

Submitter : Mr. Greg Moorer
Organization : Oak Ridge Pharmacy
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

**Collection of Information
Requirements**

Collection of Information Requirements

The pharmacy industry provides valuable prescription services for Medicaid recipients. I am deeply concerned with the proposed reimbursement model based on AMP. According to the GAO's report, community pharmacies such as mine will lose an average of 36% on each generic prescription filled for Medicaid recipients. My pharmacy will not be able to fill Medicaid prescriptions under such an environment. This will dramatically decrease access of prescription drugs for the Medicaid recipient. Without local pharmacies providing and monitoring prescriptions for this population, the cost of Medicaid will far and above exceed any savings that might be realized through AMP pricing for generic prescriptions.

Submitter : Lynda Staggs
Organization : Medical Arts Pharmacy
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

GENERAL

GENERAL

Before any pharmacy realizes a profit from filling a prescription, the cost for filling that prescription must be recouped. Recent studies fix that cost at approximately \$10.00 per prescription. Reimbursement rates must allow pharmacies to cover their cost plus make a profit. It is difficult to ascertain the true cost of a drug with so many tiers in the pricing schedules. There needs to be one fee schedule for retail and one fee schedule for institutions and both need to be based on quantity purchased. If pharmacies close because of unfair reimbursement rates, how will millions of patients in rural areas receive prescriptions? For the nation's elderly, receiving a prescription in the mail is not enough. They need and deserve a face-to-face relationship with a pharmacist. Without the thousands of interventions by pharmacists on a daily basis, a health care crisis is a real possibility.

Submitter :

Date: 02/06/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

am concerned over several issues - cost based on AMP will not reflect our acquisition cost at all so will break even at best on all outpatient meds; under 1102(b): who determines what is a physician administered medication v. a nurse administered one in the hospital outpatient setting? Have multiple incidents weekly where the physician will order the medication but not be physically present when it is given; the inclusion of a dispensing fee will not come close to covering the additional overhead present in a hospital outpatient setting - This is partially justified by statistics showing steady growth in prescription volume. I do not believe this. Actual cost cannot be recouped from only increasing volume without sacrificing quality; Reprogramming the software system to transmit the NDC codes on claims will not be an easy or cheap task

Submitter : Ms. James Burr

Date: 02/06/2007

Organization : Meadow River Pharmacy, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

This pharmacy opened in Dec. 2003. When have had a steady customer growth due to great customer service. We are always there for the customer. Although all our customers are not medicaid eligable we do serve a great many who are. We are against this, and if passed our pharmacy and our customers would suffer greatly.

Submitter : Mr. JAMES REED
Organization : EXPRESS RX DISCOUNT PHARMACY
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

GENERAL

GENERAL

DEAR SIR OR MADAME,

WITH THE IMPLEMENTATION OF MEDICARE PART D IN 2006, I HAVE HAD TO GO INTO DEBT IN EXCESS OF \$200,000.00 JUST TO STAY IN BUSINESS. REIMBURSEMENT RATES ARE WAY TOO LOW AS THEY STAND TODAY. I COSTS US AT LEAST \$10.00 PER PRESCRIPTION TO FILL NOW. HOW CAN WE STAY IN BUSINESS AND REMAIN AN ASSET TO THE COMMUNITY IF WE ARE FORCED OUT OF BUSINESS OR EVEN WORSE, BANKRUPT! THIS IS A REALITY OUT HERE IN THE PHARMACY COMMUNITY. PLEASE DO NOT CUT REIMBURSEMENTS TO US AND PLEASE INFORCE A TIMELY PAYMENT FROM THE THIRD PARTY ADMINISTRATORS AS THEY ARE THE MAIN COST TO THE MEDICARE PART D PROGRAM.

RETAIL PHARMACY GETS THE LEAST MONEY OF ANY PART OF THE PROGRAM BUT CONSULTS WITH THE PATIENT EVERY TIME THERE IS A PROBLEM WITH THE TPA WITH OUR CUSTOMERS PRESCRIPTIONS.

BELIEVE ME PLEASE! PHARMACY CANNOT SURVIVE ANY FORM OF LESSER REIMBURSEMENT.

