single, independent pharmacy in rural Missouri that cannot negotiate collectively for lower prices with other pharmacies in the same condition, how much bargaining power does CMS think I have? This rule will hurt patients in my community and will devastate my pharmacy and others like it across the country.

Submitter : Mr. Joseph Davy **Date:** 02/20/2007

Organization : Planned Parenthood Greater Miami, Palm Beach

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1213-Attach-1.DOC

#1213

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the Chief Financial Officer of Planned Parenthood of Greater Miami, Palm Beach & Treasure Coast, Inc. (PPGMPBTC), a non-profit organization operating outpatient clinics in Miami-Dade, Palm Beach, Martin, and St. Lucie Counties, Florida. We provide family planning services, breast and cervical cancer screenings, STI testing and treatment, and gynecological services to uninsured and underinsured women, men, and teens. PPGMPBTC serves over 43,000 patients each year, over 90% of whom are uninsured or underinsured. PPGMPBTC is committed to continuing to provide these services at low cost to this population who likely would not be able to access these services anywhere else.

For over 35 years, PPGMPBTC has been able to provide these services to the South Florida population. Providing low cost oral contraceptives well below retail prices to women of child bearing years allows them to plan pregnancies at a time in their lives when they are most ready to raise a family. Nearly 50% of our clients are at or below the poverty level and over 60% fall below 200% of the federal poverty level. As you are likely aware, unintended pregnancy is one of the leading causes of the continuation of the cycle of poverty. Clearly, these individuals have a great need for low cost affordable health care, including oral contraceptives, which we have been able to provide as a safety net provider.

PPGMPBTC has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. Losing nominal pricing from drug manufacturers will have a dramatic impact on our ability to continue to provide these services. We estimate that 50%-70% of our clients would not be able to afford oral contraceptive drugs at the higher prices we would be forced to charge if we cannot access nominal pricing for oral contraceptives as a safety net provider.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Many of our Planned Parenthood sister health centers across the country are Title X clinics, and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. The majority of PPGMPBTC clinics however, are not federally funded. Therefore, we do not qualify as a 340B covered entity and, as such, will not qualify for low-cost oral contraceptives if not defined as a safety net provider.

Clearly, PPGMPBTC serves as a key safety net provider to our communities. We have formed strong partnerships with other service providers in our communities to provide low income individuals with a range of health and social services. Our ability to continue to provide low-cost oral contraceptives to the community rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, we do not qualify for the three categories listed above.

We sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will reconsider and exercise its authority to name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. PPGMPBTC is clearly a safety net provider and we strongly urge CMS to include nonprofit, outpatient clinics like ours in its definition of safety net providers.

Again, failure to define PPGMPBTC and other nonprofit outpatient clinics like ours would have severe detrimental effects on the communities we serve. Unintended pregnancy rates would undoubtedly increase continuing the cycle of poverty for these families in need. When defined as a safety net provider, we will be able to continue to provide low cost oral contraceptives to low income families preventing thousands of unintended pregnancies annually, in turn, allowing these individuals to plan for when to raise a family and helping to break the cycle of poverty in our communities.

Respectfully submitted,

Joseph Davy, MT, CPA
Chief Financial Officer
Planned Parenthood of Greater Miami, Palm Beach & Treasure Coast, Inc.

Submitter : Heide Bajnrauh **Date:** 02/20/2007

Organization : Arnold and Porter LLP

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-2238-P-1214-Attach-1.PDF

1214

Roche

February 20, 2007

BY HAND DELIVERY AND EMAIL
www.cms.hhs.gov/regulations/eRulemaking

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

RE: Comments on Proposed Rule Related to the Medicaid Drug Rebate Program, (CMS-2238-P)

Dear Acting Administrator Norwalk:

Hoffmann-La Roche Inc. ("Roche") appreciates the opportunity to submit these comments on the proposed rule to implement provisions of the Deficit Reduction Act of 2005 ("DRA") that was published by the Centers for Medicare and Medicaid Services ("CMS") in the *Federal Register* on December 22, 2006.[1] Roche supports CMS's efforts to implement the Medicaid prescription drug provisions of the DRA in a manner that will make the Medicaid drug pricing requirements more cohesive, transparent, and stable. Roche endorses the comments on this proposed rule submitted by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO"), and offers these comments for additional emphasis and as a supplement to the submissions made by those organizations.

Roche understands the challenges CMS faces in advancing the healthcare system for Medicaid beneficiaries so that they receive high-quality services at an appropriate cost. While we generally support most of the efforts proposed by CMS to promote fair drug[2] reimbursement practices, we ask for clarification and guidance regarding the following issues.

I. Definition of Retail Pharmacy Class of Trade - 42 C.F.R. § 447.504

Roche applauds CMS's efforts to clarify the definition of retail pharmacy class of trade, which is a key component in calculating the Average Manufacturer Price ("AMP"). We offer the

[1] Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

[2] The term "drug" refers to both drugs and biologicals.

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following comments on CMS's proposals for the determination of AMP, and in particular on the proposed definition of retail pharmacy class of trade. AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."[3] The proposed rule would define retail pharmacy class of trade as "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager ("PBM"), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[4] Roche believes that this definition is consistent with the concept, originally suggested by PhRMA, that the "optimum approach [to defining the retail pharmacy class of trade] is to use a function-based analysis that recognizes that the function of an entity in the distribution chain [should] govern whether particular transactions should be included in the calculation of AMP."[5] The proposed definition adds needed specificity but is also flexible enough to accommodate new entities that sell to the general public. However, to ensure consistency of CMS's overarching principle that only entities that are open to the general public be accounted for in AMP, CMS should specify that certain types of retail or mail order pharmacies that do not sell to the general public, such as hospital outpatient pharmacies and in-clinic or closed-walled pharmacies are not included in the retail pharmacy class of trade.

A. Prices to Other Federal Programs

In the rule's treatment of included and excluded sales and prices for both AMP and Best Price purposes, CMS proposes to exclude, as prices to other federal programs, "[a]ny depot prices (including TRICARE)." Roche agrees that prices to federal programs should be excluded from AMP and Best Price. However, Roche requests that, in the Final Rule, CMS clarify why TRICARE is considered "a depot price."

