CMS-2238-P-330

Submitter : **Mr. Richard De Vere** **Date: 02/09/2007**

Organization : **Dismukes Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Under the proposed reimbursement regulations outlined in this proposal, I will have to take one of two actions. I will either have to discontinue my participation in the medicaid vendor drug program or I will have to close the pharmacy entirely. Since 90% of We must be reimbursed at a fair price for our products and services or all of us will suuffer.

Submitter : **Mr. steven nelson** **Date: 02/09/2007**

Organization : **Okeechobee Discount Dugs and Big Lake Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Pharmacy Owner for over 25 years, In the profession for over 37 years. Extremely active in the community and served on over 15 boards.Only Pharmacy in Okeechobee County to provide delivery service to shut ins.

Collection of Information Requirements

Collection of Information Requirements

AMP reduction on reinbursement on prescriptions. Particularly generic drugs.

GENERAL

GENERAL

Please reversc this bill, and get off the backs of pharmacy. Go after thc PBM's/Insurance companies and drug manufactures who are making record wind fall profits. All us to make a "fair and descent" living!!!

Response to Comments

Response to Comments

Would drive us out of business.

Submitter : **Thomas Cory** **Date: 02/09/2007**

Organization : **Standard Pharmacy**

Category : **Drug Association**

Issue Areas/Comments

Background

Background

Adjusted Medicaid Reimbursement to Pharmacies

Collection of Information Requirements

Collection of Information Requirements

Redefine AWP

GENERAL

GENERAL

See Attachment - failure to make adjustments to the proposl cluld result in dcminished accessibility of the Medicaid population

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See GAO Report - Talk to a community pharmacist

CMS-2238-P-332-Attach-1.PDF

CMS-2238-P-332-Attach-2.PDF

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

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

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

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

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

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

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

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

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

> than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006." -GAO-07-239R p.4

This finding validates community pharmacy's contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates

AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. **AMP was never intended to serve as a baseline for reimbursement,** and may not have been an effective measure for manufacturer rebates as outlined in the report "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States" (GAO-05-102).

However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in "Best Price" but should not be included in AMP.

An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

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

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

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

AMP Must Be Reported Weekly

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

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

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

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

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

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

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

CMS discusses impact on pharmacy:

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

Impact on small pharmacies demonstrated by GAO findings

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

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

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

Summary of Key Points:

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

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

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

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

Submitter : **Mr. Dennis Foreman** **Date: 02/09/2007**

Organization : **Wal-Mart Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Administrator Leslie Norwalk, I would like to make some comments on the pending definition of AMP for retail pharmacy medicaid reimbursement.

Collection of Information Requirements

Collection of Information Requirements

1. The formula for AMP-based Federal Upper Limits (FUL) in the proposed rule will not cover pharmacy acquisition costs for multiple source generic medications. 2. AMP was never intended to serve as a basis for reimbursement. 3. To be an appriopriate benchmark, AMP must be difined to reflect actual cost paid by retail pharmacy. This will be accomplished by 1. Excluding all rebates and price concessions made by manufacturers which are not available to retail pharmacy. 2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible the way that brick and mortar pharmacies are publicly accessible. 3. Reporting AMP at 11 digit NDC level to ensure accuracy on a weekly basis. 4. Employ a complete definition of cost to dispense which on average is $10.50.

CMS-2238-P-334

Submitter : Mr. STUART FELDMAN **Date:** 02/09/2007

Organization : CROSS RIVER PHARMACY

Category : Pharmacist

Issue Areas/Comments

Background

Background

REIMBURSEMENT

GENERAL

GENERAL

I DON'T KNOW HOW MUCH LONGER WE CAN HOLD ON. FORTUNATELU WE ARE IN A RELATIVELY HIGH INCOME BUSINES ARE AND DO A RELATIVELY SMALL % OF MEDICARE RX'S..HOWEVER MY MAJOR FEAR IS THAT IF THE GOVT ALLOWS THE SEVERE DOWNWARD SPIRAL OF PHARMACY REIMBURSEMENT VIA THE WAC FORMULA IT WILL NOT BE VERY LONG BEFORE ALL OF THE PROVATE PBM'S FOLLOW SUITE. IT WILL THEN BE IMPOSSIBLE TO CONTINUE TO DO BUSINESS AS THE ONLY COMMUNITY PHARMACY IN OUR AREA. THE GOVT NEEDS TO TAKE A LOOK AT THE REAL COSTS OF DOING PHARMACY BUSINESS, STOP SELLING OUT TO THE BIG PLAYERS AND LISTEN TO THOSE WHO ARE PROVIDING HEALTH CARE.

Submitter : **Mr. Charles Moore** **Date: 02/09/2007**

Organization : **Charlie's U-Save Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The use of AMP as currently defined as the basis for the reimbursement of the cost of generic drugs for Medicaid patients will reduce payment for those drugs to a level where my pharmacy will not be able to provide them to Medicaid patients. The AMP was designed as a way for drug manufacturers to report what they are charging for their product to CMS,and is to their advantage to report the lowest prices they charge(which are NOT available to the retail pharmacy providers), since the lower the cost, the lower the rebates they have to pay. To be accurate for the retail pharmacy sector, the prices charged to classes of trade such as the VA, mail order pharmacy, and direct to the consumer programs by the drug manufacturers must be excluded from the AMP calculation. The drug manufacturers will not give retail pharmacy the same low prices, or the rebates they give to these classes of trade, and any reimbursement from CMS/Medicaid that is based on those prices will be much lower than the the net cost of goods available to my retail business. My business has already felt the impact of low dispensing fees and low reimbursement from the Medicare D drug plans(our net profit was down $40,000 from 2005, which means NO profit for 2006), and as you are well aware, the SSI disability people and senior Medicaid eligible people have been moved into the Medicare D plans. To further reduce the reimbursment for the remaining Medicaid recipients to a level where as a business man I can no longer afford to accept the Medicaid contract will limit the availability of pharmacy services to the patients in my area. My pharmacy is the only independent pharmacy in a 40 mile radius that offers not only prescriptions, but other health related services to the Medicaid clients in our area. The health needs of those patients will not be served in a timely fashion if their last remaining access to pharmaceutical care is limited by forcing independent(and chain) pharmacies to refuse Medicaid contracts, or go out of business if they accept them. I have spent all my pharmacy career trying to build a business that I could pass on to the next generation of independent pharmacists, and between Medicare D, and AMP reductions to reimbursement and am seeing all of those aspirations evaporate before my eyes! Please take into consideration the report of the GAO and the impact AMP will have on reimbursement to retail pharmacy, as well as the cost of dispensing survey information that places the national average overhead cost(not including ingredients) at $10.50 per prescription. A fair AMP figure can be arrived at, but ALL of the factors effecting retail pharmacy have to be part of the computation to make it accurate!

Submitter : Joyce MIller **Date:** 02/09/2007

Organization : Joyce MIller

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Submitter : **Mr. David Seaman** **Date: 02/09/2007**

Organization : **Community Care Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Acting Administrator Leslie Norwalk,

The proposed AMP definition under CMS-2238-P will cause great harm to the operation of my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pahrmacy to purchase the drugs we dispense. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, we will no longer be able to serve Medicaid patients. It is estimated that as defined, AMP will only cover about half the market price of generic drugs purchaed. I ask that AMP be defined so that it covers 100% of my pharmacies acquistion costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away. My pharmacy included.

Please issue a clear definition of Average Manufacturers Price that covers my pharmacies acquistion costs. The definition must be issued as soon as possible before AMP takes effect as I am concerned that it will have negative financial and social effects.

Submitter : **Date: 02/10/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower 2than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006. -GAO-07-239R p.4

This finding validates community pharmacy s contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates

AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates as outlined in the report Medicaid Drug Rebate Program Inadequate Oversight Raises Concerns about Rebates Paid to States (GAO-05-102).

However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in Best Price but should not be included in AMP.

An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

3

GENERAL

GENERAL

Small retail pharmacies are being picked on for no reason. These pharmacies are the backbone of your medicare prescription drug program. Your proposed rules will make reimbursement levels so low that these small businesses will lose money on every transaction. Large insurance companies have enjoyed double digit

growth in their profits from your program while small providers are struggling to stay in business. We are on the front lines of the health care industry and why CMS has chosen to put small pharmacies out of business is a mystery. We have given out medicine to senior citizens and low income people without getting paid. What does CMS have against us? Comments by CMS suggesting that pharmacies can make up the loss in revenue by sale of other items is ludicrous and insulting. Small pharmacies get 90 percent of thier business from prescription sales. How can they stay in business when losing money on every transaction. Why does CMS allow Large PBM companies to run its medoicare program with no intervention while scrutinizing small pharmacies to the point of irrationality. These large PBM's have been sued for shady business practices in at least 12 to 15 states. wHY HAVE YOU TRUSTED THEM WITH YOUR PROGRAM. wHY DO YOU PROPOSE TO GET 90 PERCENT OF THE MONEY FOR YOUR CUTBACKS FROM THE BACKS OF SMALL PHARMACY OWNERS WHO HAVE ALREADY SUFFERED EVERY TYPE OF CUT KNOWN TO MANKIND AND HAVE BEEN GOING OUT OF BUSINESS LIKE WILDFIRE. We have supported CMS in all thier efforts only to be cut and cut and cut and cut. Small pharmacies sometimes dispense a 500 dollar medicine for less than one dollar profit. Why are you trusting PBM's who are juggling menufacture discounts and playing the spread game to make it appear as they are saving you money when in truth they are averaging close to 20 dollars profit on every prescription while giving the retail pharmacy approximately one dollar per prescription. I ask you to reconsider these cuts and save the small independent pharmacy

Submitter : Dr. Tony Cassar **Date:** 02/10/2007

Organization : Dr. Tony Cassar

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed rate of AMP will provide margins result in pharmacies to be able to operate at best at break-even or probably result in substantial operating loses.

GENERAL

GENERAL

First, forgive me if I am not responding correctly. It is my first time.

I own an independent community pharmacy. I oppose proposed used of AMP to change reimbursement rates to pharmacies. Current state of community pharmacy is challenging at best. My margins, particularly since Medicare D implementation, have dropped dramatically compared to what I was receiving from Medicaid. We spend a substantial amount of time helping patients and doctors navigate the new Medicare plans and their formularies. We, unlike chain drug stores, make investments directly in the community by supporting community organizations and hiring locally. In addition we come in early, stay late, and deliver to clients who have difficulty with access.

Our current situation is that we simply make little or no margin at all brand name medication. For example, I provided $804 worth of medication to a patient and only received $6 margin. Hardly covering the carrying cost of such medicaiton, this was truly a losing prosition.

Instead of slashing payments for generic medication, which is what would occur with the proposed change to AMP, we should be encouraging it. Is is the use of generics that allow us to survive. Loss of indpendent community pharmacies will mean a real challenge to access in the most vulnerable communities as well as oligopolies of large pharmacy chains.

I support the review of why medication is so expensive, but reducing reimbursement to pharmacy is looking at the wrong player in the pipeline. It is like forcing gas station owners to reduce the price to consumers using price controls. Pharmacy does not control over costs of either medication or insurance to pay for them. Why isn't any concerted effort being made to take on the huge lobbying of PHARMA and the insurances. Independent pharmacy is certainly not posting the gains that you will find in these market sectors.

CMS-2238-P-340

Submitter : **Date: 02/10/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I work at an independent pharmacy where about 75% of our customers are on Medicare Part D. The problem is that the dispensing fees that we receive do not cover the costs of providing pharmacy services ...things like labor, computers, delivery services, inventory control, rent, utilities, insurance, etc. A typical $2.50 dispensing fee we receive per perscription for our typical 100 perscriptions a day doesn't even cover the labor cost of a single pharmacist, let alone any of the other costs mentioned about.

If we want quality pharmaceutical health care delivery to continue in this country, then the rules must be changed. Otherwise we will drive all the independent and community pharmacies out of business and at the same time allow record profits for health insurers, PBMs and drug manufactures.

Imagine a future without local pharmacies to provide advice, guidence, and answers concerning medication issues. The 1-800 call centers in India and China havc been great for the computer industry but not so great for the millions of American computer users.

Yes, we need to make sure that we provide drug benefits for our aging population at reasonable costs, but we also need to ensure that the future health care system we create is one that we really want. I want a future where I'll be able to go to my local pharmacy ... and I hope you do too.

Submitter : **Dr. Thomas Buford** **Date: 02/10/2007**

Organization : **Leoni Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Leoni Pharmacy is an independent retail pharmacy that has been in continuous operation for 103 years. I have owned the business since 1987. Approximately 22% of all prescriptions we fill are for Medi-Cal (California Medicaid) patients.

Collection of Information Requirements

Collection of Information Requirements

Calculation and use of AMP for reimbursement.

GENERAL

GENERAL

I implore you to reconsider the implementation of AMP in its current form. The effect on community retail pharmacy and the patients we serve would be devastating and permanent.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Information used in responding to the proposed regulations was collected from internal operating documents as well as financial statements.

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposal to include mail order pharmacy in the same class of trade as retail pharmacy is inappropriate. Mail order pharmacies are not publicly accessible like community retail stores are, and, more importantly, have access to pricing and manufacturer rebates that community retail pharmacy does not have access to. While manufacturer's commonly give rebates, these rebates have never been paid to, or received by community retail pharmacy. AMP must accurately reflect what is actually paid by community retail pharmacy for multi-source generic drugs. Perhaps mail order pharmacies should have their own version of AMP, reimbursing them at their cost. But to include their costs in retail pharmacy's AMP calculation is completely inappropriate. Additionally, AMP's must be updated weekly to be able to accurately reflect cost changes that occur on a daily basis by manufacturers. To report these changes less frequently is disregarding reality. Multi-source generic products have price fluctuations, both up and down, that necessitates weekly updates. Also, CMS must include a complete and accurate definition on the cost to dispense. The definition must include valuable pharmacist time that is required to care for medicaid patients and fill their prescriptions. This should include counseling, phone calls, faxes, e-mails, contacts with Medi-Cal and PBM's, overhead costs associated with running a business, and a reasonable profit. Business that does not remain profitable closes, thus a reasonable profit must be included in the dispensing fee definition. The GAO has stated that the currently proposed AMP calculation would result in community retail pharmacy being paid 36% below acquisition cost. No amount of dispensing fee would cover this shortfall. Both the AMP and the dispensing fee need to be realistic. All price concessions, rebates, or other discounts given by manufacturers must excluded from AMP for retail pharmacy, since community retail pharmacy is excluded from receiving these manufacturer perks. All mail-order and PBM pricing must be excluded from the AMP, as both are extended special manufacturer pricing that is not available to retail pharmacy, and mail-order pharmacies and PBM's are not publicly accessible as retail pharmacy is. AMP must be reported using the full 11 digit NDC number; using only 9 digits would not accurately reflect the cost of the drug being dispensed to the patient.

Response to Comments

Response to Comments

If CMS implements these proposals to AMP, my pharmacy's profit would decline by approximately 70%. Medi-Cal patients would no longer be profitable for us to serve, and not only would I have to stop accepting Medi-Cal patients, but because of the decrease in prescription volume, I would have to lay off employees as well. I am not sure at this point if I would be able to stay open under this scenario, but at the very least I would have to evaluate whether or not my return on investment would warrant closing my store and redeploying assets elsewhere. I find it absolutely absurd that CMS is proposing a reimbursement reduction of this magnitude while their own assesment says that the impact would be significant on small, independent pharmacies. CMS' own estimates put the 'savings' at $2 billion by 2011: this equates to the average pharmacy seeing a decrease in profit of roughly $35,000 annually. I assure you this is not a small fraction of my profit. My store is staffed appropriately right now for the number of patients and prescriptions we fill. To offset that $35,000 loss, I would have to let go two employees. With two fewer employees, we could no longer provide appropriate care for our patients. Additionally, the GAO findings show that the proposed rule would cause small independent pharmacies to lose 36% on each transaction. No business can continue when losing money on every transaction. No increase in volume can make up for this loss. There isn't 36% worth of fat to be cut out of my operation.