SINCERELY,

JAMES REED (OWNER)

EXPRESS RX DISCOUNT PHARMACY

7032 EAST BRAINERD ROAD

CHATTANOOGA, TENNESSEE 37421

(E-MAIL: EXPRESSRXTN@AOL.COM)

PHONE 423-899-3278

Submitter : Mr. James Cary
Organization : ClearSpring Pharmacy
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

GENERAL

GENERAL

It is my understanding that CMS is considering reimbursing Pharmacy care providers for dispensed drugs at the Average Manufacturer Price or AMP . This will not work for the following reasons, different drug outlets, i.e. hospital versus retail, chain pharmacy versus independent pharmacy, low income versus everything, closed-door/mail-order versus retail. All of these different venues purchase drugs at different prices and to add more confusion there are back-end rebates.

My suggestion is to use actual NET ACQUISITION PRICE then add a reasonable profit and fill fee. This will simplify the process and allow community pharmacy to continue to serve Medicare patients.

Thank-you
James S. Cary
ClearSpring Pharmacy, Ltd.
Wheat Ridge, CO 80033
303-940-1689 x14

Submitter : Dr. Dean Flanagan
Organization : Americare Pharmacy Inc
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

Response to Comments

Response to Comments

AMERICARE PHARMACY INC
515 WEST CALIFORNIA
GAINESVILLE, TX 76240
940-668-6868
apinc94@suddenlinkmail.com

Leslie Norwalk
CMS

My name is Dean Flanagan Pharm D, MBA, CDE, I own and operate Americare Pharmacy Inc in Gainesville, Texas. I am confident that implementation of the AMP-based FULs will have devastating effects on my pharmacy and the patients that I serve.

As reported, I can not absorb a thirty six percent loss on Medicaid or Medicare prescriptions. The profit margins in a community pharmacy are razor thin now. I have been holding out in the hopes that reimbursement will improve with legislation to allow negotiations between pharmacy providers and drug benefit managers. Community Pharmacy has been forced to provide services at the drug benefit manager's desired compensation rate or opt out of the profession.

For the past ten plus years, I have seen profit margins shrink. I am the only pharmacist in the pharmacy, I work fifty five hours, six days of each week. The profitability of my profession does not allow me to hire a second Pharmacist or a part-time Pharmacist. The AMP-based FULs will no doubt be a death blow to community pharmacy.

I have a few questions for you. Why are generic drugs the target of this legislation, when brand drugs represent the greatest share of drug cost in the health care budget? Why is the pharmacy provider expected to provide the majority of the budget reduction when the drug cost represents the bulk of the cost of a prescription?

Why would you ask me to take a thirty six percent loss on the cost of the drug ingredient rather than make the request from the manufacturer? Why would you favor legislation to shift market share from generic drugs to brand drugs? If you truly desire a budget reduction, why would you multiply the cost of a health care program, by forcing providers to utilize brand drugs when generic drugs represent a small fraction of the cost of a brand? Why would you favor legislation that will, without doubt increase the cost of the health care program? Was this agenda planned to reduce the budget or supply a win-fall for the brand manufacturer? What PAC influenced the legislation to exempt brand drugs and target generic drugs? Could this be the same group that developed a clause to prohibit drug price negotiation by CMS on economies of scale for the Medicare prescription drug program? Who benefits from legislation that shuns the most cost effective and budget friendly class of drugs in favor of the far more costly brand drugs. It is blatantly apparent to me who the winner is in this legislative agenda, are you one of the winners?

Let me give some suggestions on how to solve the health care issues and provide a meaningful health care program for the United States. Shift a few billion dollars from the war industry grants and energy industry grants into providing health care to middle class Americans who have worked and sacrificed their entire life for this country.

Thank you

Dean Flanagan Pharm D, MBA, CDE

Submitter : Mr. David Seaver
Organization : MA Soc of Health-System Pharmacists
Category : Health Care Professional or Association

Date: 02/06/2007

Issue Areas/Comments

GENERAL

GENERAL

A hospital will have to maintain barcoding at the point of patient medication administration. Many, if not most, hospitals do not have an outpatient bar code medication administration system. Hospitals bill out by medication, be it a brand or generic medication.