As CMS may be aware, the Department of Defense's ("DoD") TRICARE health care program provides coverage for prescription drugs through three different delivery systems: the military treatment facility, mail order and retail pharmacy. Under the Veterans Health Care Act ("VHCA"), a "depot contracting system" is as "a centralized commodity management system" through which covered drugs are "procured by" a federal agency. The price controls in the VHCA apply to drugs procured by DoD (and other specified agencies) through a depot contracting system.

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[3] SSA § 1927(k)(1)(A) (emphasis added).

[4] 71 Fed. Reg. at 77196 (proposed 42 C.F.R. pt. 447.504(e)).

[5] See PhRMA comments to the Office of the Inspector General of the Department of Health and Human Services ("OIG") regarding the meaning of "retail pharmacy class of trade" in the OIG Report: "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," No. A-06-06-00063, Appendix F at 3-5 (May 2006).

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In our view, with respect to TRICARE, drugs are procured only by the military treatment facility and mail order pharmacy and thus only those entities can be party to a depot contracting system under the VHCA. Distribution of drugs through the retail pharmacy network does not fall within the statutory definition of a depot contracting system, because drugs dispensed to DoD beneficiaries at retail pharmacies are not procured by DoD (or any other federal agency). Instead, the retail pharmacies acquire those drugs through commercial arrangements between the retail pharmacies and wholesalers. Accordingly, CMS should confirm that sales through the retail pharmacy program are not depot prices for purposes of the Medicaid Rebate Act.

The DoD recently announced that it will consider voluntary rebate proposals from manufacturers covering retail pharmacy sales. Under any such agreements, manufacturers would pay negotiated rebates to DoD for drugs dispensed by retail pharmacies to DoD beneficiaries. In our view, the sales and associated rebates under such agreements would be analogous to the sales and associated rebates in government programs, such as the Medicare Part D program and state pharmaceutical programs, under which the government acts as a third party payor for drugs dispensed by an entity in the retail pharmacy class of trade. Consistent with CMS's proposed approach for dealing with Part D and similar third party payor rebates, therefore, rebates under voluntary agreements should be included in AMP as a price concession.

With respect to Best Price, Roche believes that the prices and any voluntary rebates offered under voluntary rebate agreements with DoD should be excluded from the Best Price determination. However, the exclusion of these prices (net of rebates) should not be based on the statutory exemption for depot prices (because, as noted, there is no procurement by DoD of the drugs that are sold through its retail pharmacy network). Instead, it should be based on the statutory exemption for "any price charged on or after October 1, 1992, to ...the Department of Defense."[6] Any rebates offered to DoD under its voluntary rebate program would be a price concession paid to the DoD relating to covered drugs. Accordingly, we believe this exemption is an appropriate basis for excluding rebates paid to DoD for drugs sold to DoD beneficiaries through the retail pharmacy network. CMS should make this distinction clear in the Final Rule.[7]

B. Administrative and Service Fees

CMS proposes that manufacturers should include all fees that do not satisfy the definition of a "bona fide service fee" in the calculation of AMP.[8] CMS proposes to define a bona fide service fee as: "a fee paid by a manufacturer to an entity, that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that a manufacturer would

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[6] SSA. Section 1927 (c)(1)(C)(I).

[7] To the extent, CMS considers TRICARE retail pharmacy program in a "depot" category, it should make clear that it is interpreting its Medicaid rebate statute and not interpreting the VHCA, which CMS lacks the authority to interpret.

[8] 71 Fed. Reg. at 77, 180, 77, 195. Id. at 77, 195, 77, 197-98 (proposed 42 C.F.R. pt. 447.502, .504(i), .505(e)(1)).

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otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not an entity takes title to the drug."[9] The proposed definition is similar to the definition adopted in the ASP final rules.[10] CMS should clarify that recent interpretations in the Medicare Physician Fee Schedule Final Rule[11] of the bona fide service fee definition also apply in the AMP and Best Price context.

In addition to the proposed exception for bona fide service fees, Roche recommends that CMS consider permitting manufacturers to exclude from AMP all fees for services that meet the requirements of the personal services safe harbor to the anti-kickback statute.[12] These safe harbor requirements include sufficient safeguards to insure that any such fees are fair market value for bona fide services.

CMS should also clarify the circumstances under which fees to group purchasing organizations ("GPOs") can be excluded from AMP. Although in the 2007 Medicare Physician Fee Schedule, CMS concluded that fees to GPOs should be excluded from ASP if they meet the definition of bona fide service fees, it would be helpful to have additional guidance on when GPO fees should be excluded from AMP and Best Price calculations.

One approach that Roche supports was previously offered by the Health Industry Group Purchasing Association (the trade association for GPOs). They suggested that fees to GPOs should not be treated as price concessions "unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization."[13] CMS may also want to clarify that GPO fees do not affect AMP calculations when the GPO negotiates purchase prices for member hospitals for drugs used in the inpatient setting, since the underlying sales to hospitals would be excluded from AMP in this circumstance.

II. Requirements for Manufacturers - Section 447.510

A. Base Date AMPs and Reference AMPs

The formula used to calculate Medicaid rebates for innovator drugs requires manufacturers to pay an "additional rebate" equal to the difference between a drug's current AMP and its inflation-adjusted "base date" AMP, which is generally the AMP for the first full quarter in which the drug

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[9] 71 Fed. Reg. 77174 at 77176, 77180.

[10] Id. at 77180.

[11] Medicare Physician Fee Schedule final rule, 71 Fed. Reg. 69624, 69666-8.

[12] 42 C.F.R. § 1001.952(d).

[13] January 2, 2007 Health Industry Group Purchasing Association letter to CMS, at 2.