Submitter : **Date: 02/10/2007**

Organization :

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Reimbursments to Pharmacies

Collection of Information Requirements

Collection of Information Requirements

36% lower payments!

GENERAL

GENERAL

Less enrollment in Pharmacy Colleges, more shortage of pharmacists, rejection of state and federal funded " careless programmes" and and eventually " Death of Pharmacist" profession!

Regulatory Impact Analysis

Regulatory Impact Analysis

Currently, Independent Pharmacies are struggling hard, Centralization, forceful mail orders, big corporate's globalisation---ALL are destroying the traditional American values! Greed by the " Big Fish" will eventually lead to the "law of jungle" without social and intellectual values..a phenomenon which Europe has long ago rejected!

Submitter : **Mr. James Pennington** **Date: 02/10/2007**

Organization : **Seaside Family Pharmacy, L.L.C.**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Not completely sure of info desired for this section, but will proceed with personal "background". I am a community pharmacy owner with much at stake, thus keen interest in the way prescription reimbursements are affected by referenced docket:CMS-2238-P. I have 34 years experience in the retail drug store industry, but just 9 months as an owner of my own business. My store is small and convenient to a fairly large community of seniors and younger families (70/30 mix). We offer traditional pharmacy services to our clients including free delivery. We accept all medicare part d plans.
Our business is progressing as expected and if the trend continues we should have 2007 sales of approximatly $1.8 million (97% of that will be from prescription sales and about 90% of rx sales are from third parties such as medicare part d plans and other insurance plans). Now for the bad news. It will be very difficult for my small operation (4 employees including self) to break even in 2007!

Please see general comments.

GENERAL

GENERAL

It is obvious that my business must at least break even for me to continue to remain open and to provide what I believe is an essential service to my community So, my commentary to you is simply a request to allow me the opportunity to continue to provide service to my community and jobs for at least 4 people. How can you help?

1. Allow me and other independent pharmacy owners a level playing field. Not fair to allow rebates/discounts etc to PBMs, Ins. company pharmacies and government agencies and not to the independent business owner. Why not just get rid of the complicated and difficult to regulate rebate system (which invites or even demands conflict of interest). To the drug manufacturer...just submit your best price. If it is fair as compared to others..you will be on the formularies.

2. Regulate the PBMs and insurance companie's contracts with retail pharmacy. Currently independent pharmacies are handed a take it or leave it contract for services and have only the choice of having that business or not having it (remember, 90 % of my business is via third party contracts). Please keep in mind that these contracts are designed by companies, some of whom are under investigation in 20 or more states for using 'questionable business practices'...this a matter of congressional record.

3. Considering item #2., a GAO study recently determined that the average cost to dispense a prescription is $10.50. I would appreciate your consideration of this information when considering reimbursements for medicare/medicaid rx's. What would be wrong with a simple system (no rebates/discounts(kickbacks))that prices each prescription at net cost (*not AWP) + $10.50??? Simple to administer, regulate and oversee.

Thank you.

J.D, Pennington, Pharmacist

Submitter : Mr. Jaroslaw Palylyk **Date:** 02/10/2007

Organization : Rx Care Pharmacies Inc.

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

Background

Background

We are a long term care pharmacy servicing skilled, assisted living, and group home facilities for the mentally retarded

Collection of Information Requirements

Collection of Information Requirements

The proposed legislation and the reduction of the cost basis reimbursement to pharmacies for medicaid recipients will be devastating to both the patient as well as the pharmacies servicing those patients. The time and effort involved in filling prescriptions in special compliant unit dose packaging, checking for any interactions and finally for delivery will never ever be covered by the proposed fees and costs associated with the proposed legislation. Please reconsider the issues, speak to the pharmacy leaders across the country and the health care workers associated with the facilities serviced to understand all the issues in a much more realistic way.

Submitter : Mr. JEFF NEIDIG **Date:** 02/10/2007

Organization : MEDI-WISE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Regulatory Impact Analysis

Regulatory Impact Analysis

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

Submitter : **Dr. Anna D'Andrea** **Date: 02/10/2007**

Organization : **OPA**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

Attention: Acting Administrator Leslie Norwalk.

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

Thank you for your time,

Dr. Anna D'Andrea, PharmD

Submitter : **Mr. Mark Baychuk** **Date: 02/10/2007**

Organization : **Vitality Drugs**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I own a retail pharmacy close to Lij and Schneiders and the proposed cost will be devasting to my pharmacy. We supply services like compounding for children, which at this time is not reimbursed already, we have 2 drivers which are out all day delivering to the hospital and to the elderly in the neighborhood, we also go as far as picking up food for the elderly if needed in bad weather. We supply a large amount of surgicals, and injectables also. The cost of doing all this is enormous and the constant increase in the cost of insurance for health, vehicles and pharmacy raise as much as 18 percent per year. The cost of rent is enormous. The amount all insurances are reimbursing are steadily decreases as also you are proposing. Our utilitys increase each year also. So with all this happening to pharmacys ,does any one think a pharmacy can surive in this environment? Instead of a decrease in payments the pharmacys there needs to be INCREASES. So please stop this because the needs of all our communties will be negatively affected by this.

Submitter : **Mr. Dennis Blank** **Date: 02/10/2007**

Organization : **Mr. Dennis Blank**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

AMP has of yet been to show an accurate provider product cost. Until such, as well as how the current product basis of cost relates to the cost of service provided, it should not even be cosidered as as a new structure for reimbursement. AMP is so low, it will eliminate prescription providers, and as a net result, reduce needed drug therapy services to the public. STOP before irreversable damage is done to the society.

CMS-2238-P-349

Submitter : **wilton youngblood** **Date: 02/10/2007**

Organization : **lowe's marketplace pharmacies**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I WISH THE GOV. WOULD GO AFTER THE MANUFACTURERS FOR LOWER COSTS INSTEAD OF ALWAYS COMING TO THE RETAIL OUTLETS FOR PRICE CUTS. IT COSTS US ABOUT $9.44 TO ACTUALLY FILL A RX TODAY. IT IS DIFFICULT FOR US TO OBTAIN DRUGS FROM COMPANIES OUTSIDE THE LARGE WHOLESALERS, SO IT MAKES IT DIFFICULT TO BUY AT SOME CHEAP-CHEAP GENERIC PRICE. THANKS, W.E. YOUNGBLOOD DIRECTOR OF PHCY OPERATIONS LOWE'S MARKETPLACE PHARMACIES.

GENERAL

GENERAL

SEE BACKGROUND

Submitter : **Mr. Timothy Kirk** **Date: 02/10/2007**

Organization : **Bedford Pharmacy, LLC**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Submitter : Mr. scott palmer **Date:** 02/10/2007

Organization : A & P PHARMACY, INC

Category : Pharmacist

Issue Areas/Comments

Background

Background

GOVERNMENT NEEDS TO UNDERSTAND THAT THE COST OF FILLING A PRESCRIPTION GOES WELL BEYOND THE COST OF THE DRUG. EACH PHARMACY MUST EMPLOY ANCILLARY STAFF TO WAIT ON THE CUSTOMER, TO ANSEWER THE PHONE, TO FAX AND PHONE THE DR. FOR CLARIFICATION, REFILL REQUESTS, AND INSURANCE ISSUES. THE PHARMACIST MUST HAVE TIME TO COMMUNICATE WITH THE CUSTOMER TO MAKE SURE THEY UNDERSTND THEIR MEDICATION, IT'S PURPOSE, WHEN TO TAKE, POSSIBLE EFFECTS AND SIDE EFFECTS, AND WHAT THEY SHOULD EXPECT FROM THEIR MEDCIINE. WITH MAIL ORDER NOT HAVING TO DEAL WITH THE PUBLIC PER SE, AND PRIMARILY RELYING ON WRITTEN TEXT TO COMMUNICATE WITH THE CONSUMER, WE AT THE RETAIL LEVEL ARE LEFT WITH THE RESPONSIBILITY OF HAVING TO PROVIDE VALUBLE INTELLIGENCE TO THE CONSUMER WHILE NOT RECEIVING THE UNFAIR COST DISCOUNTS THEY DO. THEY DO NOT HAVE TO DEAL WITH INSURANCE, FOR IN FACT THEY REPRESENT INSURANCE. THE COST OF HEALTHCARE MUST TAKE INTO ACCOUNT MORE THAN JUST A SIMPLE COST OF THE DRUG.

Submitter : Dr. SUZANA GIFFIN **Date:** 02/10/2007

Organization : CENTRAL CARE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

If AMP is to accuratly serve both purposes CMS must define AMP to reeflect the actual cost paid by the retail pharmacy, excluding all rebates and price concessions not available to retail pharmacy.All rebates and price concessions are appropriatly included in "Best price" but should not be included in AMP. An accurate definition of AMP and BEst Practice will set an accurate baseline for reimbursement.This will ensure use of more affordable generics, thus saving money for the healthcare system while promoting effective patient care.
Community pharmacists as I serve not only as dispensing pharmacies, but we provide complete patient medication management and help patients, especially elederly stay compliant with their medications so they don't end up in the hospitals -thus reducing cost to CMS- also we prevent patients from harmful drug - drug interactions as we know not only their medication history, but also their entire medical history and serve as guardians for patients and a doubel check for physicians.

I ask CMS to seriously take community pharmacists comments and NCPA's comments before doing something so detrimental to our patients, our community and our country.

Regulatory Impact Analysis

Regulatory Impact Analysis

If AMP is to accuratly serve both purposes CMS must define AMP to reeflect the actual cost paid by the retail pharmacy, excluding all rebates and price concessions not available to retail pharmacy.All rebates and price concessions are appropriatly included in "Best price" but should not be included in AMP. An accurate definition of AMP and BEst Practice will set an accurate baseline for reimbursement.This will ensure use of more affordable generics, thus saving money for the healthcare system while promoting effective patient care.
Community pharmacists as I serve not only as dispensing pharmacies, but we provide complete patient medication management and help patients, especially elederly stay compliant with their medications so they don't end up in the hospitals -thus reducing cost to CMS- also we prevent patients from harmful drug - drug interactions as we know not only their medication history, but also their entire medical history and serve as guardians for patients and a doubel check for physicians.

Submitter : **Michael Krusling** **Date: 02/10/2007**

Organization : **Mike's Batavia Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am the owner operator of a small semi-rural independent pharmacy. Current proposed lesgislator will put me out of business, and will have a negative impact on my customers, especially those customers receiving medicaid services.

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : **Mr. kevin feicht** **Date: 02/10/2007**

Organization : **Mr. kevin feicht**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

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

Submitter : Mr. KEVIN GAHM **Date:** 02/10/2007

Organization : GAHM'S PHARMACY II, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

THE PROPOSED DEFINITION OF AMP UNDER CMS-2238-P PRESCRIPTION DRUGS WILL CAUSE GREAT HARM TO MY PHARMACY. IT IS ESTIMATE THAT THE REIMBURSEMENT WE WILL RECEIVE WILL BE FAR BELOW WHAT IT ACTUALLY COSTS MY PHARMACY TO PURCHASE THESE MEDICATIONS. I RESPECTFULLY REQUEST THAT CMS REDEFINE AMP SO THAT IT REFLECTS WHAT I ACTUALLY PAY FOR THE PRODUCT. IF REIMBURSEMENTS DO NOT COVER COSTS, I AND MANY OTHER RETAIL PHARMACIES MAY BE FORCED TO TURN AWAY THEIR MEDICAID PATIENTS WITHOUT MEDICATIONS THEY NEED. IN A POOR RURAL ENVIRONMENT SUCH AS MINE, THIS WOULD BE DEVASTATING TO MY BUSINESS, MY EMPLOYEES, AND MY PATIENTS. A PROPER DEFINITION OF AMP IS THE FIRST STEP TO SOLVING THE PROBLEM. I UNDERSTAND THAT THE SECRETARY OF HEALTH AND HUMAN SERVICES HAS BEEN GIVEN ALOT OF LEEWAY IN DEFINING AMP. I ONLY ASK THAT AMP BE AN ACCURATE PORTRAYAL OF PHARMACIES' TOTAL INGREDIENT COST SO THAT AN ADEQUATE REIMBURSEMENT MAY BE OBTAINED. AS IT IS CURRENTLY DEFINED, AMP IS ESTIMATED TO ONLY COVER HALF OF THE MARKET COST PAID BY COMMUNITY PHARMACIES. CURRENTLY, EACH MANUFACTURER DEFINES AMP DIFFERENTLY, AND WITHOUT PROPER DEFINITION, MEDICAID REIMBURSEMENTS WILL NOT DOVER PHARMACY AQUISITION COSTS. UNDERPAID PHARMACIES WILL BE FORCED TO TURN MEDICAID PATIENTS AWAY, CUTTING ACCESS TO NEEDED MEDICATIONS TO MANY POOR, ESPECIALLY IN RURAL ENVIRONMENTS SUCH AS MINE. ADDITIONALLY, THE CUTS WILL COME EXCLUSIVELY FROM GENERIC DRUGS, SO UNLESS AMP IS CORRECTLY DEFINED TO COVER AQUISITION COSTS, AN INCENTIVE WILL BE GIVEN TO DISPENSE MORE EXPENSIVE BRAND NAME MEDICATIONS THAT COULD ACTUALLY END UP COSTING MEDICAID MORE THAN LOWER PRICE MORE COST EFFECTIVE GENERIC DRUGS.PLEASE ISSUE A CLEAR DEFINITION OF AVERAGE MANUFACTERS PRICE THAT COVERS COMMUNITY PHARMACY AQUISITION COSTS AS SOON AS POSSIBLE, BEFORE THIS AMP STATUTE TAKES EFFECT, TO PREVENT COMMUNITY PHARMACIES FROM TURNING AWAY MEDICAID PATIENTS AND LIMITING ACCESS TO MUCH NEEDED MEDICATIONS FOR THE POOR.

Submitter : **Mr. Dale Tinker** **Date: 02/10/2007**

Organization : **New Mexico Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

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

The New Mexico Pharmacists Association (NMPhA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

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

Collection of Information Requirements

Collection of Information Requirements

?447.504 Determination of AMP
Defining Retail Pharmacy Class of Trade
Inclusion of Medicaid Sales
Discounts, Rebates and Price Concessions

?447.510 Requirements for Manufacturers.
Market Manipulation
Claw-back
Pricing Lag
Severe Price Shifts
Record Keeping

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

GENERAL

GENERAL

See attachment for comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See attachment for comments

Regulatory Impact Analysis

Regulatory Impact Analysis

See attachment for comments

New Mexico Pharmacists Association Comments

February 20, 2007

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

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

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§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set

forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

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

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

by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

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

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

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

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

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29."

Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to 1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers

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

§447.510 Requirements for Manufacturers.

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

Market Manipulation

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

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

discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

[3] §447.510(d)(2)

AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

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

Record Keeping

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

Additional Comments

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

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

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

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

Sincerely,

Dale Tinker
Executive Director
New Mexico Pharmacists Association
2716 San Pedro, NE, Suite C
Albuquerque, New Mexico 87110

cc. Members of Congress in New Mexico

Response to Comments

Response to Comments

See attachment for comments

CMS-2238-P-356-Attach-1.RTF

Submitter : **Ms. Heather Pasquale** **Date: 02/10/2007**

Organization : **CVS/pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am a Pharmacist, district manager for a chain drig store and on the Ohio State Board of Pharmacy. The proposed AMP rule will have a detrimental effect on pharmacy.