The usual hospital information system will not yield a 11-digit unique NDC number to submit to the State Medicaid agency. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

The impact on workflow, staffing and financial resources of the hospital is unrealistic and not justifiable given current fiscal and workforce constraints. This is an incredible burden given the current cost-cutting fiscal constraints with which hospitals are currently faced.

The claim "[W]e believe the cost of adding the NDC to each claim would be minimal", ignores the necessary Information System costs for implementing such a change. More expensive still would be a paper system.

This is a burdensome requirement whose benefits are far outweighed by the costs to implement.

Submitter : Harlan Smith
Organization : The Medicine Shoppe.
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

Background

Background

Providing cost effective prescriptions requires the use of generic drugs. If incentives favor more expensive Brand Drugs the cost of the program will go up. Not only do we need to wisely utilize generic substitution but also make sure that reimbursement is based on readily available sources to the class of trade that dispenses the medication

Collection of Information Requirements

Collection of Information Requirements

To ensure accuracy AMP should be at the 11 digit level.

GENERAL

GENERAL

Pricing must be fair to community pharmacy. AMP and FULs must reflect realistic acquisition cost for this class of trade. It is impossible for pharmacy to sell prescriptions for less than they pay for them.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Mail Order pharmacies need to be transparent on their true cost. These figures should not be included in community pharmacist standards without community pharmacy being able to purchase at True FULs and AMP.

Regulatory Impact Analysis

Regulatory Impact Analysis

the very existence of a delivery system depends on fair and equitable reimbursement. Last year my income was about 30% of the standard due to keeping my store open and my employees with jobs in order to provide high quality pharmacy services to our patient base.

Response to Comments

Response to Comments

Timely updates of prices must be made. Good pharmacy services keep patients from more expensive emergency room visits and hospitalizations. Optimizing the pharmacy approach to the health and quality of life of patients is a very cost effective way to lessen total health care expenditures. The trust patients place with their community pharmacy indicates the importance of one on one care. I would not want to have my personal Dr visit over the phone or self diagnostics from reading a pamphlet. Patients need pharmacist to explain the proper use of their medications.

Submitter : Mr. John Eklund
Organization : Preston's Care Pharmacy
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

GENERAL

GENERAL

The formula for AMP-based federal upper limits in the proposed rule will underpay pharmacies based on our actual acquisition cost for multiple source generic drugs by up to 40%. Yes BELOW OUR COST. I do not understand how the GAO can conclude that the proposed AMP ruling will cause each independent pharmacy to LOSE MONEY FILLING PRESCRIPTIONS, yet, the AMP RULE, seems to chug along. Pharmacies are already underpaid for their services by large PBM's who dictate pharmacy reimbursement, while enjoying huge profits themselves. We are often paid less than our costs yet continue to serve the public. The average cost to fill a prescription has been calculated to be \$10.50, while fees paid to us are less than four dollars, often \$1.25 per prescription. Anyone from any government agency is welcome to come to my pharmacy to see my invoices and the amounts that I am paid for prescriptions and see that Pharmacists are not the reason for high prescription drug costs. Possibly the government should look into the practices of the PBM's, seek transparency in their transactions and look into their profitability. Then the government would know who is getting rich and who is doing the WORK!

Prices paid to manufacturers are NOT THE PRICES I PAY. Rebates and price concessions made by manufacturers are NOT GIVEN TO ME!

Antitrust laws established to prohibit price fixing, combined with the manufacturers policies of different 'classes of Trade' have allowed PBM's to hand pharmacies non-negotiable contracts, establish mail order outlets (which receive prices I can only dream of), giving them the ability to become the force that they have become.

AMP was never intended to serve as a basis for pharmacy reimbursement.

To be an appropriate benchmark, AMP must be defined to reflect the ACTUAL COST PAID BY RETAIL PHARMACY. This will be accomplished by excluding all rebates and concessions made by manufacturers which ARE NOT AVAILABLE TO RETAIL PHARMACY (Class of trade!) and by excluding ALL MAIL ORDER 'PHARMACIES' AND PBM PRICING from AMP calculations. As I said these prices never were and continue to be NOT OFFERED TO COMMUNITY PHARMACY.