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was sold. CMS proposes that manufacturers be allowed to "recalculate base date AMP in accordance with the definition of AMP in § 447.504(e) of this subpart."[14] Thus, CMS recognizes, appropriately in our view, that manufacturers must have the option to adjust base date AMP to account for the changes set forth in the DRA and the Final Rule. Otherwise, the additional rebate amount could increase by an amount that is more than the amount by which innovator drug prices exceed the rate of inflation.

Roche believes that CMS should reiterate in the Final Rule that manufacturers are permitted, but not required, to make reasonable adjustments to base date AMP to address both the statutory changes (such as the exclusion of customary prompt pay discounts and the requirement to include authorized generic sales in AMP) and the upcoming regulatory changes to the AMP calculation methodology (such as changes to the definition of retail pharmacy class of trade). With respect to the change to the AMP calculation mandated by the DRA (i.e., the exclusion of prompt pay discounts), Roche recommends that CMS permit manufacturers, at their option, to adjust their pre-2007 drugs' base date AMPs by the amounts of the prompt pay discounts offered in the quarters in which their base date AMPs were established.

Additional changes to the AMP calculation that CMS may implement through its AMP regulations (e.g., a revised definition of the "retail pharmacy class of trade") could have a similar effect. Roche believes that Congress through the DRA did not intend to create artificially inflated additional rebates as a byproduct of revisions to the AMP calculation methodology. CMS should afford manufacturers the appropriate latitude in revising base date AMP to avoid the unintended consequence of erroneously inflated additional rebates.

Roche further recommends that CMS specify in its AMP regulations approaches that manufacturers may use to adjust base date AMPs to account for the effect of these changes and continue to consult with manufacturers to develop other approaches that may be preferable given their particular data management systems.

B. Reference AMP for Restatement Purposes

Roche also requests clarification on the reference AMP to be submitted during a restatement period. It is currently unclear which baseline AMP should be referenced for restatement submissions addressing a quarter prior to the DRA implementation.

C. Quarterly AMP Submissions Should Be Based on Quarterly Sales

Roche recommends that CMS clarify that quarterly AMP submissions be based on quarterly sales, not the aggregate or average of the three monthly AMPs submitted during the same quarterly period. Monthly AMP submissions are subject to volatility due to commercial customer quarterly

[14] Id. at 77185.

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payment obligations. Further, Roche recommends that smoothing for monthly AMP only, and recommends that CMS adopt the 12-month rolling average methodology that is currently applicable to ASP, beginning the period January 2007.

E. AMP and Best Price Certification

The Proposed Rule[15] requests that for manufacturer submissions (both monthly and quarterly) certification is required based on the current ASP certification guidelines. Roche proposes that the certification language be revised as applied to AMP and Best Price data submissions because the civil monetary penalty standard applicable to the reporting of ASP figures does not contain an explicit "knowing" requirement.

The Medicaid statute for civil money penalty provisions[16] states manufacturers are subject to penalty only for "knowingly" providing false information to CMS. However, the civil money penalty provision applicable to ASP submissions cites liability if a manufacturer "has made a misrepresentation in the reporting of the manufacturer's average sales price for a drug or biological," without specifying whether the misrepresentation was made knowingly or not.[17]

Roche proposes that the certification language include reference to the manufacturer's best knowledge at the time of submission.

III. Additional AMP and Best Price Issues

A. Requirement of Social Security Number for AMP and Best Price Reporting

The Drug Data Reporting System (DDR) requires that the employee posting submissions on the system on behalf of a manufacturer provide his or her Social Security number. Due to the sensitive nature of a Social Security number accompanied by other personal information and the rise of identity theft, Roche respectfully recommends that access to the system include the corporation's Tax ID number (TIN) or Social Security number associated with the corporation instead of the individual's social security number.

B. Public Availability of AMP data and Federal Upper Payment Limits

Roche recommends that access to manufacturer AMP and FUL data via internet be restricted on a secure site (with password requests) only for member practitioners, providers, and

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[15] Id. at 77198

[16] SSA § 1927(b)(3)(C)

[17] 69 Fed. Reg. 17,935, 17941 (April 6, 2004).

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government agencies authorized to view such data. Open access to this information could allow competitor manufacturers to access AMP information that could lead to derived competitive intelligence on specific products and affect both commercial and Medicaid supplemental rebate offers.

* * *

We appreciate the opportunity to provide our comments and recommendations. We hope that our suggestions will assist CMS in its mission to provide Medicaid beneficiaries with access to high quality therapies. Thank you for your attention to this matter. Please feel free to contact me if you have any questions or need additional information.

Respectfully submitted,

Evan T Morris

Evan Morris
Executive Director, Federal Government Affairs and
Public Policy
Hoffmann-La Roche Inc.

Hoffmann-La Roche Inc. 1425 K Street, N.W. Suite 650 Washington, D.C. 20005 Federal Government Affairs Tel. 202-408-0090 Fax 202-408-1750

Submitter : Mrs. Lisa Perks **Date:** 02/20/2007

Organization : Planned Parenthood of Central Ohio, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1215-Attach-1.DOC

#1215

February 20, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the Executive Director of Planned Parenthood of Central Ohio (PPCO), a non-profit health care provider. Since 1932, PPCO has provided critically-needed health care and education services in our multi-county central Ohio region. With approx 46 staff members, 5 health center sites and a $4M annual operating budget, PPCO is the region's largest provider of preventive reproductive health care for low- to moderate-income persons. We are regarded as the low-cost, quality source for preventive health care serving those in need including uninsured, underinsured and persons in transition between jobs and/or between school and work. For 75 years, we have responded to changing and growing community needs and are guided by our core principle: to maintain access to nondiscriminatory and confidential quality health care for all regardless of income, race, gender, ethnicity and/or lack of information.

Because the Title X program funding has not kept pace with inflation or the escalating costs to deliver health care, over the past several years, PPCO has had to consolidate Title X sites in order to serve the largest numbers of patients with the least amount of site overhead expenses. In addition, beginning 2004, Ohio's state family planning funding earmark was redirected to broader "women's health" outcomes and to local health departments—many of whom who are without the capacity or expertise to provide gynecological care. However, because of PPCO's commitment to access, we continue to operate two of our five health centers without Title X funding. Reduced fees are supported by individual, corporate and foundation fund-raising, patient contributions, community grants and events.