GENERAL

GENERAL

Community pharmacies, both chains and independents, will lose money on virtually every one of those prescriptions. The Government Accountability Office (GAO) says that community pharmacies will be paid on average 36% below their acquisition cost for every Medicaid generic drug prescription they fill under a reimbursement formula proposed by the Centers for Medicare & Medicaid Services (CMS). This would effectively put many pharmacies out of business! Please consider a different alternative as this will have a negative effect on pharmacies. With the increase in senior population, losing pharmacies due to loss of profits will have a negative impact on healthcare overall. We need the pharmacies to remain open. The drug manufactors make over 15% profit and community pharmacy makes 2%, why is every rule aimed at community pharmacy.

CMS-2238-P-358

Submitter : **Dr. Richard de Blaquiere** **Date: 02/10/2007**

Organization : **White Cross Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I have several general comments that pertain to this legislation.

First, I think that any part of this legislation that is based on Pharmacy Benefit Manager (PBM)data is unusable considering the nature of PBMs. These companies are continually in legal battles over their practices. This is why state governments have had to enact transparency laws in many cases. PMB's have also not lived up to their promises. In particular, PBMs have touted their ability to contain prescription drug costs. Obviously, their would not be a need for any deficit reduction measures if PBMs had actually been successful at this.

Second, This legislation is misguided. It is aimed at reducing costs from the very sector of the pharmaceutical sector that has actually saved costs. In addition, it doesn't actually reduce the cost of any drug, it simply reduces the reimbursement to the provider. While this may save the government money, it is not actually reducing price. The impact of this will be an incentive to dispense a more expensive medication and the further deterioration of prescription drug healthcare.

Submitter : **Mr. Suresh Wattamwar** **Date: 02/10/2007**

Organization : **Sure drugs**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

AMP: Payment for the prescription drugs based on proposed AMP.

Regulatory Impact Analysis

Regulatory Impact Analysis

Proposed regulation is a windfall for the closed doore pharmacies at the cost of the retail pharmacists. The formula should be based on 3 seperate catagories like Closed door pharmacies, Hospital & nursing home Pharmacies and Retail pharmacies. Each one should be reembursed based on their AMP. The market place has diffrent prices for each groups and each one should be based on their purchase prices. The other solution will be asking the manufacturrs to charge average price but same to every one like every place in the world. It is important that your desion should be based on the understanding of place of a retail pharmacy in the patients mind and the result of your action on the existance of the retail pharmacies.
Thank you.

Submitter : Mr. Kenneth Wingate, RPh **Date:** 02/10/2007

Organization : Mr. Kenneth Wingate, RPh

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

Submitter : **Mr. daniel christensen** **Date: 02/10/2007**

Organization : **pssny**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I have been practicing community pharmacy in upstate ny for 32 years. The pharmacy is progressive doing only health and wellness items. We deliver quality care and deliver to patients' homes. Medicaid clientele are a large portion ofthe business because the chains won't bother with high maintenance people and stock the little used or expensive pharmaceuticals and surgical supplies (braces home equipment) that require extra time and effort.

Collection of Information Requirements

Collection of Information Requirements

The proposed reimbursement reductions will jeopardize my job. My employer is cut to the bone now, the first thing to go would probably be home delivery... we cannot charge medicaid recipients a delivery charge! These aren't just numbers on paper, they represent peoples lives and certainly my way of life and means to make a living and pay my my taxes.....which in NY are certainly another topic. Pharmacies simply cannot stand further erosion of what little profit is available now.

Submitter : **Dr. Jarrod Grossman** **Date: 02/10/2007**

Organization : **Columbus Rx West**

Category : **Health Care Professional or Association**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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

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

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

Submitter : **Date: 02/11/2007**

Organization :

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

Pharmacists have been "on the front line" of Medicare Part D implementation. We have had to be the ones helping our customers make the decisions about which plan, the ones to explain the finer details of the plan when something doesn't go the way it was supposed to (ie higher copays, deductibles etc), and the ones having to hear all the complaints from customers about their plans. Yet, pharmacy reimbursement keeps taking a hit with lower and lower rates. We take great care of our customers and so that means having to let some prescriptions leave the store at a loss to us because our customers are loyal to us and we feel obligated to allow the loss. I feel that by continuing to cut reimbursement to pharmacies you are going to be hurting the very face of pharmacy, and eventually, there will be a downfall in the retail profession. Then who is going to monitor/help all the millions of people who depend on our advice and service. For once, don't take the cost of rising prescription drugs out on the people who only deliver the finished product to the patients. The insurance companies aren't going broke like pharmacies are, and neither are the drug companies.

Submitter : Mr. lewis glantz **Date:** 02/11/2007

Organization : stop and shop pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

the issue is note the cost submitted by pharmacys. the issue is the cost involved with pbms and the drug manufacturing industry.look at the profit the pbms are making. with todays technology the gov should have the ability to bill directly for medicar part d and eliminate the hundrerds of millions that the pbms are making. the govt should also get reductions for the drug companys for the overprice drugs

Submitter : Mr. HUGH BONNORONT **Date:** 02/11/2007

Organization : BUNNY'S PHARMACY INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

THE PROPOSED DEFINITION OF COST UNDERR CMS-2238P WILL BE LESS THAN
WHAT WE HAVE TO PAY OUR SUPPLIERS. THE DEFINITION SHOULD BE 100% OF THE NORMAL AQUISITION COST. PLEASE REDEFINE WHAT AQUISITON
COST IS.

Response to Comments

Response to Comments

MEDICAID PAYS OUR PHARMACY FOR FILLING PATIENT PRESCRIPTIONS & SUPPLIES. IF PAYMENT IS LESS THAN OUR COST WE WILL NO LONGER BE ABLE TO CONTINUE THIS SERVICE.

Submitter : Mr. TRAVIS OKULEY **Date:** 02/11/2007

Organization : OKULEY'S PHARMACY INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AMP PRICING FOR GENERIC PRESCRIPTION DRUGS WILL PUT US OUT OF BUSINESS. PLEASE CONSIDER REVISING!!! WE WILL BE FORCED NOT TO PARTICIPATE IN MEDICAID PROGRAMS. THIS WILL GREATLY AFFECT MANY OF OUR PATIENTS.

Submitter : **Mr. Richard Lau** **Date: 02/11/2007**

Organization : **Briarmill Phaarmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications.

Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.

To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will accomplished by:

1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
3. Reporting AMP at the 11-digit NDC level to ensure accuracy.

Submitter : Mrs. KIEU OKULEY **Date:** 02/11/2007

Organization : OKULEY'S PHARMACY & HOME MEDICAL

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

PLEASE REVISE AMP PRICING FOR GENERIC DRUGS. WE WILL NOT BE ABLE TO CONTINUE BEING A MEDICAID PROVIDER. THIS WILL GREATLY AFFECT MANY PATIENTS IN OUR AREA.

Submitter : **Mr. Charles Rohrbaugh** **Date: 02/11/2007**

Organization : **Sunrise Pharmacy, Inc**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I believe the idea of an AMP is acceptable. My only issue is lumping mailorder and hospital pharmacies in with retail pharmacies. The above mentioned Pharmacies receive generous price breaks from wholesalers and manufacturers alike, thus their AMP should be calculated separately from other retail Pharmacies. That would give more legitamate 'target' prices for government purposes without unduly penalizing retail pharmacy.

Retail Pharmacies are unfairly restricted by regulations that are waived for Hospital and Mailorder Pharmacies that drive the cost to dispense up, besides already paying higher prices for the drugs we sell.

I support the AMP, but only if Hospital and mailorder pharmacy pricing is removed from the equation. Thanks.

Submitter : **Brad Wood** **Date: 02/11/2007**

Organization : **Whiston Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I am mailing to regards to CMS-2238-P. I am a retail pharmacist working in an independent pharmacy which serves a very high number of both medicaid and medicare customers.

GENERAL

GENERAL

I am very much concerned that the proposed AMP-based formula will not cover even our acquisition costs for many of the multiple-source generic medications. My understanding of AMP is that it never was intended to serve as a basis for reimbursements and in order to do so it would have to be redefined to reflect the actual cost paid by retail pharmacies. Please reconsider this proposal as it certainly does not serve the best interest of the medicare/medicaid population who rely on the relationships and professional services provided by retail pharmacies or the retail pharmacies themselves who may find themselves unable to remain viable with the proposed reimbursements. Thank you.

Submitter : **Dr. James Bowman** **Date: 02/11/2007**

Organization : **Moose Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I work in rural independent community pharmacy that serves numerous Medicaid patients. Please read my general comment below and realize that such a change would either force us to stop accepting Medicaid or switch patients to brand name medications that would sky rocket the price of Medicaid more so than now.

GENERAL

GENERAL

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

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

2. AMP should not be a benchmark for reimbursement because it never reflects the actual cost of a retail pharmacy's acquisition cost. The AMP price reflects rebates paid by manufacturers to third party payers such as Medicaid, Caremark, Medco, and Express Scripts. These rebates are unavailable to retail pharmacies. The acquisition cost of mail order pharmacies owned by third party payers like Caremark and Medco are also reflected in the AMP, but should not because these pharmacies are not open to the general public and only accessible by people covered under these payers. Furthermore, mail order pharmacies are extended special prices that are not extended to publicly traded pharmacies like CVS, Walgreens, and privately owned pharmacies.

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

Respectfully,
James Bowman

Submitter : **Dr. Joseph Reina** **Date: 02/11/2007**

Organization : **J Rx Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

My name is Dr. Joseph Reina, PharmD. I am a 25 year old pharmacist. I am a graduate from St. John's University College of Pharmacy and Allied Health Professions. I am also a member of APha. I would like to comment on the proposed CMS regulation to change pharmacy re-imbursement to a formula based on AMP. I am currently opening a new independent pharmacy and it is very scary. It was always my dream to do so because I love being a pharmacist and I grew up in a family retail business so it is a combination of two passions. What has become very scary is that I recently started to sign contracts with insurance companies I found out that based on some of their re-imbursement rates I can actually lose money dispensing a prescription. I am not too sure about how Medicaid re-imbursement rates are now because although I have worked in a pharmacy for over seven years, when you work for a large chain you do not really learn anything about the 'business'. What I do know is that if these proposed regulations go into affect, independent pharmacies will not be able to survive. When you do the numbers they just do not add up. How can you run a business if the largest portion of it, in this case prescriptions, only breaks even on the actual cost of the product and you do not even take the cost of running the business into consideration? This is a real shame because the owners of independent pharmacies are people like me. People who love the job and know that they can provide so much more for their patients if they are allowed to do so, which in chain pharmacies is impossible. At the same time that it is my pleasure to provide these services, it is just impossible to do if I can not make money. After all I believe everyone is entitled to make a living.

Submitter : **Mr. Fabian Estrada** **Date: 02/11/2007**

Organization : **APhA, Pharmacy student**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Reimbursing pharmacists only 250% of the generic drug price according to the average manufacturer seems low. The state is trying to focus on reducing medication costs by reducing what the state should pay. From my experience in counseling patients at the retail level, I notice that about 50% of patients do not use their medications correctly. The state wants to focus on reducing costs, but why not focus on improving the patient's health by assuring that they are using their medications correctly. Many patients claim that their doctors do not explain the proper way to use prescriptions. I believe that healthcare expenditures would decrease for the state if the state focused on patient education and medication compliance. The state may pay less for each prescription dispensed, but if the patient is not using them correctly this may lead to hospital costs increasing which may increase the number of prescriptions per patient in the long run. Also, many pharmacies can order medications for next day delivery if the patient needs it. But who will cover the fee charged to the pharmacy for the delivery, not the state. Should the patient wait until the pharmacy's regular order date? What if the medication is rarely used but needed to maintain life? I agree that cutting costs is important, but please don't try to superficially fix this problem and let it resuface later. Instead, attack the problem from the root. Patient education on proper usage and compliance is key to ultimately reducing costs for the state. Although results will not be immediate.

Submitter : **Mr. David Isaacs** **Date: 02/11/2007**

Organization : **Giant Eagle Pharmacy/Diabetes Care Center**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

I have been a pharmacist in the Cleaveland, Ohio area for 32 years, working mostly in inner-city and inner-ring suburbs

GENERAL

GENERAL

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

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

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

Submitter : Mr. Sam Scuderi **Date:** 02/11/2007

Organization : PSSNY

Category : Pharmacist

Issue Areas/Comments

Background

Background

Pharmacists have always been paid using the AWP. This is going to change and create a health care crisis.

GENERAL

GENERAL

I am against using amp as the new standard of payment. This can only lead to more community pharmacies closing because of the reduced payments for medicaid and medicare prescriptions.Because of the reduced payment using the amp standard chain pharmacies will cut back on the clerical help and add an additional burden to pharmacists. Some pharmacies may not to be able to fill medicaid or medicare prescriptions because of the lower payment for generic drugs. Generic pharmaceutical organizations have encouraged pharmacists to dispense generic drugs when and where possible depending on how the prescription is written. Even the federal governemt felt this would save medicare patients substantial savings. However,in light of the new amp reimbursement standard, how can pharmacy survive?

Submitter : **Nancy Faust** **Date: 02/11/2007**

Organization : **Nancy Faust**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

CMS-2238-P has a provision to use the Average Manufacturer's Price (AMP) as the reimbursement for prescription medications. This is an unreasonable plan since a pharmacy cannot purchase medications at this cost. If the cost of the medication is greater than the reimbursement, then pharmacies and the pharmacists will no longer be available to serve the public in health care. The only way that a pharmacist is compensated for his/her expertise is through the sale of the medications that are dispensed. It is irrational to expect a pharmacy to dispense medications with little or no compensation and continue be a viable part of health care.

Submitter : **Corinne Garza** **Date: 02/11/2007**

Organization : **Hicksville Pharmacy and Home Medical**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear Legislators,

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

Sincerely,
Corinne Garza R.Ph.
Hicksville Pharmacy and Home Medical
116 E High St
Hicksville, OH 43526
Telephone (419) 542-6218

Submitter : **Mr. Jackson Bray** **Date: 02/11/2007**

Organization : **Capital Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Using AMP to price Medicaid Rx will result in loss of profit on these rx to a negative figure. If this results we will have to stop participating in then Medicaid program. We can not contiune to supplement government programs at a negative profit margin. We pay our taxes and can not be asked to supplement government programs that can not manage their money.

Submitter : **Mr. Mark Ebner** **Date: 02/11/2007**

Organization : **Klein's Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

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Submitter : **Mrs. Melody Peak** **Date: 02/11/2007**

Organization : **Mrs. Melody Peak**

Category : **Individual**

Issue Areas/Comments

GENERAL

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Submitter : **Ms. Bryan Peak** **Date: 02/11/2007**

Organization : **Ms. Bryan Peak**

Category : **Individual**

Issue Areas/Comments

GENERAL

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CMS-2238-P-382

Submitter : **Mr. Edward Schreiner** **Date: 02/11/2007**

Organization : **Stoll's Pharmacy, Inc.**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Please See Attachment for my complete comments.

CMS-2238-P-382-Attach-1.DOC

#382

February 11, 2007

R.E. Comments concerning CMS-2238-P: Implementing the Medicaid Drug Rebate Program provision of the Deficit Reduction Act of 2005

To Whom It May Concern,

I am a registered pharmacist practicing in a small, family-owned independent pharmacy in Waterbury, Connecticut. My pharmacy has been in business in downtown Waterbury, CT for over sixty years. A large portion (>25%) of the prescriptions filled at my pharmacy are reimbursed under the Medicaid program.

As currently written, the implementation of AMP-based FULs for use in the Medicaid program will have a devastating impact on my ability to continue operating my pharmacy. As you are aware, AMP-based FULs will not cover retail pharmacy acquisition costs for an extensive number of multiple-source generic medications. In the latest GAO report (GAO-07-239R), the GAO specifically finds that the estimated AMP-based FULs in their 77 drug sample were, on average, 36% lower than the average retail pharmacy acquisition costs for the first quarter of 2006. The report indicates that, in the majority of instances, the formula for AMP-based FULs in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic drugs. These finding illustrate my belief that AMP is not appropriate as a baseline for reimbursement unless it is redefined to reflect realistic pharmacy acquisition costs.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some pharmacies, such as my own, will consider closing completely, as this reimbursement mechanism will have a devastating impact on my ability to service a large Medicaid patient population. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name drugs, thus driving Medicaid costs even higher.