Again, it seems that the large, profitable, institutions are influencing government decisions while the little guy's voice goes unheard.

Respectfully,

John Eklund, RPh.

Submitter : Mr. JOHN OCONNELL
Organization : Mr. JOHN OCONNELL
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

GENERAL

GENERAL

The change from AWP to AMP is going to be just fine....assuming that AMP is an accurate reflection of our actual acquisition cost (AAC). the GAO study finding that AMP will be 36%, on average, below our AAC is disturbing. Just because you feds run a deficit doesnt mean that small business can. Without adequate reimbursement, we will not provide services. Without adequate reimbursement, i will make sure to give my customers your phone number and you can figure out what they should do.

Submitter : Dr. Brian Vu
Organization : Carepoint Pharmacy, Inc.
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

Background

Background

The proposed AMP calculation for generic drugs will be detrimental to independent pharmacies, which have 90% of their business dependent on medical prescription revenue.

Our pharmacy, in particular, serve an important segment of the low-income patient population--minorities who cannot speak English. Most of our patients are Hmong, Vietnamese, Cambodian, Thai, Laotian, and Hispanic and we have translators to give the correct drug information. If these non-English speaking patients were to get their medications at the retail chain pharmacies (because all of the independents would be out of business, the pharmacies would not have translators. Thus, the non-English speaking patients would not receive the appropriate drug information and find themselves in the emergency rooms at hospital all across the state due to incorrect usage of medications. Thus, this would cost more money to the taxpayers.

GENERAL

GENERAL

Bottom line is that independent pharmacies cannot stay in business with the new AMP calculation. The new calculation does not cover the cost of product that independents must pay and does not cover the overhead cost to dispense the medication. If independent pharmacies all go out of business, this will be a severe barrier to quality, personal, access to pharmacies for the patients, especially non-English speaking patients.

The AMP calculation needs to cover the cost of drugs, overhead cost to dispense the drug (employees, PGE, vials, labels, phone, etc...), and a decent profit in order to keep the independent pharmacies in business. Many independent pharmacy owners are making less money than they would working for retail chain pharmacies, especially after the medicare part D hit their bottom lines. Now, with the threat of AMP, independent do not stand a chance. The real segments that will be devastated are the patients, because poor pharmacy care from chains, and the taxpayers, because they will share in the cost of patients entering emergency rooms due to incorrect drug usage.

Sincerely,

Brian Vu, Pharm.D.
Carepoint Pharmacy

Submitter : MARY GLAVAN
Organization : PURE SERVICE PHARMACY
Category : Pharmacist

Date: 02/06/2007

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. Robert McGivern
Organization : Ohio Pharmacists Association
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

**Collection of Information
Requirements**

Collection of Information Requirements

The definition under CMS2238P will cause more Independent Pharmacies to go out of business. The reimbursement will be far below actual costs to the pharmacy that I work in. CMS should redefine AMP so that it reflects what we actually pay for product. The way they define it now it only covers 1/2 the cost on average.
HELP SMALL PHARMACIES

Submitter : Dr. Carrie Fish
Organization : MedCenter Pharmacy
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

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. David McPeek
Organization : Seifried Pharmacy, Orrville, OH
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Prescription reimbursement will be based on acquisition prices no retail pharmacy has access to.

Regulatory Impact Analysis

Regulatory Impact Analysis

I don't understand how this can even be considered! Basic business principles are based on selling for more than you buy for; this will not be the case if this is put into effect.

Response to Comments

Response to Comments

Could put me and many other pharmacies who serve Medicaid patients out of business. Only alternative under these conditions is to turn Medicaid patients away, which I really don't want to do.

Submitter : Mr. George Bartell
Organization : The Bartell Drug Company
Category : Health Care Industry

Date: 02/06/2007

Issue Areas/Comments

Background

Background

My name is George D. Bartell, Chairman and CEO of the oldest drugstore chain in the country, headquartered in Seattle, Washington and operating 54 stores in major population centers in Western Washington.