Annually, PPCO serves about 18,000 unduplicated patients logging more than 28,000 medical visits for reproductive health care. Only 8,200 of these clients and 13,000 visits are served through Title X sites. Core preventive health services include pelvic/breast exams, pap smears, STD testing and birth control information and supplies. We offer a one-stop access point for patients in need of birth control information, health care exams and supplies.

Without access to low-costs contraceptives, PPCO would be forced to close two sites and/or discontinue preventive health care services. These sites are located in the near north and near east areas of Columbus—areas that rank 3rd and 4th as areas of great need in central Ohio (the Title X sites serve those that rank 1st and 2nd). This means that as many as 9,800 low-income patients and about 15,000 medical visits would go unserved/unmet. The majority of the patients could not otherwise afford the health services—particularly oral contraceptives—that we provide.

The North and East Health Centers serve those women and men who are not eligible for or choose not to seek or travel to Title X-funded services but for whom market rate health care is

unaffordable and/or unavailable. But for the discounted pharmaceuticals purchased by PPCO, these women could not obtain these products and the existing Title X system could not absorb them.

In fact, while these sites operate at significant losses, PPCO's North and East Health Centers have been able to serve women in need of low-cost reproductive health care services for three reasons:
1) Based on contraceptive volume and client need, we have historically been able to purchase oral and other contraceptive drugs from manufacturers willing to provide them at nominal prices,
2) To date, we have been able to raise funds to meet the gap between modest patient fees and our cost to deliver services/contraceptives, and
3) We are committed to providing reproductive health care to those in need.
In addition, PPCO has established and invested in multiple health center sites, significant technology and medical infrastructure, and employs committed personnel. The agency utilizes delivery models that are efficient and effective in serving those in need. However, fund-raising cannot begin to underwrite anything other than nominal contraceptive costs.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Three of Planned Parenthood of Central Ohio's five health centers are Title X clinics and therefore 340B covered entities. Their ability to purchase oral contraceptives at very low prices is assured. Because of limited Title X grant resources, PPCO's North and East Health Centers are not federally funded. Therefore, even though PPCO is a recipient of Title X funds, these two sites at present do not qualify as 340B covered entities.

PPCO's North and East Health Centers serve as a vital safety net provider to our community. Our ability to continue to provide health care at these sites rests with our ability to purchase contraceptive drugs at nominal prices. However, the Centers for Medicare and Medicaid Services (CMS) did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule.

Clearly reducing access to affordable, preventive health care for low-income persons is not the intent of the Deficit Reduction Act nor is it good public policy.

We sincerely hope that the Centers for Medicare and Medicaid Services (CMS) will reconsider and exercise its authority to name "other safety net providers" that would be eligible to purchase drugs at nominal prices without affecting the best price calculation. PPCO is clearly a 75-year safety net health care provider and we strongly urge CMS to include in its definition of safety net providers nonprofit health centers like ours.

Respectfully submitted by,

Lisa G. Perks
Executive Director
Planned Parenthood of Central Ohio
206 East State Street
Columbus, Ohio 43215

Submitter : Derek Holyfield **Date:** 02/20/2007

Organization : Duncan's Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1216-Attach-1.RTF

#1216

February 20, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and co-owner of Duncan's Pharmacy, a community retail pharmacy located at 137 South Main Street in Dyer, Tennessee. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

In my opinion, the proposed changes will have an incredibly detrimental effect to our health care system. In this day and age where large retail chains and PBMs attempt to cheapen patients' lives in order to make a quick profit, community pharmacists carry out prescription orders from doctors, dentists, and other health care professionals with the intention of ensuring the patients' health and well being. If the changes continue without further modification, it is inevitable that many community pharmacies will be forced to close because reimbursement for medication would not cover the acquisition cost that pharmacies like mine are paying.

Before I became co-owner of a community pharmacy, I worked at a large chain where the basic rule was "make them wait for their prescriptions so they will go buy something else." I quickly learned that I did not want to be a part of this organization for the rest of my career. These large chains are able to purchase larger quantities at a lower price, yet still charge prices that are often more than most community pharmacies. The chains and PBMs only have one thing in mind and that is profit.

The lives of thousands of my patients, as well as millions of other patients at community pharmacies across the nation, will be directly impacted if these changes proceed as written.

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy where over 90% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Derek Holyfield, Pharm. D
126 Nancewood Drive
Alamo, Tennessee 38001
731-696-3288
731-692-3578 Duncan's Pharmacy

cc: Senator Lamar Alexander
Senator Bob Corker
Representative John Tanner

Submitter : **Mr. Michael Farmer** **Date: 02/20/2007**

Organization : **Farmer's Prescription Shop**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,
My family owns 3 pharmacies in Barrow and Oconee counties in Georgia.I steadfastly disagree with the new definition of AMP that is scheduled to be implemented later this year. I echo 100% the sentimenmts expressed by NCPA and the possible extinction of the independant community pharmacy due to fiscal damage from the proposed reimbursement cuts.These changes in payment methodology make no sense, because a pharmacist is paid more for brand pharmaceuticals than less expensive generic medications. Pharmacists have the ability to manage costs if given the chance. The health care infrastructure of Medicaid patients throughout the country does need an overhaul, but there are other ways to achieve this. This new definition of AMP will cause many pharmacies, including mine, to seriously consider disenrolling in Medicaid pharmacy programs. If massive losses in community pharmacy providers occur, you will spend twice these proposed savings in ER and hospital costs. Thank you for your consideration.