AMP is now to serve two distinct and contrary purposes: 1) as an index for manufacturer rebates paid to states, and 2) as a baseline for pharmacy reimbursement. AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer rebates, as outlined in GAO-05-102 "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concern About Rebates Paid to States".

If AMP is to accurately serve both purposes and to be an appropriate benchmark, **CMS MUST define AMP to reflect the actual cost paid by retail pharmacies**. This will be accomplished by; (1) excluding all rebates and price concessions made by manufacturers that are NOT available to retail pharmacies, (2) excluding all mail order facilities and PBM pricing from AMP calculation (*Mail order facilities and PBMs are extended special prices from manufacturers that are not available to retail pharmacies and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible),* and (3) reporting AMP at the 11-digit NDC level to ensure accuracy, as suggested by

CMS. All rebates and price concessions are appropriately included in the definition of "Best Price" but should not be included in AMP.

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade (which should include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass-merchants and supermarket pharmacies), it should include and exclude components according to their impact on the actual acquisition costs paid by retail pharmacies. CMS rightly excludes manufacturer rebates to state Medicaid programs, the Department of Defense under TRICARE and the VA program. Rebates paid to PBMs and mail order facilities should also be excluded in calculating AMP as these rebates are not available to the retail pharmacy class of trade. Should manufacturers include PBM/mail-order rebates in AMP calculations, the AMP would be driven below available market price, thus undermining FUL and shrinking the rebates states receive.

An accurate definition and differentiation of AMP and Best Price will not only lead to greater rebates to state agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices or rebates. The impact on participating pharmacies also cannot be mitigated by an increase in state-set dispensing fees. It is unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing (as determined by the most recently completed Cost of Dispensing Study conducted by the accounting firm Grant, Thornton, LLP that used data from over 23,000 community pharmacies and 832 million prescriptions to determine cost dispensing figures). As indicated by this study, increases in state-set dispensing fees may address the true cost of dispensing but will have no impact on negating the discrepancy between the proposed AMP and actual drug acquisition cost at the retail pharmacy level.

In conclusion, I strongly request that CMS change the definition of AMP to reflect actual acquisition cost paid by the retail pharmacy class of trade. All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculation. An AMP-based reimbursement that underpays retail pharmacy will have dire consequences for patient care and access.

Sincerely Submitted,

Edward Schreiner, R.Ph.
Stoll's Pharmacy, Inc.
185 Grove Street
Waterbury, CT 06710

Submitter : **Logan Davis** **Date: 02/12/2007**

Organization : **Samford University**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule does not address pharmacist's concerns for adequate reimbursement under an Average Manufacturer's Price (AMP) based reimbursement formula or our concerns regarding payment for pharmacist services (dispensing fee):

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics.

These pharmacies may have access to rebates and price concessions that may not be accessible to community pharmacy. Consequently, community pahrmacists are concerned that AMP may be set at a rate lower than what community pharmacy can purchase generic drug products.
The proposal does not address dispensing fees and continues to let States determine the 'reasonable' dispensing fee they are required to pay pharmacists. We are concerned that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a $4 dispending fee when studies indicate that the average cost to dispense a medication is approximately $10.

My home county is Sumter County, Alabama. This county is in the poor, rural black belt of Alabama. There are two pharmacies in this county and both are independent pharmacies. They will not be able to accept Medicaid prescriptions if the changes in this proposal are made. These patients will experience an even further reduction of total health and their lack of health care will cost the Medicaid system even more by increasing emergency room visits.

Please see attached documents for the study outlining cost of dispensing, the GAO report, and the National Community Pharmacy Association's comments on this issue.

CMS-2238-P-383-Attach-1.PDF

CMS-2238-P-383-Attach-2.PDF

CMS-2238-P-383-Attach-3.PDF

383

Grant Thornton LLP

National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies

Executive Summary

January 2007

Grant Thornton

Prepared for:

The Coalition for Community Pharmacy Action (CCPA)

NATIONAL COST OF DISPENSING (COD) STUDY
FINAL REPORT
JANUARY 26, 2007

Executive Summary

A. Objective and Overview of the National Cost of Dispensing Study

Grant Thornton LLP was engaged by the Institute for the Advancement of Community Pharmacy (IACP), doing business as the Coalition for Community Pharmacy Action (CCPA) on behalf of the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), to perform an independent study to identify and quantify the costs incurred by pharmacies across the United States in dispensing prescriptions. The primary purpose of the study was to provide a comparative analysis of dispensing costs across all states and types of payers, including Medicaid. To perform this study, Grant Thornton partnered with The MPI Group.

Data were submitted for over 24,400 pharmacies, of which 23,152 provided complete and usable data and are included in the computations shown in this report. The survey requested data for the six months from March through August of 2006, a period selected to avoid any unusual, one-time expenses that some pharmacies may have incurred during the implementation of Medicare Part D. The 23,152 pharmacies reported filling more than 832 million prescriptions during this time, of which over 65 million – or 7.8% – were paid by Medicaid. National computations include data from all states.

The Cost of Dispensing Model uses five cost elements, which are explained in detail in the full report:

- Prescription department salaries and benefits
- Other prescription department costs
- Facilities costs
- Other store/location costs
- Allocated corporate overhead, where applicable

The overall cost of dispensing for all prescriptions reported by the pharmacies was computed first. The cost of dispensing specific to Medicaid prescriptions was then calculated by adjusting the overall COD to reflect differences in time required to fill Medicaid prescriptions, as reported by pharmacists, and the interest costs associated with carrying Medicaid receivables.

This report focuses on four views of the overall COD and the Medicaid COD:

- Cost of dispensing on a per-prescription basis.
- Cost of dispensing on a per-store basis (that is, every store is counted equally, regardless of its prescription volume).
- Cost of dispensing for prescriptions filled by stores in rural locations and in urban locations.
- Cost of dispensing on a per-prescription basis and a per-store basis by state.

The full report provides detailed information about development of the survey instrument, distribution and tabulation of surveys, review of the data, confidentiality considerations, and the computational model for determining the cost of dispensing.

It should be noted that Grant Thornton did not conduct an audit of these data. Accordingly, with the publication of this report, our findings are not to be understood to express an audit or limited assurance opinion in accordance with auditing standards generally accepted in the United States of America.

B. Summary of Findings

Most charts in the report show cost of dispensing (COD) in two ways – per prescription and per pharmacy. One reason these numbers can vary significantly is that high-volume pharmacies typically have a lower COD than low-volume pharmacies. Therefore, the COD per prescription can be lower than the COD per pharmacy because lower-cost prescriptions make up a larger proportion of the population used to compute the COD. On the other hand, the COD per pharmacy treats every pharmacy equally, regardless of its prescription volume; a lower-volume, higher-cost pharmacy has the same impact on the COD per pharmacy as a higher-volume, lower-cost pharmacy. The COD per pharmacy provides the reader with information about the costs of the stores, regardless of how many prescriptions each one dispensed.

The overall COD was calculated for more than 832 million prescriptions dispensed by 23,152 pharmacies in all 50 states, the District of Columbia and Puerto Rico. The average (mean) overall COD per prescription was $10.50; the average overall COD per pharmacy was $12.10. This difference indicates there are substantial variations in the number of prescriptions filled per pharmacy and that pharmacies with the greatest volume of prescriptions have significantly lower dispensing costs compared with pharmacies with the lowest volumes. It is apparent that total prescription volume is a key variable related to a pharmacy's cost of dispensing.

Overall Cost of Dispensing					
	Frequency	**Mean [3]**	**Median [4]**	**25th Percentile [5]**	**75th Percentile [5]**
COD per prescription [1]	832,377,163	$10.50	$9.86	$8.48	$11.70
COD per pharmacy [2]	23,152	$12.10	$10.86	$9.07	$13.50

1. Weighted data by volume of prescriptions; each prescription COD as one value (i.e., a pharmacy with 5,000 prescriptions has 5,000 values in the array of COD data).
2. Unweighted data; each pharmacy's COD as one value, regardless of the pharmacy's prescription volume.
3. Mean is the average value
4. Median is the midpoint value of responses
5. Percentiles: The 25th percentile is the value below which 25% of responses fall. The 75th percentile is the value below which 75% of responses fall.

The Medicaid cost of dispensing was similarly computed for more than 65 million prescriptions filled by the 22,123 pharmacies that reported Medicaid prescriptions and for which a Medicaid COD could be computed. The national average COD was $10.51 per prescription and $12.81 per pharmacy. The average COD for Medicaid prescriptions does not differ significantly from the overall COD shown in the table above. However, the Medicaid COD per pharmacy is $0.71 higher

than the overall COD per pharmacy, suggesting that lower-cost, higher-volume pharmacies fill a disproportionately greater percentage of Medicaid prescriptions. As noted below, this may also be affected by lower-cost rural pharmacies' filling more Medicaid prescriptions than urban stores on a per-pharmacy basis.

Medicaid Cost of Dispensing					
	Frequency	**Mean**	**Median**	**25th Percentile**	**75th Percentile**
Medicaid COD per prescription [1]	65,037,250	$10.51	$9.87	$8.52	$11.62
Medicaid COD per pharmacy [2]	22,123[3]	$12.81	$11.22	$9.36	$14.06

1. Weighted data by volume of Medicaid prescriptions for which a Medicaid COD could be computed; each Medicaid prescription COD as one value.
2. Unweighted data; each pharmacy's Medicaid COD as one value, regardless of its Medicaid prescription volume.
3. 1,029 pharmacies reported no Medicaid prescription volume and/or did not provide sufficient information to compute a Medicaid COD.

Of the 23,152 pharmacies in the database, 19,811 were classified as urban and 3,185 as rural by matching the stores' zip codes with Metropolitan Statistical Areas (156 pharmacies could not be classified by MSA). Rural stores' overall COD and Medicaid COD, per prescription, were approximately 8% below the COD's of urban pharmacies, but the overall prescription volume, per store, was about the same for both the urban and rural pharmacies. On the other hand, rural pharmacies filled 55% more Medicaid prescriptions per store than urban pharmacies. The majority of the 8% difference in COD between urban and rural pharmacies with comparable prescription volumes appears to be caused by lower payroll costs in rural stores.

Survey respondents were asked to estimate the average work time for all activities required to dispense a prescription for each type of payer – Medicaid, Medicare Part D plans, other third-party plans, and customers with no third-party payer. Survey respondents for which a Medicaid COD could be computed reported that, on average, prescriptions paid by Medicare Part D are the most time-consuming (12.5 minutes), followed by Medicaid (11.7 minutes), other third-party payers (10.6 minutes) and prescriptions paid directly by customers (8.7 minutes).

Similarly, the survey asked respondents to report the average time to receive payment for Medicaid, other third-party (including Medicare Part D), and customer-paid prescriptions. The responses for Medicaid varied significantly from one state to another, but on average, the pharmacies reported receiving payment from Medicaid 19.9 days after billing, compared with 23.7 days for other third parties (including Medicare Part D). On a state-by-state basis, the survey shows that Medicaid programs' days to pay range from a high of 50.6 days average (30 days median) in Illinois to a low of 9.9 days average (10 days median) in Texas. The COD model used in this study added approximately $.01 per day to the COD for each day payment was outstanding, based on the average prescription selling price and interest rates applicable during the study period.

The full report, for which this is the Executive Summary, presents more detailed data nationally and for most states. State-level information for Alaska, the District of Columbia, Hawaii, Maine, North Dakota, and Puerto Rico is omitted, either because the number of pharmacies for which complete data were submitted was very small or due to confidentiality concerns if the data were presented fully.

Service Providers and Sponsors for Cost of Dispensing Study

Grant Thornton LLP

Grant Thornton LLP is the U.S. member firm of Grant Thornton International, one of six global accounting, tax and business advisory organizations. Grant Thornton is the leading accounting firm serving mid-cap, small-cap and privately held companies and other organizations, and is a preferred provider of specialist financial, tax and advisory services.

Today, Grant Thornton is represented by over 519 offices in major cities in 112 countries, and by more than 20,000 personnel throughout the world. Grant Thornton has 50 offices throughout the United States; clients are served by over 400 partners and nearly 5,000 U.S. personnel.

The MPI Group

The MPI Group, Inc. is a Cleveland, Ohio based research firm which is rapidly becoming one of the world's fastest-growing, most respected management intelligence firms, completing surveys, studies and white papers for organizations around the globe. MPI is currently at work on projects in industries ranging from manufacturing to information technology to distribution to healthcare, on topics ranging from performance benchmarks to financial process metrics to customer value analysis and ROI.

CCPA

The Coalition for Community Pharmacy Action (CCPA) is an alliance between the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), which together represent more than 55,000 community pharmacies. CCPA's mission is to ensure that patients have continued access to affordable medicines and prescription care from their trusted and accessible health professional - the community pharmacist.

CCPA's sponsorship of this project was made possible by a significant financial contribution from the Community Pharmacy Foundation. The Community Pharmacy Foundation's primary purpose is to assist community pharmacy practitioners by providing resources for research and development to encourage new capabilities and continuous improvements in the delivery of patient care. CCPA acknowledges the generosity of the Foundation and its directors for this support.

NCPA

The National Community Pharmacists Association (NCPA), founded in 1898, represents the nation's community pharmacists, including owners of more than 24,000 pharmacies, more than 68,000 pharmacists and more than 280,000 full-time employees. The nation's independent pharmacies, independent pharmacy franchises, and independent chains dispense nearly half of the nation's retail prescription medicines.

NACDS

The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 37,000 pharmacies, employ 114,000 pharmacists, and fill more than 2.3 billion prescriptions yearly. Other members include more than 1,000 suppliers of products and services to the chain drug industry.

383-b

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

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

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

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

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

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

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

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

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

> than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006." -GAO-07-239R p.4

This finding validates community pharmacy's contention that AMP is not appropriate as a baseline for reimbursement unless it is defined to reflect pharmacy acquisition cost.

The application of a faulty AMP definition in calculation of the FUL will force many independent pharmacies to discontinue service to their Medicaid patients and some independents will close completely. This lack of access to timely and safe prescription drug care will lead to additional costs to state Medicaid budgets for increased doctor visits, emergency room care, hospital stays and long term care expenses. Those pharmacies that remain in the Medicaid program will face a perverse incentive to dispense more profitable, higher-cost brand name medicines, thus driving Medicaid costs even higher.

None of these serious consequences have been accounted for in the proposed rule; in fact, the proposed rule creates many of these consequences.

Conflict in the Use of AMP as a Baseline for Reimbursement and an Index for Rebates

AMP is now to serve two distinct and contrary purposes: 1) as a baseline for pharmacy reimbursement, and 2) as an index for manufacturer rebates paid to states. **AMP was never intended to serve as a baseline for reimbursement,** and may not have been an effective measure for manufacturer rebates as outlined in the report "Medicaid Drug Rebate Program – Inadequate Oversight Raises Concerns about Rebates Paid to States" (GAO-05-102).

However, if AMP is to accurately serve both purposes, CMS MUST define AMP to reflect the actual cost paid by retail pharmacy, excluding all rebates and price concessions NOT available to retail pharmacy. All rebates and price concessions are appropriately included in "Best Price" but should not be included in AMP.

An accurate definition of AMP and Best Price will not only lead to greater rebates to state Medicaid agencies, but will also set an accurate baseline for adequate reimbursement rates. This will encourage the use of more affordable generics, thus saving money for the entire system while promoting effective patient health care.

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

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

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

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

AMP Must Be Reported Weekly

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

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

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

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

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

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

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

CMS discusses impact on pharmacy:

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

Impact on small pharmacies demonstrated by GAO findings

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

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

Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.

Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

Policing and Oversight Process for AMP and Best Price Must Be Included

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.

All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

Summary of Key Points:

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

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

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

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

383-6

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

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

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

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

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

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

OVERVIEW

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#383-C

United States Government Accountability Office
Washington, DC 20548

December 22, 2006

The Honorable Joe Barton
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: *Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*

Dear Mr. Chairman:

Spending on outpatient prescription drugs in Medicaid—the joint federal-state program that finances medical services for certain low-income adults and children—has accounted for a substantial and growing share of Medicaid expenditures.[1] Medicaid's total spending on outpatient prescription drugs grew from $4.6 billion in fiscal year 1990 to $40 billion in fiscal year 2004—or from 7.0 to 14.2 percent of Medicaid's total expenditures for medical care. State Medicaid programs do not directly purchase prescription drugs; instead, they reimburse retail pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries.[2] For some outpatient multiple-source prescription drugs, state Medicaid programs may only receive federal matching funds for reimbursements up to a maximum amount known as a federal upper limit (FUL).[3,4] Required by law as a cost-containment strategy, FULs are calculated as 150 percent of the lowest price for a drug, from among the

[1]Medicaid consists of 56 distinct programs created within broad federal guidelines and administered by state Medicaid agencies. The 56 Medicaid programs include one for each of the 50 states; the District of Columbia; Puerto Rico; and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, and the Virgin Islands. Hereafter in this report, we use "state Medicaid programs" to refer to these 56 programs.

[2]Retail pharmacies are licensed nonwholesale pharmacies that are open to the public.

[3]FULs must be established for each multiple source drug for which there are three or more therapeutically equivalent drug products. 42 U.S.C. § 1396r-8(e)(4) (2000). Therapeutically equivalent drug products can be substituted with the full expectation that they will produce the same clinical effect as the prescribed drug.

[4]By regulation, FULs apply to multiple-source prescription drugs that the Food and Drug Administration considers to have at least three therapeutically equivalent versions and at least three manufacturers or suppliers. 42 C.F.R. § 447.301 and 447.332 (2005).

prices published nationally in three drug pricing compendia.[5] State Medicaid programs have the authority to determine their own reimbursements to retail pharmacies[6] for covered outpatient multiple-source prescription drugs, as long as those reimbursements do not exceed established FULs in the aggregate.

The Deficit Reduction Act of 2005 (DRA) included provisions that changed the methodology for calculating FULs.[7] Beginning January 1, 2007, a drug's FUL will be based on the average manufacturer price (AMP). AMP represents the average of prices paid to manufacturers by wholesalers for a drug distributed to the retail pharmacy class of trade, including retail pharmacies, and is typically less than any of a drug's published prices in the three pricing compendia. Each therapeutically equivalent version of a multiple-source drug has an AMP, and beginning January 1, 2007, a drug's FUL will be calculated as 250 percent of the lowest AMP from among a drug's therapeutically equivalent versions. The Congressional Budget Office estimated that when implemented, AMP-based FULs could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010 and by about $11.8 billion from 2007 to 2015.[8]

Though representing a potential cost saving measure for Medicaid, the change in FUL calculation methodology—using AMP instead of the lowest published price—has raised concerns among retail pharmacies serving Medicaid beneficiaries. Drug manufacturers are required to report AMP data on their drugs to CMS. Because these data are not publicly available, retail pharmacies cannot determine what the relationship will be between AMP-based FULs and the prices the pharmacies pay to acquire these drugs.[9]

Because of your interest in the potential effects of the AMP-based FULs on retail pharmacies, you requested information on how AMP-based FULs will compare with retail pharmacy acquisition costs. We estimated what the AMP-based FULs would have been if they had applied in 2006 and compared them with average retail pharmacy acquisition costs from 2006 for frequently used and high expenditure multiple-source outpatient prescription drugs in Medicaid.

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[5]The Centers for Medicare & Medicaid Services (CMS), the agency that oversees Medicaid, identifies which drugs are subject to FULs. The Deficit Reduction Act of 2005 also included additional provisions relating to Medicaid reimbursement of outpatient prescription drugs.

[6]Many state Medicaid programs require retail pharmacies to dispense the lower cost therapeutically equivalent version of a drug to Medicaid beneficiaries when one is available. Under these mandatory generic substitution policies, the higher cost version of the drug remains available to beneficiaries if the prescribing physician receives prior authorization. In cases when retail pharmacies are authorized to dispense the higher cost version of the drug, the FUL does not apply.

[7]Pub. L. No. 109-171, § 6001, 120 Stat. 4, 54-59 (2006) (to be codified at 42 U.S.C. § 1396r-8).

[8]Congressional Budget Office Cost Estimate. S. 1932, Deficit Reduction Act of 2005. January 27, 2006.

[9]The price a retail pharmacy pays to acquire a drug from a manufacturer or wholesaler is known as a pharmacy's drug acquisition cost.

To estimate the AMP-based FULs and compare them with average retail pharmacy acquisition costs, we used first quarter 2006 Medicaid utilization data[10] to select a sample of multiple-source outpatient prescription drugs subject to Medicaid FULs. To develop our sample, we identified the 50 drugs that were the most frequently used—that is, represented 53 percent of the outpatient prescription drugs subject to FULs and dispensed to Medicaid beneficiaries in the first quarter of 2006—and the 50 drugs that were the highest expenditure—that is, accounted for 56 percent of Medicaid spending on outpatient prescription drugs subject to FULs in the first quarter of 2006,[11] with some drugs overlapping the two categories. Our resulting sample contained 77 multiple-source outpatient prescription drugs, which comprised 27 frequently used prescription drugs in Medicaid, 27 high expenditure prescription drugs in Medicaid, and 23 prescription drugs that overlapped both categories.

We obtained AMP data from the Centers for Medicare & Medicaid Services (CMS), which requires manufacturers to report AMP data within 30 days of the end of every calendar quarter. We obtained the average retail pharmacy acquisition cost data for the first quarter of 2006 from IMS Health, which obtains these data on sales transactions from approximately 100 manufacturers and over 300 distribution centers, including drug wholesalers and chain warehouses. These manufacturers and distribution centers are responsible for over 85 percent of total market dollar volume. IMS Health projects these data to represent national average acquisition costs for each drug in our sample in the first quarter of 2006.[12] The average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual acquisition costs because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers.[13]

For each of the 77 drugs in our sample, we estimated what the AMP-based FULs would have been had they applied in 2006. Using AMP data from the first quarter of 2006, we followed DRA provisions and selected the lowest AMP for each group of therapeutically equivalent versions and multiplied those AMPs by 250 percent. We did not exclude any outlier AMP data in order to be consistent with how CMS officials told us they will be implementing DRA provisions beginning January 1, 2007. We

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[10]Medicaid utilization data reported to CMS include information on the total number of units and dollar amount for which state Medicaid programs reimbursed retail pharmacies for covered drugs dispensed to Medicaid beneficiaries. As of July 2006, when we selected our sample, utilization data from Iowa, Minnesota, New Jersey, and Rhode Island were not included because these states had not reported their Medicaid utilization data for the first quarter of 2006.

[11]In ranking drugs by their share of Medicaid expenditures for multiple-source outpatient prescription drugs in the first quarter of 2006, we excluded any dispensing fees paid to pharmacies as a part of state reimbursement formulas. Each state pays pharmacies, for each prescription dispensed, a professional dispensing fee intended to cover the pharmacy's labor and overhead costs, such as pharmacists' salaries, drug packaging, rent, and utilities.

[12]For any given drug, the acquisition costs of individual pharmacies may be higher or lower than the national average.

[13]These rebates may vary as retail pharmacies negotiate their rebates based on various factors, including the type of drug, manufacturer, and volume of purchases. In addition, they can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis.

compared these estimated AMP-based FULs with average retail pharmacy acquisition cost data from the first quarter of 2006 for the 77 drugs in our entire sample and for each of the three categories of drugs our sample comprises—the frequently used drugs, the high expenditure drugs, and the drugs that overlapped both categories.[14] In order to assess the extent to which AMP-based FULs are likely to vary over time, we also examined the variation in lowest AMPs for the drugs in our sample from the third quarter of 2005 through the third quarter of 2006. We determined that the data used were sufficiently reliable for our purposes. For more detail on our scope and methodology, see enclosure I. The list of 77 drugs we reviewed is included in enclosure II. We performed our work from July 2006 through November 2006 in accordance with generally accepted government auditing standards.

Results in Brief

The AMP-based FULs we estimated using AMP data from first quarter 2006 were lower than average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs in our sample. For our entire sample of 77 multiple-source outpatient prescription drugs, we found that these estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for the first quarter of 2006. The extent to which the AMP-based FULs were lower than average retail pharmacy acquisition costs differed for high expenditure drugs compared with the frequently used drugs and the drugs that overlapped both categories. In particular, the estimated AMP-based FULs were, on average, 65 percent lower than average retail pharmacy acquisition costs for the 27 high expenditure drugs in our sample and 15 percent lower, on average, for the 27 frequently used drugs in our sample. For the 23 drugs that overlapped both categories of drugs, the estimated AMP-based FULs were, on average, 28 percent lower than the average retail pharmacy acquisition costs. In addition, we also found that the lowest AMPs for the 77 drugs in our sample varied notably from quarter to quarter. Despite this variation, when we estimated what the AMP-based FULs would have been using several quarters of historical AMP data, these estimated FULs were also, on average, lower than average retail pharmacy acquisition costs from the first quarter of 2006.

Though the difference between AMP-based FULs and retail pharmacy acquisition costs was in some cases sizable, the extent of this difference may change because of several factors, including the quarter-to-quarter variation in AMPs used to set FULs as well as the presence of rebates that retail pharmacies may obtain from drug manufacturers and wholesalers. To the extent that the utilization of multiple-source outpatient prescription drugs by retail pharmacies remains similar in 2007 and later to the utilization patterns captured in our sample of drugs for the first quarter of 2006, the gap between estimated first quarter 2006 AMP-based FULs and pharmacy acquisition costs could persist, once the AMP-based FULs are implemented in 2007. However, to the extent that the cost-containment measures of the AMP-based FULs influence pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset.

[14]In our comparison of the AMP-based FULs and retail pharmacy acquisition costs, we did not consider dispensing fees.

In reviewing a draft of this report, CMS disagreed with our finding that the AMP-based FULs were lower than the average retail pharmacy acquisition costs for most of the 77 drugs in our sample. In particular, CMS had significant concerns with our estimates of both pharmacy acquisition costs and AMP-based FULs and stated that our findings had not accounted for changes in these two variables that are likely to take place after DRA provisions are implemented in January 2007. In our view, we used the most complete, accurate data sources available at the time of our analysis for our purposes—to estimate both retail pharmacy acquisition costs and AMP-based FULs, had the latter applied in the first quarter of 2006. Furthermore, in our draft report we identified the limitations of the data sources used in our estimates and acknowledged that the difference between retail pharmacy acquisition costs and AMP-based FULs could change following implementation of DRA provisions in 2007. Only after AMP-based FULs are implemented in 2007 will there be an opportunity to determine the extent to which these FULs facilitate both cost-effective Medicaid drug expenditures and adequate reimbursement for retail pharmacies.

Background

Medicaid is a joint federal-state entitlement program that finances medical services for certain low-income adults and children.[15] While federal guidelines require that all state Medicaid programs offer certain basic benefits, each state Medicaid program determines the extent to which it will cover optional benefits. Outpatient prescription drug coverage is an optional benefit that all state Medicaid programs have elected to include in their Medicaid benefit packages. State Medicaid programs do not directly purchase drugs; instead they reimburse retail pharmacies for covered outpatient prescription drugs dispensed to Medicaid beneficiaries. For some outpatient multiple-source prescription drugs, state Medicaid programs may only receive federal matching funds for reimbursements up to a maximum amount known as a FUL.

Medicaid Federal Upper Limits

FULs were first established in 1987 as a cost-containment strategy in an effort to limit the amount that Medicaid could reimburse retail pharmacies for certain multiple-source outpatient prescription drugs.[16] FULs have been established for multiple-source drugs that have at least three manufacturers or suppliers and CMS publishes a list of drugs that have FULs in the State Medicaid Manual.[17] FULs are expressed on a

[15]Within guidelines established by federal statutes, regulations, and policies, each state (1) establishes its own eligibility standards; (2) determines the type, amount, duration, and scope of services; (3) sets the rate of payment for services; and (4) administers its own program.

[16]52 *Fed. Reg.* 28,648 (July 31, 1987). Legislation was enacted in 1990 making the application of FULs a statutory requirement. (Pub. L. No. 101-508, sec. 4401(a)(3), § 1927(f)(2), 104 Stat. 1388, 1388-143 (to be codified, as amended by DRA § 6001(a)(1)–(2), 120 Stat. 54-55, at 42 U.S.C. § 1396r-8(e)(4)).

[17]In addition, FULs are only established when multiple-source drugs are listed as "A" rated-drug products—that is, that the Food and Drug Administration (FDA) considers to be therapeutically equivalent to other pharmaceutically equivalent products—in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*. This list is commonly known as the Orange Book and identifies drug products approved on the basis of safety and effectiveness by FDA.

per-unit basis—for example, per tablet. As of first quarter 2006, the list included more than 500 multiple-source drugs.[18]

CMS determines the FUL for a multiple-source outpatient prescription drug by grouping a drug's therapeutically equivalent versions together and setting a FUL for each group. Each of a drug's therapeutically equivalent versions has several published prices associated with it, including the average wholesale price (AWP),[19] wholesale acquisition cost (WAC),[20] and direct price (DP).[21] All of these prices are published in each of the three national drug pricing compendia—First DataBank, Medi-Span, and Red Book—which use different methods for determining these published prices. The lowest published price for a FUL group—that is, a drug—may be any one of these three prices, and this can vary depending on the FUL group. Until provisions in DRA take effect January 1, 2007, CMS sets a FUL by identifying a drug's therapeutic equivalent with the lowest price—either AWP, WAC, or DP—in any of the three national drug pricing compendia, and multiplying that price by 150 percent.

A state's total reimbursements for Medicaid prescription drugs subject to FULs must not exceed, in the aggregate, the payment levels established by the FULs over a year. States may exceed the FUL for an individual prescription drug as long as their aggregate expenditures for all prescription drugs subject to FULs do not exceed the amounts that are calculated using the rate established by the FUL.

State Medicaid programs consider several methods for reimbursing pharmacies for multiple-source prescription drugs. In general, states base their Medicaid reimbursements to a retail pharmacy for a covered outpatient prescription drug on the lowest of the following: a state's best estimate of retail pharmacies' acquisition costs for the drug;[22] the usual and customary charge of the retail pharmacy that dispensed the drug;[23] the FUL for the drug, if applicable; or the state's maximum allowable cost (MAC) for the drug,[24] if applicable. When the FUL for a drug is not the

[18]Transmittal No. 37, Federal Upper Limit Drug List, November 20, 2001. Federal Upper Limit (FUL) Changes to Transmittal No. 37, June 23, 2006.

[19]AWP is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies.

[20]WAC is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions.

[21]DP as published by First DataBank represents the manufacturer's published catalog or list price for a drug product to nonwholesalers. DP does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions.

[22]States may establish their own methodologies for estimating retail pharmacies' drug acquisition costs. Most states in the first quarter of 2006 chose to estimate these costs by taking a percentage discount from the AWP.

[23]The usual and customary charge for a drug is the full retail price that individuals without prescription drug coverage pay when purchasing drugs at a retail pharmacy.

[24]States that administer MACs publish lists of selected multiple-source drugs with the maximum price at which the state will reimburse for those medications. Pharmacies generally do not receive payments that are higher than the MAC price. The MAC lists differ from the FUL list, as states have more

lowest of these four amounts, Medicaid typically reimburses pharmacies at a rate lower than the FUL.