Collection of Information Requirements

Collection of Information Requirements

See Attachment A

GENERAL

GENERAL

See Attachment A

CMS-2238-P-91-Attach-1.RTF

ATTACHMENT A

MODEL COMMENTS TO CMS
SUBMIT COMMENTS TO:
[HTTP://WWW.CMS.HHS.GOV/ERULEMAKING.](http://www.cms.hhs.gov/erulemaking)
COMMENTS DUE FEBRUARY 20th

=====

February 6, 2007

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

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

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

Our Company operates 54 pharmacies in Washington State. We are a leading provider of pharmacy services in the communities in which our stores are located.

This proposed regulation, if adopted, would have a significant negative economic impact on my pharmacies. It could jeopardize our ability to provide pharmacy services to Medicaid beneficiaries and the general public, and even our ability to remain in business. This regulation should not move forward unless substantial revisions are made. Incentives need to be retained for pharmacies to dispense low-cost generic medications.

I request that CMS please take the following actions:

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

that do not reflect the prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires. Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not traditional retail pharmacies. Retail pharmacies like mine do not have access to the special prices offered to these classes of trade.

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. While this may appear to be reasonable, perhaps generous, for the reasons stated in this letter it would force retail pharmacies like mine to sell most generic prescriptions at less than our cost of goods, even before the cost of filling the prescription is considered. The cuts will be devastating to retail pharmacies. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system. The findings of the GAO study confirm our own opinions and our own analysis.
- **Require that States Increase Pharmacy Dispensing Fees:** CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs. Current dispensing fees have been acceptable to retail pharmacies because retail pharmacies made a profit on the sale of the prescription. With the profit removed, the dispensing fee in my state covers half, at best, of our actual cost of dispensing.

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

Sincerely,

George D. Bartell
Chairman and CEO, Bartell Drugs

Submitter : Ms. carol sparks
Organization : Ms. carol sparks
Category : Health Care Professional or Association

Date: 02/06/2007

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.

Submitter : Mr. donald hare
Organization : Mr. donald hare
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

Response to Comments

Response to Comments

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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 : Mrs. Danielle Forsythe
Organization : Pure Service Pharmacy
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

GENERAL

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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 : Ms. Jo Prang
Organization : BHP, Inc. dba Medicap Pharmacies of the Black Hill
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

Background

Background

Prescription Drugs; AMP Regulation CMS 2238-P RIN 0938-AO20 The BHP, Inc. Corporation is writing to provide our views on CMS December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. Our Corporation operates 4 pharmacies in our area. We are a dependable, personal-service oriented provider of pharmacy services in the communities in which our stores are located.

Collection of Information Requirements

Collection of Information Requirements

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

GENERAL

GENERAL

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

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

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

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

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

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

Regulatory Impact Analysis

Regulatory Impact Analysis

the cost of doing a prescription in my pharmacy is the estimated national average of \$10.17. Any insurance that does not include at the very least an \$8 fee and offer at least an 18% profit margin are going to be refused at our pharmacies from now on. And yet, this will result in a loss of 10% of my business. Add this to the over 25% loss of Medicare Part D if this mis-guided AMP goes through, and I will have lost over a third of my business. I doubt anyone can stay in business six months after such a loss. Either that, or I can continue to take the poor-paying insurances that attach only the product to the price, and not the pharmacist time and expertise, and keep Medicare Part D with AMP and go out of business in 6 weeks. No private business can survive what you are expecting us to "hand-out", which is essentially paying the Medicare Part D customer to get their prescriptions from us.

Response to Comments

Response to Comments

I urge you to reconsider this whole issue of AMP. The burden has been and will continue to be on the backs of pharmacists and pharmacies to make Medicare Part

D successful. However, the impact of fewer pharmacies providing services will be profound. The poor and house-bound will be underserved and therefore the death-rate will rise.