Sincerely,
Michael Farmer
Farmer's Prescription Shop
232 E. Broad St.
Winder, Ga. 30680
770-867-9072

Submitter : Dr. Jennifer Hagen **Date:** 02/20/2007

Organization : Wolff's Mushel Health Mart Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Seriously, does the service community pharmacy has to offer mean nothing? In the past two weeks I have referred two people to the clinic one of which needed to be admitted and one which needed medication right away. I helped a person with the flu seek out Tamiflu and start appropriate OTC medication. I helped people with stomach flu, people who couldn't go to the bathroom and referred someone with ringworm. I did two MTM cases and made therapeutic changes which will save insurance several hundred dollars. I picked up a new patient who needed a pharmacy enrolled in a Tikosyn program because Walmart was too busy to enroll and help this person out. These are just some of the extra things I have done in the past few weeks. I fear that if the government does not recognize the service that community pharmacists provide that someone will have to pick up these costs and services, probably at the expense of loss of quality of life or increase in doctors visits and finally medicare dollars.

I work in Little Falls, MN and the effect of lower reimbursement will put Wolff's Mushel Drug out of business, we just can't compete with mail order and large corporations. The owner has taken out a line of credit just to stay in business and get past this first phase of poor Part D reimbursement. I fear he may need to close if things don't get better.

Even though I don't get paid as much as other pharmacists at big corporations I choose to work in community pharmacy because of what I can do for people. I am the last stop in the health care team and I take the time to answer questions that the physician may not have had time for. I like helping people and putting my six year degree to work.

In a few months there will be a super Walmart in Little Falls and Walgreen's has already purchased land and is projected to be completed within two years. If our pharmacy closes it will be hard on the elderly population some of whom have expressed that they don't want to have to go to a store where the have to walk a mile from the parking lot to the pharmacy only to wait for an hour to get their medicine.

Please reconsider the definition of retail pharmacy which will be used in the calculation of AMP and please consider a fair dispensing fee that reflects the actual cost of providing a full range of professional services.

Submitter : **Carole Ray** **Date: 02/20/2007**

Organization : **Carole Ray**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please explain how a pharmacy is suppose to survive and stay in business at 36% below acquisition cost.....The amp reimbursement will put all the independent pharmacies out of business....the rural areas of Georgia would have nowhere to go without the independent pharmacy...they open account and hold tickets until they have money but no one can do this at 36% below the cost of the medication...

Submitter : Ms. Judith Cahill **Date:** 02/20/2007

Organization : Academy of Managed Care Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

The Academy of Managed Care Pharmacy (AMCP) is pleased to have the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Medicaid Program; Prescription Drugs; Proposed Rule.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to achieve positive patient outcomes. The Academy's 5,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

GENERAL

GENERAL

The Academy's comments on specific items within the proposed rule appear on the attachment.

CMS-2238-P-1220-Attach-1.DOC

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

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

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

Submitter : **Mr. mike latif** **Date: 02/20/2007**

Organization : **Benuellie bros**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1221-Attach-1.DOC

1221

ATTACHMENT A

MODEL COMMENTS TO CMS

SUBMIT COMMENTS TO:

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

COMMENTS DUE FEBRUARY 20th

==========

February 20, 2007

Centers for Medicare and Medicaid Services

Attention CMS 2238-P Mail Stop C4-26-05

7500 Security Blvd

Baltimore, Maryland 21244-1850

Subject: Medicaid Program: Prescription Drugs; AMP Regulation

CMS 2238-P RIN 0938-AO20

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

Our Corporation operates ___1__ pharmacies in Hawaii states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

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

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

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

Sincerely,

Mike latif

Submitter : Mr. Frank Barnes **Date:** 02/20/2007

Organization : University of North Carolina Hospitals

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment in letter format

CMS-2238-P-1222-Attach-1.DOC

#1222

February 20th, 2007

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

To Whom it May Concern:

We are responding on behalf of the University of North Carolina Hospitals to the request for comments on regulations proposed to implement the Deficit Reduction Act of 2005 ("DRA"), published in the December 22, 2006 Federal Register. The University of North Carolina Hospitals is a 700 bed teaching hospital located in Chapel Hill, North Carolina, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program.

We have a number of concerns about the proposed regulations. As a general comment, the proposed guidelines do not recognize the widely-established realities of U.S. hospital care, especially the fact that hospital services are integrated into wider health care systems incorporating a mixture of hospital and clinic services and utilizing different organizational structures with common ownership at the healthcare system level. Recognition of this fact of healthcare organizations would probably remove most problems associated with the proposed regulations. Three specific concerns about the regulations are discussed below.

First, the proposed regulations would create extremely onerous financial and administrative burdens for our hospital by requiring the reporting of NDC information for drugs administered in hospital outpatient settings ("clinics"), for the following reasons:

a. The requirement appears pointless since 340B hospital clinic-administered drugs are exempt from rebates (section 1927(j)(2) of the Medicare statute applies). If no rebates will be obtained, what is the point of all the expense and disruption which will occur in order to achieve no end?
b. Hospital electronic billing systems do not presently have the capability to include NDC numbers identifying clinic-administered drugs. It would require a very substantial investment to change the institution's electronic financial systems to allow inclusion of the NDC number and to perpetuate it throughout all the pathways required to achieve the CMS objective.
c. The clinics where the drugs are administered are located some distance from the offices where the UB-92 billings actually take place. There is no simple way to communicate the NDC number of the drugs being administered by the clinic staff, to the billing office.

d. Frequently, a multi-drug cocktail is administered and this has but one entry on the UB-92. Which NDC should be used?
e. The UB-92 billing document, mandated by the Federal Government, has no place on it where an NDC can be entered.
f. The NDC cannot reliably be entered by the billing staff since they have no idea which NDC was used. Any given drug might have several NDC's corresponding to several brands on the shelf at one time so it is not possible for a remote staff member to know which was used.
g. The system, as proposed, is rife with the potential for error, placing hospitals at risk of audit penalties for attempting to comply with a system that is burdensome, poorly conceived and which defies the best effort of the staff to comply with it.
h. Finally, we consider it highly speculative that the 15-second CMS estimate will suffice to allow all the above factors to be considered, and the drug's NDC to be determined and entered onto the billing document.

Second, the proposed policies would substantially decrease the savings this hospital receives through use of 340B-priced drugs in the clinic, since if the State insists on filing for rebates from the manufacturer, we would have no alternative but to cease using the 340B program. This would cost the hospital approximately two million dollars in increased drug expense which would in turn limit our ability to expand services to the poor and indigent, which is precisely what the 340B program was enacted to accomplish. Again, it is our interpretation that section 1927(j)(2) of the Medicare Statute intends to exempt hospital-based clinics from rebates.