Deficit Reduction Act of 2005 and Medicaid FULs

DRA modified the methodology used to set FULs for certain multiple-source outpatient prescription drugs for Medicaid.[25] Rather than 150 percent of the lowest published price of the therapeutically equivalent versions, starting January 1, 2007, DRA required that CMS calculate FULs as 250 percent of the lowest AMP among a drug's therapeutically equivalent versions. AMP data are collected by CMS and are not publicly available. (Fig. 1 illustrates how Medicaid FULs are calculated before and after DRA provisions take effect January 1, 2007.)

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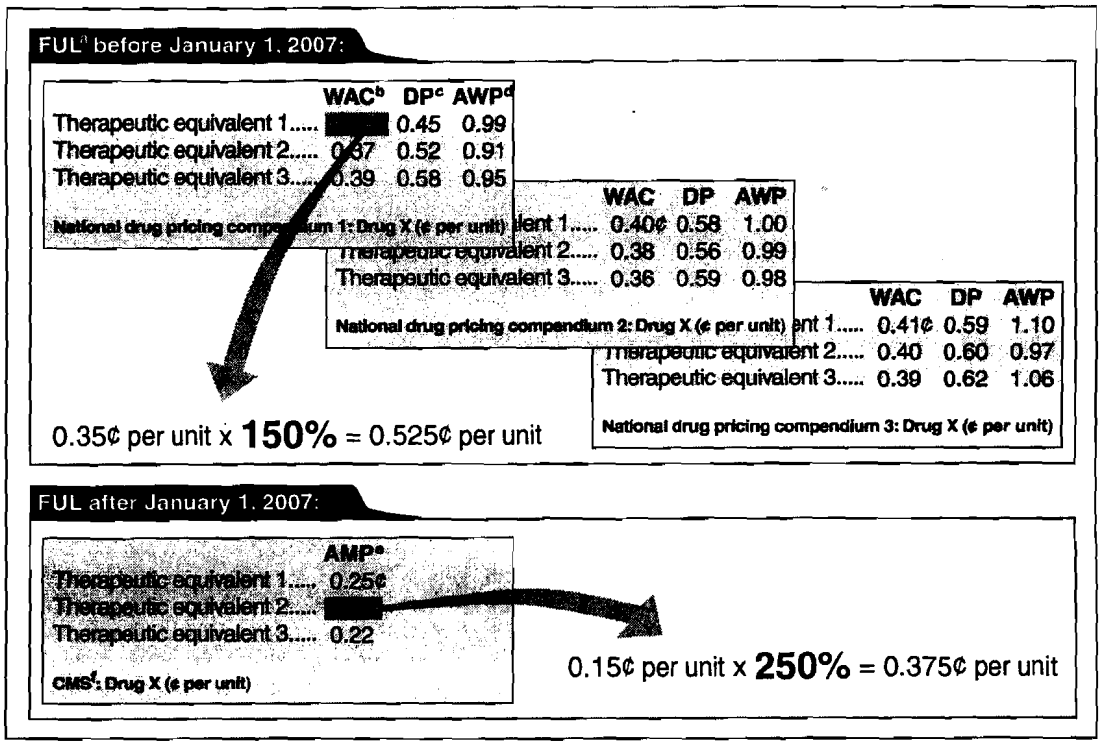
discretion in determining what drugs to include on their MAC lists. Generally, state MAC lists include more drugs, and establish lower reimbursement prices, than the FUL list. As of first quarter 2006, 43 states administer MACs.

[25]DRA § 6001,120 Stat. 54-59.

Figure 1: Illustration of FUL Methodology Before and After January 1, 2007



Source: GAO.

Note: The drug pricing compendia in fig.1 are published by First DataBank, Medi-Span, and Red Book.

[a]FUL is the federal upper limit for reimbursement of certain Medicaid outpatient prescription drugs.

[b]WAC is the manufacturer's list price for wholesalers or other direct purchasers before any rebates, discounts, allowances, or other price concessions.

[c]DP as published by First DataBank represents the manufacturer's published catalog or list price for a drug product to nonwholesalers. DP does not represent actual transaction prices and does not include prompt pay or other discounts, rebates, or reductions.

[d]AWP is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies.

[e]AMP represents the average of prices paid to manufacturers by wholesalers for a drug distributed to the retail pharmacy class of trade, including retail pharmacies.

[f]CMS is the agency that oversees Medicaid.

DRA included additional provisions relating to prescription drugs. One provision changed the criteria under which FULs must be established. Until January 1, 2007, FULs must be established for multiple-source drugs for which there are three or more therapeutically equivalent products.[26] Beginning on January 1, 2007, the DRA provides that FULs be established for multiple-source drugs for which there are at least two therapeutically equivalent products.[27] DRA also mandated several changes relating to

[26]42 U.S.C. § 1396r-8(e)(4) (2000).

[27]DRA § 6001(a)(1), 120 Stat. 54 (to be codified at 42 U.S.C. § 1396r-8(e)(4)).

the AMP. For example, DRA required that prompt payment discounts be excluded when manufacturers calculate AMP. DRA also required the Secretary of Health and Human Services to make manufacturers' reported AMP data available on a monthly basis to states, and to post those amounts on a Web site accessible to the public beginning July 2006.[28] These requirements were established in order to give states pricing information that was not previously available to consider in setting reimbursement amounts.

Estimated AMP-Based FULS Were Lower Than Average Pharmacy Acquisition Costs for Most Drugs in our Sample

For most of the 77 drugs in our sample, the AMP-based FULs we estimated using AMP data from the first quarter of 2006 were lower than average retail pharmacy acquisition costs for the same period. In particular, the percentage difference between the estimated AMP-based FULs and average retail pharmacy acquisition costs was more pronounced for high expenditure drugs than it was for frequently used drugs. Though lowest AMPs can vary notably from quarter to quarter, when we estimated what AMP-based FULs would have been using several quarters of AMP data we found that that these estimated FULs were also lower than average retail pharmacy acquisition costs for most of the drugs—and in particular the high expenditure drugs—in our sample. Furthermore, the difference between AMP-based FULs and retail pharmacy acquisition costs could change following the implementation of DRA provisions in January 2007, to the extent that retail pharmacies acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers.

Based on First Quarter 2006 Data, AMP-Based FULs Were Lower Than Average Acquisition Costs, with Difference Most Pronounced for High Expenditure Drugs

The AMP-based FULs we estimated using first quarter 2006 AMP data were lower than the average retail pharmacy acquisition costs for the same period for most—59 out of 77—of the drugs in our sample. The estimated AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs for our entire sample of drugs.[29] Further, for 43 of the 77 drugs, we found that the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies. While the estimated AMP-based FULs were lower than average retail pharmacy acquisition costs for our entire sample of drugs, this difference was most pronounced for the 27 high expenditure drugs, compared with the 27 frequently used drugs and with the 23 drugs that were both high expenditure and frequently used in our sample.

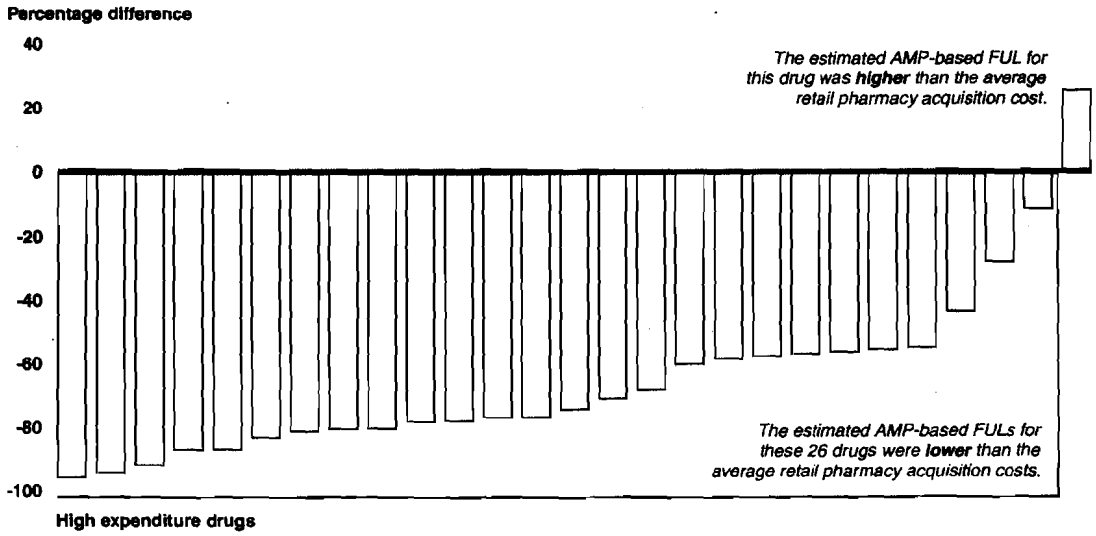
[28]While CMS released AMP data to states starting in July of 2006, the implementation of the provision requiring AMP data to be posted on a publicly available Web site has been delayed until January 1, 2007.

[29]Excluding statistical outliers from our analysis resulted in a less than 1 percent change in the average percent difference between average retail pharmacy acquisition costs and estimate AMP-based FULs.

High Expenditure Drugs

For 26 of the 27 high expenditure drugs in our sample, the AMP-based FULs we estimated using first quarter 2006 data were lower than the average retail pharmacy acquisition costs for this period (see fig. 2). The estimated FULs for these 27 drugs were, on average, 65 percent lower than average retail pharmacy acquisition costs.[30] We also found that for 21 of the 27 high expenditure drugs, the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies.

Figure 2: Comparison of Estimated AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 27 High Expenditure Outpatient Drugs in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

Frequently Used Drugs

For 17 of the 27 frequently used drugs in our sample, the AMP-based FULs we estimated using first quarter 2006 data were lower than the average retail pharmacy acquisition costs for this period (see fig. 3). For these 27 frequently used drugs, the estimated AMP-based FULs were, on average, 15 percent lower than average retail pharmacy acquisition costs.[31] We also found that for 11 of the 27 frequently used drugs, the estimated AMP-based FULs fell below the lowest acquisition cost available to retail pharmacies.

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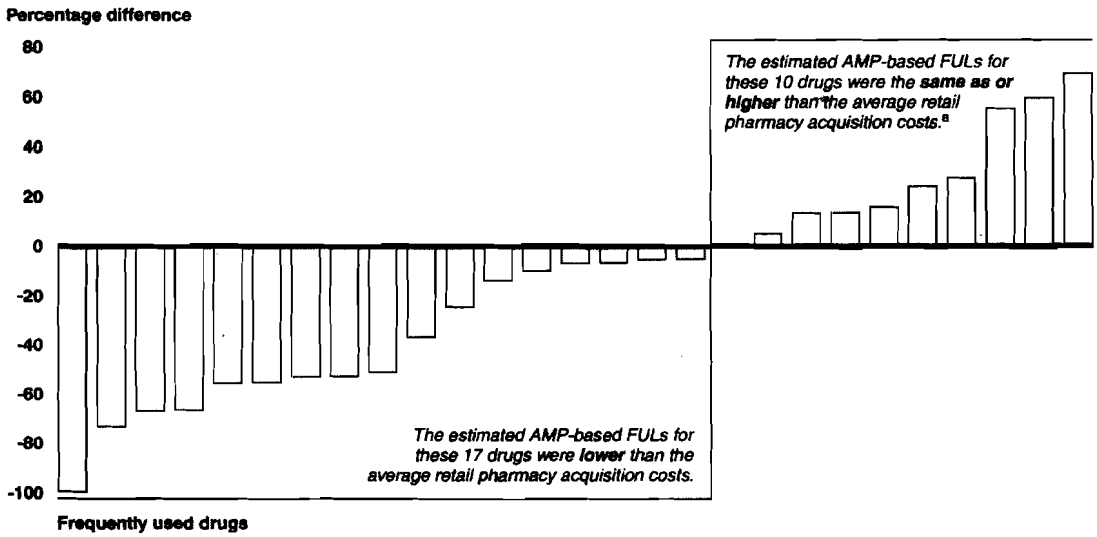
[30]In the first quarter of 2006 the average acquisition cost per unit for the 27 high expenditure drugs in our sample was $0.49.

[31]In contrast with the average acquisition cost per unit for the 27 high expenditure drugs in our sample—$0.49—the average acquisition cost per unit for the 27 frequently used drugs was $0.05 in the first quarter of 2006.

Figure 3: Comparison of Estimated AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 27 Frequently Used Outpatient Drugs in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

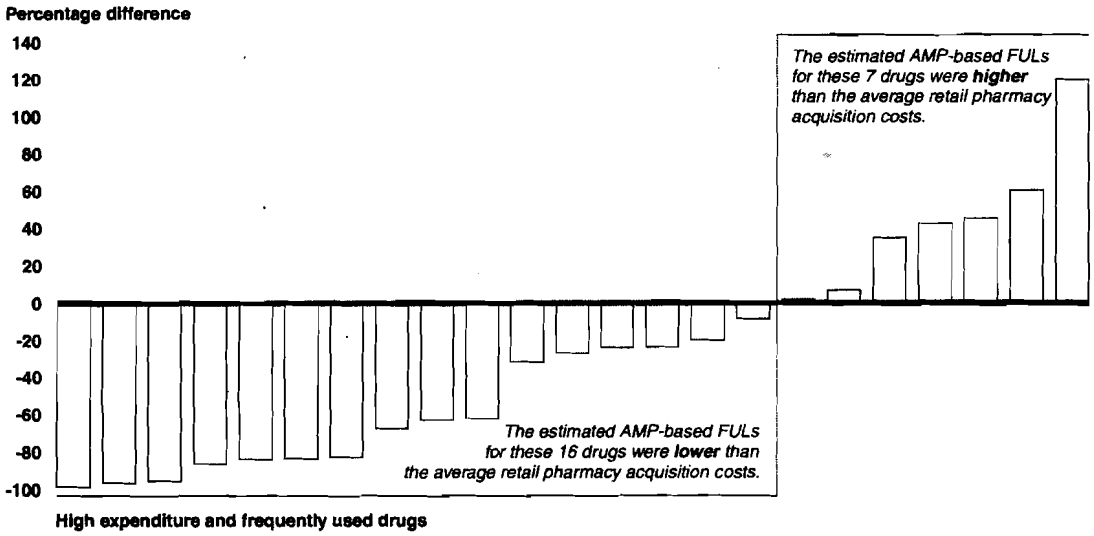
[a]One drug had an estimated AMP-based FUL the same as the average retail pharmacy acquisition cost.

High Expenditure and Frequently Used Drugs

For 16 of the 23 drugs that were both high expenditure as well as frequently used, the AMP-based FULs we estimated using first quarter 2006 AMP data were lower than the average retail pharmacy acquisition costs for this period (see fig. 4). Further, the estimated AMP-based FULs for the 23 drugs were, on average, 28 percent lower than average retail pharmacy acquisition costs.[32] We also found that for 11 of these 23 drugs the estimated AMP-based FULs fell below the lowest acquisition costs available to retail pharmacies.

[32]For the 23 high expenditure and frequently used drugs, the average acquisition cost per unit was $0.08.

Figure 4: Comparison of AMP-Based FULs and Average Retail Pharmacy Acquisition Costs for 23 Outpatient Drugs That Were Both High Expenditure and Frequently Used in Medicaid, First Quarter 2006



Source: GAO analysis of AMP data from CMS and average retail pharmacy acquisition cost data from IMS Health.