Submitter : Mrs. Maria Fowler
Organization : Hoffman's Pharmacy
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

Background

Background

My name is Maria Fowler, and I am the owner of Hoffman's Pharmacy, an independent, community pharmacy that has been serving Ashtabula County's health care needs since 1941. In addition to filling prescriptions and providing our patients with health care information, we provide special services such as free prescription delivery, prescription compounding, and charge accounts, and we also are the only pharmacy in our county which services Hospice of the Western Reserve. We serve an impoverished area, where the average home price is \$42,000 and a majority of our patients are Ohio Medicaid recipients.

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 : Mrs. Barbara Wamsley

Date: 02/06/2007

Organization : Mrs. Barbara Wamsley

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Response to Comments

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Submitter : Mr. JOSEPH WUIS

Date: 02/06/2007

Organization : SELF EMPLOYED, NCPA, MPA, APHA

Category : Pharmacist

Issue Areas/Comments

Background

Background

I AM A 64 YEAR OLD PHARMACY OWNER WHO HAS OWNED OVER 12 DIFFERENT PHARMACIES IN MY LIFE: I HAVE SEEN MANY CHANGES IN THE 40 YEARS BUT NONE AS POORLY THOUGHT OUT AS THE CURRENT AMP. THIS WILL COST THE TAXPAYER BILLIONS AND RESULT IN A LOWER LEVEL OF TREATMENT AND PATIENT SERVICE.

GENERAL

GENERAL

THE ATTEMPT TO REDUCE COSTS IN MEDICAID SPENDING IS TOTALLY GOING TO MISS THE OBJECTIVE AND RESULT IN ELEVATED COSTS. THIS WILL ABSOLUTELY OCCUR IF A BELOW COST (AMP) METHOD TO DETERMINE PHARMACY COST BASE IS USED IN DETERMINING REIMBURSEMENT. I AND ANY OTHER INDEPENDENT OR CORPORATE OWNER WILL BE CERTAIN TO ATTEMPT TO SWITCH THE PATIENT TO A MORE COSTLY (BUT PROFITABLE) BRAND NAME MEDICATION INSTEAD OF THE COST EFFECTIVE (BUT UNPROFITABLE) GENERIC. WHO IS THE PERSON WHO THOUGHT OF THIS IDIOT PLAN BECAUSE THEY HAVE OBVIOUSLY TAKEN A HEFTY BRIBE FROM THE BIG PHARMACEUTICAL INDUSTRY WHO WILL REAP BILLIONS FROM THIS PLAN. PLEASE NOTE THE PHARMACY WILL ONLY CONTINUE TO MAKE THE NORMAL MARGINS AND NOT A WIND-FALL LIKE THE BRAND NAME COMPANIES. AMP IS NOT CURRENTLY A WORKABLE ANSWER AND MUST BE REJECTED.

Submitter : Mrs. Jill Raicevich

Date: 02/06/2007

Organization : OPA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The way pricing is going. There is no way to provide a QUALITY pharmacy experience to people who really need counseling. The incentive is not there even if the most well intentioned RPh. is there to help. They will be driven out of business. My husband and I have thought of starting an independent pharmacy but are scared into staying with the big chains who clearly don't practice what they preach. Does anyone remember the phrase "A friend for Life". they were bought out by companies who care more about drive-thrus & selling lotto tickets, and keeping their RPh's on duty in their 24hour stores. How nice it would be to find a company that would treat their RPh's like professional, family men& women. That won't happen if they have to continue to make up for lost money by selling out to the government & insurance reimbursements.

Submitter : Mr. Steven Fettman
Organization : Davies Pharmacy, Inc.
Category : Pharmacist

Date: 02/06/2007

Issue Areas/Comments

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We offer free delivery service to many Medicaid patients. With the proposed cuts, it will restrict access to their meds since so many are home-bound or don't have transportation.

We are still battling the lower reimbursement from Medicare D and have had to cut our store hours as a result. We are an independent pharmacy that has been part of Canton, Ohio for almost 45 years. With these cuts we will have to cut our services as well as access to medications.

Please redefine AMP and be sympathetic to the small business owners that truly care about their patients.

Submitter : Dr. Candace Haugtvedt

Date: 02/06/2007

Organization : Ohio State University

Category : Pharmacist

Issue Areas/Comments

**Collection of Information
Requirements**

Collection of Information Requirements

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