Third, the proposed changes to the rules related to the treatment of prompt pay discounts used in computing Average Manufacturer Price ("AMP") could raise the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers (e.g., Children's Hospitals) eligible for nominal pricing. We estimate that inclusion of the prompt pay discounts in the AMP calculation would cost us an additional $110,000 in drug expense and this can have no other effect than to make it more difficult to provide care to indigent patients and disadvantaged children.

We hope that the problems mentioned above will cause serious consideration to be given to the proposed regulations and that they will be revised in such a manner as to not harm DSH hospitals and to not invalidate the intention to assist indigent patients Congress demonstrated when it passed the Veteran's Health Care Act of 1992 which established the 340B program.

Sincerely,

Gary L. Park President	John P. Lewis Senior Vice President Chief Financial Officer	James C. Mcallister, III Director of Pharmacy	Frank Barnes Pharmacy Business Manager

Submitter : Mr. Tom Myers **Date:** 02/20/2007

Organization : AIDS Healthcare Foundation

Category : Other Health Care Provider

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

DS HEALTHCARE FOUNDATION COMMENTS FOR DOCKET CMS-2238-P PRESCRIPTION DRUGS February 20, 2007 To Acting Administrator Leslie Norwalk: Please see attachment Tom Myers General Counsel AIDS Healthcare Foundation 6255 W. Sunset Blvd., 21st FL Los Angeles, CA 90028 323-860-5259 tomm@aidshealth.org

GENERAL

GENERAL

see attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

AIDS HEALTHCARE FOUNDATION

COMMENTS FOR

DOCKET CMS-2238-P

PRESCRIPTION DRUGS

February 20, 2007

To Acting Administrator Leslie Norwalk:

Please see attachment

Tom Myers
General Counsel
AIDS Healthcare Foundation
6255 W. Sunset Blvd., 21st FL
Los Angeles, CA 90028
323-860-5259
tomm@aidshealth.org

CMS-2238-P-1223-Attach-1.DOC

CMS-2238-P-1223-Attach-2.DOC

#1223

AIDS HEALTHCARE FOUNDATION

COMMENTS FOR

DOCKET CMS-2238-P

PRESCRIPTION DRUGS

February 20, 2007

To Acting Administrator Leslie Norwalk:

AIDS ("AHF") is exactly the kind of organization, treating exactly the kind of Medicaid patients, which the proposed Medicaid pharmacy reimbursement levels will most hurt. AIDS Healthcare Foundation operates precisely the kind of small pharmacies, in low-income areas with high concentration of Medicaid beneficiaries, upon whom CMS states it cannot quantitatively estimate the effects of the proposed regulations. Pursuant to CMS' request for "any information that may help us better assess the effects before we make final decisions," AHF submits these comments:

AHF is a non-profit organization that provides medical care and advocacy to Americans with HIV/AIDS regardless f ability to pay. It is the largest private provider of such care in the United States, treating over 17,000 people with HIV/AIDS annually in 12 outpatient clinics in California and Florida. Consistent with its mission and nonprofit status, the vast majority of AHF's patients are low income, and are insured either through Medicaid or the Ryan White CARE Act, or have no insurance or means of payment.

In order to better coordinate and improve the care of these patients, AHF has established pharmacies many of its clinics. In this way, doctors can better communicate with the pharmacists, patients can more easily obtain their medications, and the pharmacists have unique, specialized training in AIDS pharmacy issues. Many of AHF's clinics and pharmacies are in low income and/or underserved geographic areas. Many of AHF's pharmacies participate in the 340B drug price program for eligible patients, a program designed to provide relief and access to pharmaceutical therapy to underserved populations receiving primary health care from safety net primary care providers.

Because AHF's pharmacies are located within clinics, and are geared solely to serve the health needs of people with HIV/AIDS, the sole source of revenue for the clinics is the sale of drugs. There are no food sales, no cosmetics, magazines, etc. Moreover, these pharmacies are by and large within AHF's outpatient clinics, and are not storefront establishments accessible by the general public. AHF's client base is necessarily and deliberately limited to promote patient adherence to medication regimens, and HIV/AIDS confidentiality for the very targeted population. In addition, any excess revenue generated by the pharmacies is put back into fulfilling AHF's nonprofit mission.

In 2005, AHF's pharmacies had approximately $56 million in revenue; nearly **half** of that came from Medicaid patients. AHF's margin on this revenue is approximately 7%.

In short, AHF's pharmacies are set up to serve those most in need of Medicaid covered services – low income people living in underserved areas, who suffer from a highly complex disease that is fatal if not treated properly. The existence of AHF's pharmacies, with their expertise in serving this population, frankly is the epitome of Medicaid's goals of eliminating financial barriers to medical care, and guaranteeing that Medicaid recipients receive equal or even better care than people with private insurance.

Ironically and unfortunately, the proposed regulations regarding pharmacy reimbursement will completely undermine this care, as the impact on pharmacies like AHF's, which do the bulk of the very difficult, complex care that many Medicaid recipients require, will be enormous.

It is unclear what study CMS did regarding the effects of these regulations on the Medicaid populations served by these pharmacies, in terms of numbers, acuity, complexity of health conditions and pharmacy needs. In fact, it appears that CMS has done very little study of the impact of these regulations on the pharmacies themselves, stating in the rulemaking guidance that it is

> **Unable to quantitatively estimate effects [of the rules] on small retail pharmacies, particularly in low-income areas.**

While CMS may unable to estimate this, the General Accounting Office has recently issued a report finding that the proposed rules could cut pharmacy reimbursement by an average of **36%** for multiple source drugs. While AHF understands that CMS disputes the GAO's findings, it is clear that the impact of these rules will be large.