Though Lowest AMPs Can Vary Over Time, AMP-Based FULs Estimated for Several Quarters Were Also Lower Than Acquisition Costs

Our comparison of estimated AMP-based FULs and average retail pharmacy acquisition costs involves AMP data that can vary notably from quarter to quarter. In particular, we found variation in the lowest AMPs—which will set AMP-based FULs, beginning January 1, 2007—for the 77 drugs in our sample. For example, from the first of quarter 2006 through the second quarter of 2006,

- 36 of the 77 drugs had a median increase of 33 percent in their lowest AMPs;
- 11 of the 77 drugs had no change in their lowest AMPs; and
- 30 of the 77 drugs had a median decrease of 33 percent in their lowest AMPs.

Similarly, the lowest AMPs for the 77 drugs in our sample varied from quarter to quarter over the period covering the third quarter of 2005 through the third quarter of 2006. Despite this variation in lowest AMP values, when we estimated what AMP-based FULs would have been in each of several quarters—namely, the fourth quarter of 2005 through the second quarter of 2006—we found that the estimated FULs for each of these quarters were also lower, on average, than average retail pharmacy acquisition costs from the first quarter of 2006.[33] Even if we made the comparison using the quarter—from among the fourth quarter of 2005 through the second quarter of 2006—in which each drug's estimated AMP-based FUL was the highest, the

[33]This analysis assumes that first quarter 2006 acquisition costs are a valid proxy for acquisition costs in the fourth quarter of 2005 and the second quarter of 2006.

estimated AMP-based FULs for 49 of the 77 drugs remained lower than first quarter 2006 average retail pharmacy acquisition costs. Across our entire sample of 77 prescription drugs, the estimated AMP-based FULs were 12 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006. This analysis also showed differences across the three groups of drugs in our sample:

- For the high expenditure drugs, AMP-based FULs for 24 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 41 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

- For frequently used drugs, AMP-based FULs for 10 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 11 percent higher, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

- For the high expenditure and frequently used drugs, AMP-based FULs for 15 out of 27 drugs remained lower than average retail pharmacy acquisition costs. Across this group of drugs, the estimated AMP-based FULs were 4 percent lower, on average, than the average retail pharmacy acquisition costs from the first quarter of 2006.

Difference between AMP-Based FULs and Retail Pharmacy Acquisition Costs Could Change Following Implementation of DRA Provisions in 2007

Though the difference between AMP-based FULs and retail pharmacy acquisition costs in the first quarter of 2006 was in some cases sizable—on average 65 percent for the high expenditure drugs in our sample—it is important to recognize that the extent of this difference may change, because of several factors. These factors include the quarter-to-quarter variation in the AMPs used to set FULs, the DRA-required change in the definition of AMP that excludes prompt payment discounts from the calculation of AMPs, which may increase AMPs, and the presence of rebates that retail pharmacies may obtain from drug manufacturers and wholesalers that may lower retail pharmacy acquisition costs. In addition, because FULs apply to state Medicaid program aggregate expenditures for relevant outpatient multiple-source drugs in a year, states may reimburse for some drugs in excess of the FULs as long as these higher reimbursements are offset by others that are below the FULs.

Furthermore, the difference we found between AMP-based FULs and retail pharmacy acquisition costs also reflects the particular multiple-source outpatient prescription drugs pharmacies purchased and dispensed to Medicaid beneficiaries in the first quarter of 2006. To the extent that in 2007 and in future years this utilization remains similar to the utilization captured in our sample of drugs for the first quarter of 2006, the gap we found could persist. However, to the extent that the cost-containment measures of the AMP-based FULs influence retail pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset. Only after AMP-based FULs are implemented in

2007 will there be an opportunity to determine the extent to which these FULs are facilitating both cost-effective Medicaid drug expenditures and adequate reimbursements for retail pharmacies.

Agency and Other External Comments

CMS reviewed a draft of this report and provided written comments, which are reproduced in enclosure III. CMS disagreed with our finding that the AMP-based FULs were lower than the average retail pharmacy acquisition costs for most of the 77 drugs in our sample. In particular, CMS had significant concerns with our estimates of both pharmacy acquisition costs and AMP-based FULs and stated that our findings had not accounted for changes in these two variables that are likely to take place after DRA provisions are implemented in January 2007. In our view, we used the most complete, accurate data sources available at the time of our analysis for our purposes—to estimate both retail pharmacy acquisition costs and AMP-based FULs, had the latter applied in the first quarter of 2006. Furthermore, in our draft report we identified the limitations of the data sources used in our estimates and acknowledged that the difference between retail pharmacy acquisition costs and AMP-based FULs could change following implementation of DRA provisions in 2007.

In its written comments, CMS raised issues regarding our estimates of retail pharmacy acquisition costs, our estimates of AMP-based FULs, and our discussion of the impact of DRA provisions:

Our Estimates of Retail Pharmacy Acquisition Costs

CMS stated that our draft report did not provide source documents or evidence of how IMS Health arrived at the acquisition costs used in our comparison. Our draft report explained that IMS Health collects acquisition cost data from actual sales transactions from manufacturers and distribution centers, which represent over 85 percent of total market dollar volume, and projects these data to represent national average acquisition costs. We could not provide CMS with the acquisition cost data used in our analysis because, while they are commercially available, they are proprietary. Specifically, our data use agreement with IMS Health prohibits us from releasing its data to third parties, such as CMS.

CMS also questioned the validity of our estimation of retail pharmacy acquisition costs because we did not account for the rebates retail pharmacies may receive from wholesalers and manufacturers. In our draft report we stated that the IMS Health data did not account for such rebates, and we identified this as a limitation of our analysis. However, as CMS officials acknowledged to us, there are no known data sources of pharmacy acquisition costs of multiple-source outpatient prescription drugs that account for rebates. Identifying rebates is difficult because retail pharmacies negotiate their rebates based on various factors and can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis. We have amended our report to clarify these issues.

Our Estimates of AMP-Based FULs

CMS stated that in estimating the AMP-based FULs for our analysis we did not exclude outlier AMP data. According to CMS, excluding outlier AMP data could have "significantly" raised our estimates of AMP-based FULs for many multiple-source outpatient prescription drugs. As we stated in our draft report, we did not exclude outlier AMP data from our analysis because, during the course of our work, CMS officials indicated that they would not exclude any outlier AMP data when they begin calculating AMP-based FULs in January 2007. To be consistent with the methodology CMS indicated the agency will use when implementing DRA provisions, we did not exclude outlier data from our estimates of AMP-based FULs. However, in their comments, CMS indicated that they intend to address outlier AMP data, as appropriate, in calculating the AMP-based FULs.

During the course of our work we identified outliers in the AMP data underlying the FULs for several drugs in our analysis. However, excluding these outliers did not significantly reduce the gap we found between the estimated AMP-based FULs and retail pharmacy acquisition costs. We have amended our report to include this information. We agree with CMS's revised approach to publish clear criteria for (1) identifying and excluding outliers from the AMP data that underlie each FUL group and (2) identifying which therapeutically equivalent versions of each drug are nationally available and should thereby be considered when setting the FUL.[34]

Potential Impact of DRA on Retail Pharmacy Acquisition Costs and AMP-Based FULs

CMS stated that our analysis did not account for several ways in which DRA may affect retail pharmacy acquisition costs and the AMP-based FULs. CMS suggested that our estimation of retail pharmacy acquisition costs will likely not reflect such costs after the implementation of DRA provisions in January 2007. CMS expects that the AMP-based FULs implemented as a result of DRA will drive retail pharmacies to fill more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs—thereby reducing these pharmacies' acquisition costs. In CMS's view, our study erroneously assumed that pharmacies' utilization of multiple-source outpatient prescription drugs—and therefore pharmacy acquisition costs—will remain unchanged after the implementation of DRA. While we estimated average pharmacy acquisition costs for the multiple-source outpatient prescription drugs in our sample using utilization and cost data from the first quarter of 2006, we also acknowledged in our draft report that retail pharmacies could change their utilization of multiple-source outpatient prescription drugs in 2007 and later to lower their acquisition costs. Specifically, our draft report stated that "to the extent that the cost-containment measures of the AMP-

[34]In a media release dated December 15, 2006, CMS indicated that it will publish in the *Federal Register* a proposed rule to implement provisions of the Deficit Reduction Act of 2005 that highlights proposed changes in the payment for certain drugs in the Medicaid program. See http://www.cms.hhs.gov/apps/media/fact_sheet.asp (December 15, 2006).

based FULs influence pharmacies to acquire lower cost therapeutically equivalent versions of drugs or negotiate lower prices from manufacturers and wholesalers, the gap between AMP-based FULs and acquisition costs could be narrowed or offset."

CMS also pointed out that our study did not include an analysis of how retail pharmacies could mitigate the effects of AMP-based FULs by filling more Medicaid prescriptions with lower cost versions of multiple-source outpatient prescription drugs. However, as part of our analysis, we compared estimated AMP-based FULs to the lowest available acquisition cost for each of the multiple-source outpatient prescription drugs in our sample. As we reported in our draft, for most the drugs in our sample—43 of 77—the estimated AMP-based FUL fell below the lowest acquisition cost available to retail pharmacies.

CMS had concerns that in estimating the AMP-based FULs we used AMP data that included customary prompt payment discounts, even though DRA requires their exclusion from AMP beginning in 2007. According to CMS, prompt payment discounts decrease AMPs, and so using AMP data that include such discounts will decrease AMP-based FULs. In our view, the impact of excluding prompt payment discounts from the AMP data we used to estimate AMP-based FULs is unclear. In our previous work, we have found that prompt payment discounts are, on average, 2 percent of the sales transactions to which they apply.[35] However, we have also reported that manufacturers vary in the purchasers to whom they offer prompt payment discounts and whether they include these discounts in their calculations of AMP. Therefore, attempting to account for prompt payment discounts for all of the multiple-source outpatient prescription drugs in our analysis would have, in some cases, overstated the impact of these discounts on our estimates of AMP-based FULs. We agree with CMS that the changes in the definition of AMP as required by DRA will likely increase AMP-based FULs. However, our previous work suggests that excluding prompt payment discounts from the calculation of AMP-based FULs would not have offset the gap we reported between retail pharmacy acquisition costs and estimated AMP-based FULs. In our report, we have clarified the issue of prompt payment discounts and its impact on our analysis.

In addition to their concerns related to the estimates used in our draft report, CMS noted that our analysis did not address existing state cost containment efforts, such as MAC programs, to reduce Medicaid reimbursements for outpatient prescriptions drugs. While the relationship between AMP-based FULs and state Medicaid cost containment efforts is a valid comparison, the issue was beyond the scope of our report, which compared estimated AMP-based FULs to retail pharmacy acquisition costs.

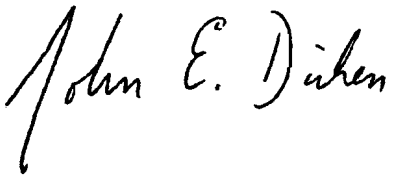
[35]See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

Finally, we agree with CMS that changing the basis of the FUL from the AWP to the AMP was a step in the right direction towards achieving savings for the federal government on Medicaid expenditures for multiple-source outpatient prescription drugs. However, these savings should be achieved while ensuring that reimbursements to retail pharmacies are adequate to provide Medicaid beneficiaries access to multiple-source outpatient prescription drugs. As we stated in our draft report, only after AMP-based FULs are implemented in 2007 will there be an opportunity to determine the extent to which these FULs facilitate both cost effective Medicaid drug expenditures and adequate reimbursement for retail pharmacies.

CMS also provided technical comments that we incorporated as appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its date. We will then send copies of this report to the Administrator of CMS and other interested parties. The report will also be available at no charge on GAO's Web site at http://www.gao.gov. If you or your staff have any questions about this report, please contact me at (202) 512-7119 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs can be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure IV.

Sincerely yours,



John E. Dicken
Director, Health Care

Enclosures—4

Scope and Methodology

To examine the relationship between the Medicaid federal upper limits (FUL) estimated using first quarter 2006 average manufacturer price (AMP) data and the average retail pharmacy acquisition cost for frequently used and high expenditure drugs in Medicaid, we used first quarter 2006 Medicaid utilization data from the Centers for Medicare & Medicaid Services (CMS)[36] to select the 50 most frequently used and the 50 highest expenditure multiple-source outpatient prescription drugs in Medicaid subject to FULs.[37] Combined, these two lists comprised a sample of 77 unique drugs representing 53 percent of Medicaid prescriptions and 56 percent of Medicaid expenditures for drugs subject to the FUL in the first quarter of 2006.[38] We obtained the list of drugs subject to the FUL from CMS and, because the AMP-based FULs were not available during the course of our work, estimated what the AMP-based FULs would have been using AMP data from the first quarter of 2006 for each of the 77 drugs.

Our analyses are limited to multiple-source outpatient prescription drugs that were subject to FULs for the first quarter of 2006 and do not include those drugs that may be added to the FUL list beginning January 1, 2007, per the expanded multiple-source definition in the Deficit Reduction Act of 2005 (DRA). Additionally, we compared corresponding AMP data with retail pharmacy acquisition cost data for each drug in our sample by National Drug Codes (NDC).[39]

To estimate FULs under the AMP-based methodology, we first extracted AMP data for the first quarter of 2006 for each of the 77 drugs in our sample from CMS's Medicaid Drug Rebate Initiative (MDRI) system. CMS requires manufacturers to report AMP data within 30 days of the end of every calendar quarter. We then selected the lowest AMP for the first quarter of 2006 for each group of therapeutically equivalent drugs and multiplied it by 250 percent. These AMP data do not account for the impact of the DRA-required change in the definition of AMP which excludes

[36]Medicaid utilization data reported to CMS include information on the total number of units and dollar amounts reimbursed for each drug. As of August 2006 when we selected our sample, Iowa, Minnesota, New Jersey, and Rhode Island had not reported their Medicaid utilization data for the first quarter of 2006.

[37]For drugs subject to the FUL, Medicaid covered 32.9 million prescriptions that were dispensed to Medicaid beneficiaries at retail pharmacies in the first quarter of 2006.

[38]Drugs with the same name but different strengths, forms (such as capsules or tablets), or package sizes were counted separately as unique drugs.

[39]NDCs are the universal product identifiers for drugs for human use. The Food and Drug Administration assigns the first segment of the NDC, which identifies the firm that manufacturers, repackages, or distributes a drug; the second segment identifies a specific strength, dosage form, and formulation for a particular firm; and the third segment identifies package size. A single drug can have multiple NDCs associated with it. For example, a drug made by one manufacturer, in one form or strength, but in three package sizes would have three NDCs. Three-segment NDCs are denoted by 11 digits while two-segment NDCs are denoted by 9 digits, and do not account for package size.

prompt payment discounts.[40] In addition, in estimating the AMP-based FULs, we did not exclude any outlier AMP data in order to be consistent with how CMS officials told us they will be implementing DRA provisions beginning January 1, 2007. Nonetheless, during the course of our work, we examined the AMP data underlying each FUL group for the presence of statistical outliers.

To determine retail pharmacies' acquisition costs for the 77 drugs, we purchased national average retail pharmacy acquisition cost data from IMS Health for the first quarter of 2006. IMS Health obtains these data on sales transactions from approximately 100 manufacturers and over 300 distribution centers, including drug wholesalers and chain warehouses. These manufacturers and distribution centers are responsible for over 85 percent of total market dollar volume. IMS Health projects these data to represent national average acquisition costs for each drug in our sample in the first quarter of 2006.[41] The average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual average acquisition costs because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers.[42] We calculated an average acquisition cost for each drug by weighting the acquisition cost for each therapeutically equivalent drug by its Medicaid expenditure for first quarter 2006.[43]

To compare the estimated AMP-based FULs to the average retail pharmacy acquisition costs for each of the 77 drug groups in our analysis, we calculated the percentage difference between the AMP-based FUL and (1) the average of acquisition costs for all therapeutically equivalent drugs within a group and (2) the average acquisition cost for the lowest cost therapeutically equivalent drug within a group. We also calculated the percentage difference of the AMP-based FUL to the average acquisition cost and minimum acquisition cost separately for the 27 high expenditure drugs, 27 frequently used drugs, and 23 drugs that were considered both high expenditure and frequently used.