This impact will be particularly hard on pharmacies like AHF's. As CMS has noted, the impact of these regulations on chain, supermarket, and other pharmacies will be small, because these entities do not rely on drug sales as their primary source of revenue, and have large and diverse payors, meaning Medicaid revenue is one small part not only of drug sales, but of entire store revenues.

This is not the case for pharmacies like AHF's, where almost 50% of **total revenue** is generated by Medicaid. Even a 10% cut in Medicaid reimbursement will decimate AHF's margin, and render it pharmacies non-viable. Low-income populations throughout California and Florida will lose this valuable resource, and the quality of healthcare available in these areas of high Medicaid beneficiary populations will suffer. It need hardly be mentioned that even a slight decrease in the health of someone with a potentially fatal disease such as HIV/AIDS will cause a disproportionate increase in the

use of health care services, which will wipe out a great deal of the anticipated savings emanating from these regulations.

The regulations need to recognize the unique status and role of pharmacies like AHF's. A "one size fits all" approach clearly will not work. AHF proposes two solutions.

First, more State flexibility is required to address the unique, local situations of pharmacies like AHF's. One way to do this is to allow a greater degree of autonomy on state fill fee reimbursement. The impact on pharmacies like AHF's cannot be mitigated by an increase in state-set dispensing fees as envisioned by the regulations. 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.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies like AHF's 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.

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 like AHF's 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. This is especially true, and especially vital, when dealing with a complex disease like HIV.

Second, the language of the proposed regulations need to be changed to clarify that States still set reimbursement and fill fee rates for single source drugs. As most AIDS drugs are single source drugs still under patent, and as the cost of these drugs is by far the single largest cost of treating AIDS, this clarification is extremely important.

The proposed 42 CFR Section 447.512(b) does not make clear which "agency" will determine the price and fill fee for "other drugs," including single source drugs. In contrast, proposed 42 CFR Section 447.514(b) specifically sates that CMS will determine the AMP, and the "State agency" still determine the fill fee for multiple source drugs. The ambiguity in Section 447.512(b) should be eliminated.

Sincerely,

Tom Myers
General Counsel
AIDS Healthcare Foundation
6255 West Sunset Blvd., 21st FL
Los Angeles, CA 90028
323-860-5259
tomm@aidshealth.org

Submitter : Mr. Fred Brown **Date:** 02/20/2007

Organization : Miller's Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a retail Pharmacist working in a independant pharmacy serving a small rural farming&manufacturing community.

Collection of Information Requirements

Collection of Information Requirements

Average Manufactures Drug Prices

GENERAL

GENERAL

Please see response to comments above

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Government's own studies

Regulatory Impact Analysis

Regulatory Impact Analysis

The average price for retail purchased drugs should be determined by the average price "retail pharmacies" have to pay for them. The average price should not include discounts that are available to hospital-nursing homes-mail order pharmacies- and the government as they are not working at the retail level and con not recieve those discounts and rebates.

Submitter : Ms. Tina Welsh **Date:** 02/20/2007

Organization : Women's Health Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS-2238-P

Dear Administrator Norwalk:

I am the Executive Director of Women's Health Center, a reproductive health care clinic headquartered in downtown Duluth, Minnesota. My non-profit organization provides a wide range of reproductive health services, including annual exams, affordable birth control, sexually transmitted disease testing and treatment, pregnancy tests and breast and cervical cancer screening.

Women's Health Center has been open for 26 years. We operate family planning clinics in Duluth and five northern Minnesota counties. Last year, Women's Health Center provided care 1,524 patients, one third of who live below 200% of the federal poverty level. Women's Health Center operates a sliding-fee scale for services and supplies which is based on cost and on the individual's ability to pay as determined by their family size and income. We do not charge for family planning patients that are below 200% of the federal poverty level.

Essential to Women's Health Center's ability to serve low-income women has been the ability to purchase contraceptive drugs from manufacturers willing to provide them at nominal prices. If we are no longer able to do this, Women's Health Center will face significant financial difficulties and may be faced with deciding whether or not to continue to serve low-income patients. An additional challenge to our patients in Cook County Minnesota is that there is only one pharmacy in the entire area, therefore their access to contraceptives is extremely limited.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Women's Health Center is not federally funded and therefore does not qualify as a 340B covered entity. Nonetheless, we are an essential safety net provider in our community.

I strongly urge the Centers for Medicare and Medicaid Services (CMS) to exercise its authority to name 'other safety net providers' that would be eligible to purchase drugs at nominal prices without affecting the best priee calculation. It is vitally important to northern Minnesota women and families that 'safety net providers' be defined by CMS and that the definition includes clinics like Women's Health Center. It is essential that clinics like ours be able to provide low-cost birth control pills to patients who are financially unable to purchase them at market prices.

Thank you for your time and assistance in this urgent matter.

Respectfully submitted by,

Tina Welsh
Women's Health Center
32 East 1st Street
Suite 300
Duluth, MN 55802

Submitter : **Mr. Andrew Peterson** **Date: 02/20/2007**

Organization : **Peterson Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

CMS is considering revising formula for deteriming generic drug payment to pharmacies.

Collection of Information Requirements

Collection of Information Requirements

The new Payment formula is based on "AMP".

GENERAL

GENERAL

The new basis for generic drug payment is not adequately defined to insure that small pharmacies like mine will be reimbursed adequately to remain in business. There is no assurance that medications can be purchased by pharmacies at the low payment levels proposed by CMS.

This payment scheme needs to be re assessed and implementation delayed until a mechanism is established to allow profitability by small community pharmacies.

Submitter : Mr. Barry Christensen **Date:** 02/20/2007

Organization : Alaska Pharmacists Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1227-Attach-1.DOC

#1227

Alaska Pharmacists Association

VIA Electronic Submission

March 3, 2007

Leslie Norwalk
Acting Administrator
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

Dear Ms. Norwalk,

The Alaska Pharmacists Association(AKPhA) represents over 200 licensed pharmacists, pharmacy technicians, and pharmacies in the State of Alaska. On behalf of our membership we are writing to express our deep concerns with the Center for Medicare and Medicaid Services'(CMS) proposed payments for prescription drugs in the Medicaid program. Our comments will likely mirror those expressed by other pharmacy associations but will also include specific details of how we feel the changes will impact smaller pharmacies in our State.