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[40]In our previous work we found that prompt payment discounts are, on average, 2 percent of the sales transactions to which they apply. However, we have also reported that manufacturers vary in the purchasers to whom they offer prompt payment discounts and whether they include these discounts in their calculations of AMP. Therefore, attempting to account for prompt payment discounts for all of the multiple-source outpatient prescription drugs in our analysis would have, in some cases, overstated the impact of these discounts on our estimates of AMP-based FULs. See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 4, 2005).

[41]For any given drug, the acquisition costs of individual pharmacies may be higher or lower than the national average.

[42]These rebates may vary as retail pharmacies negotiate their rebates based on various factors, including the type of drug, manufacturer, and volume of purchases. In addition, they can negotiate rebates on a manufacturer's entire line of products rather than on a per-drug basis.

[43]We calculated a weighted average acquisition cost to account for Medicaid prescription drug utilization patterns.

We also assessed the extent to which AMP-based FULs are likely to vary over time by examining the variation of the lowest AMPs that would be used to set the estimated FULs for each of the 77 drugs in our sample from the third quarter of 2005 through the third quarter of 2006. Additionally, we compared the highest estimated AMP-based FUL from the fourth quarter of 2005 through the second quarter of 2006 to the average retail pharmacy acquisition cost for the first quarter of 2006 for each of the 77 drugs. We also performed this comparison separately for the 27 high expenditure drugs, 27 frequently used drugs, and 23 drugs that were considered both high expenditure and frequently used.

To assess the reliability of the AMP data, we reviewed relevant documentation regarding the construction and reporting of data extracted from CMS's MDRI system. To assess the reliability of the IMS Health average retail pharmacy acquisition cost data, we reviewed relevant documentation regarding the construction and reporting of the data supplied. We determined that the data used were sufficiently reliable for our purposes.

We performed our work from July 2006 through November 2006 in accordance with generally accepted government auditing standards.

Percentage of Medicaid Prescriptions and Expenditures for 77 Medicaid Outpatient Prescription Drugs GAO Reviewed, First Quarter 2006

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Acetaminophen Codeine Phosphate 300-30mg	Tablet	1.2	14	0.5	49
Acetaminophen Hydrocodone Bitartrate 500-5mg	Tablet	3.2	2	0.5	47
Acetaminophen Hydrocodone Bitartrate 500-7.5mg	Tablet	0.9	27	N/A	N/A
Acetaminophen Hydrocodone Bitartrate 500-10mg	Tablet	0.6	43	1.1	17
Acetaminophen Hydrocodone Bitartrate 750-7.5mg	Tablet	0.6	45	N/A	N/A
Acetaminophen Oxycodone HCl 325-5mg	Tablet	1.2	17	N/A	N/A
Acetaminophen Propoxyphene Napsylate 650-100mg	Tablet	1.1	19	0.6	42
Albuterol 0.9mg/inh	Aerosol	3.7	1	1.8	9
Albuterol Sulfate 0.083mg/ml	Solution	1.8	4	2.0	6
Alprazolam 0.25mg	Tablet	0.6	38	N/A	N/A
Alprazolam 0.5mg	Tablet	0.9	26	N/A	N/A
Alprazolam 1mg	Tablet	0.8	29	N/A	N/A
Amoxicillin 125/5mg/ml	Suspension	1.9	3	0.5	50
Amoxicillin 500mg	Capsule	1.6	5	N/A	N/A
Amoxicillin Clavulanic Acid 400/5mg/ml-57/5mg/ml	Suspension	N/A	N/A	1.9	7
Atenolol 25mg	Tablet	0.6	40	N/A	N/A

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Atenolol 50mg	Tablet	0.8	33	N/A	N/A
Baclofen 10mg	Tablet	N/A	N/A	0.7	30
Baclofen 20mg	Tablet	N/A	N/A	0.6	41
Betamethasone Dipropionate Clotrimazole 0.05-1%	Cream	N/A	N/A	0.8	23
Carbamazepine 200mg	Tablet	N/A	N/A	0.6	45
Carisoprodol 350mg	Tablet	0.6	44	0.8	24
Cephalexin 500mg	Capsule	1.0	22	0.7	36
Ciprofloxacin HCl 500mg	Tablet	0.5	49	N/A	N/A
Clonazepam 0.5mg	Tablet	1.3	11	0.7	29
Clonazepam 1mg	Tablet	1.1	18	0.9	21
Clonidine HCl 0.1mg	Tablet	1.0	24	N/A	N/A
Cyclobenzaprine HCl 10mg	Tablet	1.0	23	0.7	34
Diazepam 5mg	Tablet	0.6	42	N/A	N/A
Fluoxetine HCl 20mg	Capsule	1.0	21	0.7	33
Fluoxetine HCl 40mg	Capsule	N/A	N/A	1.2	16
Folic Acid 1mg	Tablet	1.2	15	N/A	N/A
Furosemide 20mg	Tablet	0.9	28	N/A	N/A
Furosemide 40mg	Tablet	1.4	7	N/A	N/A
Gabapentin 100mg	Capsule	N/A	N/A	0.7	32
Gabapentin 300mg	Capsule	0.7	36	5.1	1
Gabapentin 400mg	Capsule	N/A	N/A	1.3	12
Gabapentin 600mg	Tablet	N/A	N/A	4.2	2
Gabapentin 800mg	Tablet	N/A	N/A	2.0	5
Glimepiride 4mg	Tablet	N/A	N/A	0.5	46

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Glyburide 5mg	Tablet	N/A	N/A	0.8	26
Glyburide Metformin HCl 5mg	Tablet	N/A	N/A	1.1	18
Hydrochlorothiazide 25mg	Tablet	1.5	6	N/A	N/A
Hydroxyzine HCl 25mg	Tablet	N/A	N/A	0.8	27
Ibuprofen 400mg	Tablet	0.6	46	N/A	N/A
Ibuprofen 600mg	Tablet	1.1	20	N/A	N/A
Ibuprofen 800mg	Tablet	1.4	8	N/A	N/A
Levothyroxine Sodium 0.05mg	Tablet	0.6	47	N/A	N/A
Lisinopril 10mg	Tablet	0.8	32	0.6	44
Lisinopril 20mg	Tablet	0.7	37	0.6	39
Lisinopril 40mg	Tablet	N/A	N/A	0.6	40
Lorazepam 0.5mg	Tablet	1.3	10	0.9	20
Lorazepam 1mg	Tablet	1.2	16	1.3	13
Lorazepam 2mg	Tablet	N/A	N/A	0.6	43
Lovastatin 40mg	Tablet	N/A	N/A	0.7	35
Metformin HCl 500mg	Tablet	1.2	12	1.8	8
Metformin HCl 1000mg	Tablet	0.6	41	1.0	19
Metoprolol Tartrate 50mg	Tablet	0.8	30	N/A	N/A
Metronidazole 500mg	Tablet	0.5	50	N/A	N/A
Mirtazapine 15mg	Tablet	N/A	N/A	0.8	28
Mirtazapine 30mg	Tablet	N/A	N/A	0.7	37
Mupirocin 2%	Ointment	N/A	N/A	1.2	15
Naproxen 500mg	Tablet	0.8	31	N/A	N/A
Omeprazole 20mg	Capsule	N/A	N/A	1.4	10

Drug name and strength	Dosage form	Percentage of Medicaid prescriptions	Ranking by Medicaid prescriptions	Percentage of Medicaid expenditures	Ranking by Medicaid expenditures
Paroxetine HCl 10mg	Tablet	N/A	N/A	0.6	38
Paroxetine HCl 20mg	Tablet	N/A	N/A	2.3	3
Paroxetine HCl 30mg	Tablet	N/A	N/A	0.8	22
Paroxetine HCl 40mg	Tablet	N/A	N/A	1.2	14
Penicillin V Potassium 500mg	Tablet	0.5	48	N/A	N/A
Potassium Chloride 20mEq	Tablet	0.8	34	0.8	25
Ranitidine HCl 150mg	Tablet	1.3	9	0.5	48
Ribavirin 200mg	Capsule	N/A	N/A	2.1	4
Sulfamethoxazole Trimethoprim 800-160mg	Tablet	1.0	25	N/A	N/A
Tizanidine HCl 4mg	Tablet	N/A	N/A	0.7	31
Tramadol HCl 50mg	Tablet	1.2	13	1.3	11
Trazodone HCl 50mg	Tablet	0.8	35	N/A	N/A
Trazodone HCl 100mg	Tablet	0.6	39	N/A	N/A

Source: GAO analysis of CMS Medicaid state drug utilization data.

Note: Our sample contained 77 multiple-source outpatient prescription drugs in Medicaid for the first quarter of 2006, which comprised 27 frequently used prescription drugs, 27 high expenditure prescription drugs, and 23 prescription drugs that overlapped both categories. N/A appears in the table for drugs that were not in the overlap category.

CMS Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

DEC - 6 2006

Administrator
Washington, DC 20201

TO: John Dicken
Director, Health Care
Government Accountability Office

FROM: Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Government Accountability Office (GAO) Draft Report: "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs" (GAO-07-239R)

Thank you for the opportunity for the Centers for Medicare & Medicaid Services (CMS) to comment on the proposed report on Federal Upper Limit (FUL) reimbursement and retail pharmacy acquisition cost. This report examines the potential effects on retail pharmacies of the provision of the Deficit Reduction Act of 2005 (DRA) that requires CMS to set the FUL at 250 percent of the lowest average manufacturer price (AMP) (computed without regard to customary prompt pay extended to wholesalers) in a FUL group.

Section 1927(e)(4) of the Social Security Act requires the Secretary to establish a Federal upper reimbursement limit for certain multiple source drugs. By regulation, this limit has been set as 150 percent of the least costly therapeutically equivalent drug as listed in published compendia of cost information for drugs for sale nationally.

It has been routinely reported that, over time, the FUL was increasingly less effective in assuring that the Medicaid program paid appropriately for multiple source drugs. This fact had been documented by studies of the Inspector General of the Department of Health and Human Service (HHS), by the bi-partisan Medicaid Commission, and in testimony before the House Energy and Commerce Committee. Over time, the reported prices used to set the FUL in published compendia have become less reliable as estimates of the true acquisition cost of drugs. As long as States must rely on prices that are not based on verifiable data, reimbursement is inflated, increasing the cost to Medicaid. In mandating the use of AMP, Congress required that the reimbursement system be based on reliable data and not on self-reported manufacturer's or distributor's data that is subject to bias. The DRA changes are intend to make transparent accurate pricing data to assure that the Federal government and state Medicaid programs are paying appropriately for multiple source drugs.

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This GAO study responds to concerns of the retail pharmacy industry that establishing a FUL reimbursement based on 250 percent of AMP will be insufficient to cover retail pharmacists' costs of purchasing drugs. If this were true, the actual AMP of a drug, as reported by manufacturers, multiplied by 2.5 would be less than a pharmacy's purchase price, meaning that the handling costs and profits in the distribution chain far exceed the actual cost of the drug product.

This GAO study purports to document that the AMP-based FULs are lower than average retail pharmacy acquisition cost for the 77 FUL drug groups reviewed. We find GAO's conclusion premature and unsupported by the report. This study cannot be thoroughly analyzed or replicated because the GAO will not release the data on which it is based. It admittedly uses incomplete and misleading information, as well as nondisclosed pricing data. We believe a more thorough analysis of pharmacy acquisition costs is necessary, based on verifiable and complete data, before any report is released.

GAO Findings

Using first quarter 2006 Medicaid data, 50 drugs that were identified as the most frequently used drugs, and 50 drugs that accounted for the highest Medicaid expenditures were selected for the study. With some drugs overlapping the two categories, the resulting sample contained 77 multiple source drugs groups.

The GAO determined that for 59 of the 77 multiple source drug groups analyzed in the study, the AMP-based FUL was lower than average retail pharmacy acquisition cost. On average, GAO estimated that the AMP-based FUL was 36 percent lower than average retail pharmacy acquisition cost. For high expenditure drugs, GAO estimated that the AMP-based FUL was 65 percent lower, and it was 15 percent lower for the frequently used drugs. For the drugs that overlapped both categories, the estimated AMP-based FUL was 28 percent lower than average retail pharmacy acquisition cost.

CMS Response

Based on the methodological flaws discussed below, we do not concur with the GAO findings that the AMP-based FUL would be lower than average retail pharmacy acquisition cost. The GAO study fails to credibly document this finding and we believe the release of the report would mislead the public.

The CMS has significant concerns with the validity of the estimate GAO used to approximate pharmacist acquisition costs. The CMS is unable to validate the findings of the GAO related to average retail pharmacy acquisition cost. The report does not provide source documents or evidence of how IMS Health arrived at the acquisition cost used in the comparison study other than to state that data on sales transactions were collected. Specifically, IMS cost and utilization data by national drug code (NDC) was not provided to CMS. This brings into question the overall validity of this self-reported data. Further, the GAO states in their report that "the average pharmacy acquisition cost data that we obtained from IMS Health may be greater than actual average acquisition cost,

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because these data do not account for rebates that pharmacies may receive from wholesalers or manufacturers." Thus, even were the GAO to supply this data, we cannot determine the accuracy of the ingredient cost actually incurred by the pharmacy. Therefore, CMS has no confidence that the estimates used in this analysis adequately measure pharmacy acquisition costs.

The CMS has concerns that GAO failed to account for the differences in the definitions of AMP. The AMP data from first quarter 2006 used in this study is not a true reflection of the AMP data which will be submitted starting in January 2007. The DRA revises the definition of AMP, effective January 1, 2007, to exclude customary prompt pay discounts to wholesalers and requires drug manufacturers to include sales of authorized generics when they report their AMP. Since prompt pay discounts decrease AMPs, their exclusion would have the effect of increasing AMPs, and subsequently increasing the FULs. The absence of this factor in the analysis further calls into question the validity of GAO's findings.

The GAO also did not report on the effect that excluding outlier data would have on AMP-based FULs. The regulations, modified by the DRA, provide that FULs be set on drugs that are nationally available. We expect to address the elimination of outlier AMP data from use in calculating the FUL, as may be appropriate, before applying these new AMP-based FULs. Excluding outlier AMPs may significantly raise the FULs of many FUL groups and would further invalidate the GAO's findings.

The CMS has concerns that GAO's findings do not take into account the impact of existing state cost-containment mechanisms such as Maximum Allowable Cost (MAC) programs. While this report notes that States have MAC programs that further reduce the reimbursement used by States for multiple source drugs below the FULs, it fails to evaluate this effect on the GAO's overall comparison between acquisition costs and FULs. While we continue to disagree with the GAO's use of the average retail pharmacy acquisition cost, the report should at least compare the pharmacy acquisition cost to current State MACs instead of just the FUL.

The GAO study assumed that prescribing and filling practices will remain the same following the DRA change. In light of the DRA , we believe that assuming the same utilization of drugs within each of the 77 drug groups is incorrect. The GAO study provided no analysis of how States and pharmacies can mitigate the effect of the lower FULs by filling prescriptions with low cost generic equivalent drugs. We expect, with the implementation of the DRA provisions, that utilization will be driven to lower-priced generic versions of drugs, which will decrease costs in the overall. In addition, the GAO report fails to acknowledge that the FUL is not applied to brand name drugs when a physician certifies that these are medically necessary.

Prior Office of Inspector General reports have outlined the need for reform in Medicaid pharmacy reimbursement. The FUL amounts prior to DRA often exceeded pharmacy acquisition costs, and thus, increased cost to the States and the Federal Government. Using 250 percent of the lowest reported AMP rather than the current methodology of

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150 percent of the lowest price published in national compendia will reduce Medicaid expenditures for multiple source drugs and thus, result in billions of dollars of savings to States and the Federal Government.

Attachment

GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7119 or dickenj@gao.gov

Acknowledgments

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