Definition of "Retail Class of Trade"-Removal of PBMs and Mail Order Pharmacies and calculation of AMP

Mail order pharmacies should not be included in the definition of retail pharmacy class of trade for the purposes of determining AMP. Although mail order pharmacies serve consumers on a retail level their dispensing rate, per day (purchases), are many hundreds-times larger than a community based retail pharmacy allowing them to buy at a lower cost; a cost not available to a community based retail pharmacy. Therefore, inclusion of mail order pharmacy drug purchase pricing in the calculation of AMP will lower the reimbursement to community pharmacies below their cost of the drug.

PBM rebates, discounts or other price concessions should not be recognized in the calculation of AMP. PBMs are not distributors of drugs to retail pharmacies; they do not buy, warehouse nor do they deliver pharmaceuticals to retail pharmacies; they do not act as wholesalers. Retail pharmacies do not share in rebates, discounts or other price concessions that PBMs have negotiated.

E-mail: akphrmcy@alaska.net

4107 Laurel Street, Suite 101 • Anchorage, Alaska 99508 • (907) 563-8880 • (907) 563-7880

It is incorrectly assumed that retail pharmacies share in the cash discounts and other price reductions from a manufacturer for drugs purchased by wholesalers and eventually distributed to retail pharmacy, and therefore inappropriate to include such cash discounts and price reductions in the calculation of AMP.

Rebates paid by the manufacturer to the PDP or MA-PD should not be included in the calculation of AMP. Rebates paid to health plans are, generally, incentives to include the manufacturer's drug on a plan formulary. Manufacturer rebates paid to PDPs or MA-PDs are not considered by a wholesaler when determining the purchase price to a retail community pharmacy and, therefore, should not be included in any calculation to reimburse the pharmacy.

Sales and rebates associated with the sales to patients through direct programs should not be included in the calculation of AMP for pharmacy reimbursement. Manufacturers' patient assistance programs bypass wholesalers and pharmacies and are often greatly discounted for patients who meet the manufacturer's low income criteria for the discount or rebate programs.

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.

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, Alaska 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.

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.

E-mail: akphrmcy@alaska.net

4107 Laurel Street, Suite 101 • Anchorage, Alaska 99508 • (907) 563-8880 • (907) 563-7880

Effects on Small Retail Pharmacies

Nearly one-third of all community retail pharmacies in Alaska are considered small retail pharmacies by SBA standards. The proposed rule recognizes that these pharmacies would be directly impacted by the proposed AMP regulations but concludes that "we are unable to specifically estimate quantitative effects on small retail pharmacies". Many of our small Alaskan retail pharmacies are located in rural low income areas that serve high concentrations of Medicaid patients. The proposed rule dictates the Federal Upper Limit(FUL) for a generic drug will be based upon 250% of the lowest AMP for all versions of that generic medication. However, a December 22, 2006 report by the GAO indicated that retail pharmacies will be reimbursed on average 36 percent lower than their **COST** to purchase the medications. This change would clearly put pharmacies at risk of staying in business and would also create a disincentive to dispense generic medications.

In conclusion, the proposed payment formula will be devastating to many community Alaskan retail pharmacies, Alaska Medicaid patients, and the financing of the Medicaid program itself. The Alaska Pharmacists Association asks you to carefully consider all comments received on this matter and please contact us with any questions.

Sincerely,

Barry D. Christensen, Pharmacist
Co-Chair Legislative Committee
Alaska Pharmacists Association

CC: Senator Lisa Murkowski

E-mail: akphrmcy@alaska.net

4107 Laurel Street, Suite 101 • Anchorage, Alaska 99508 • (907) 563-8880 • (907) 563-7880

Submitter : Dr. Laura Tyson **Date:** 02/20/2007

Organization : Dogwood Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am honored to fill prescriptions for many Medicaid recipients in South Georgia on a daily basis. However, if new regulations go in to effect, it is my understanding that in order to serve these patients, I will have to lose money on every prescription. I have only been open for business for 7 months and am working hard at providing excellent care for anyone that needs it. Unfortunately, health care costs continue to rise and I have to be concerned about "breaking even". A cut in profit is not the primary concern. The ability to keep the doors open is. The Chain Pharmacies do a great job at filling prescriptions at cut rate prices, but the care is also cut rate. I do more than just fill a prescription and the Medicaid recipients of South Georgia will have to suffer if the new provision goes into effect.

Submitter : Mr. Alan Shepley **Date:** 02/20/2007

Organization : Shepley Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

2) Define AMP to Reflect Retail Pharmacy Purchasing Costs: CMS' proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires. Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade. In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.

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

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

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) and others regarding this proposed regulation.

Thank you.

Sincerely,

Alan M. Shepley R.Ph.

CMS-2238-P-1230

Submitter : Dr. Terry Forshee **Date:** 02/20/2007

Organization : Cherokee Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Cherokee Pharmacy a community retail pharmacy located at 2850 Westside Dr NW, Cleveland, TN 37312. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

Collection of Information Requirements

Collection of Information Requirements

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy, where over 85% of our business comes from prescription drugs. What the other sales in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

GENERAL

GENERAL

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions. The future of independent pharmacy in this country depends upon your strong consideration of this issue. We as independent pharmacists provide a valuable service that saves our health care system billions of

dollars each year by being the final checkpoint before patients receive their medications. We have always fought very hard to implement positive changes in our profession as witnessed by our commitment to Medicare Part D. Please allow us the opportunity to continue to compete and practice in our communities. We have held off the major chains, discount stores, mail order (in spite of regulations that give them unfair purchasing advantages), PBM's (who have been proven to provide no price savings or any other advantage to the health care system other than to siphon money into their coffers) and even Medicare Part D which in its design benefits PBMs and drug manufacturers more than patients. Now, it is up to CMS to make sure fairness is built into this new reimbursement model. Please let us help you!

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Use of 11-Digit NDC versus 9-Digit NDC

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