

Submitter : Mr. JOHN LIPSCOMB

Date: 02/20/2007

Organization : MEDICINE MART PHARMACY GAFFNEY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

AS AN INDEPENDENT PHARMACIST, I FEEL THAT THE NEW PROPOSED PRICING RULES ARE VERY HARMFUL TO PHARMACY. IT SEEMS TOTALLY INACCURATE TO BASE THE NEW PRICING BY AMP FOR INDEPENDT PHARMACY TO BE CALCULATED BY USING MAIL ORDER PRICING THAT WE ARE NOT GIVEN. THE PLAYING FIELD IS NOT LEVEL. ALSO THIS DOES NOT SEEM TO INCLUDE ANY ACTUAL COST OF DISPENSING FIGURES IN THIS PAYMENT PROGRAM. I FEEL THAT THE WHOLE PROGRAM NEEDS TO BE RE-EVALUATED.

Submitter : Dr. ROBERT DYKES
Organization : PORTER PHARMACY
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

I AM TOTALLY AGAINST THE PROPOSED CMS REGULATION SCHEDULED TO TAKE EFFECT ON JULY 1,2007. THE AMP PAYMENT SCHEDULE WILL RESULT IN US BEING PAID LESS THAN OUT ACQUISITION COST ON MANY PRESCRIPTIONS. MY PHARMACY WILL NO LONGER SERVE THE MEDICAID POPULATION IF THIS CHANGE IS IMPLEMENTED. I CAN NOT AFFORD TO LOOSE MONEY WHEN FILLING ANY PRESRIPTION. I OFFER FREE DELIVERY SERVICE TO MANY OF MY PATIENTS AS WELL AS MANY OTHER SERVICES THAT I CURRENTLY RECEIVE A MINIMUM DISPENSING FEE TO COVER THE COST OF. PATIENTS MAY HAVE TO DRIVE 20-30 MILES TO FIND A PHARMACY THAT WILL FILL THEIR MEDICINE BECAUSE WE SERVE A RURAL COMMUNITY WITH LIMITED ACCESS TO HEALTHCARE PROVIDERS. I STRONGLY OPPOSE THIS CHANGE AND SUGGEST THAT THERE IS A BETTER WAY TO SOLVE THE BUDGET PROBLEM.

Submitter : Hugh O'Neill
Organization : sanofi-aventis
Category : Drug Industry

Date: 02/20/2007

Issue Areas/Comments

Background

Background
please see the attached

GENERAL

GENERAL
please see the attached

Response to Comments

Response to Comments

Submitter : TOMMY PORTER
Organization : PORTER PHARMACY
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

I STRONGLY OPPOSE THE PROPOSED CMS REGULATION TO CHANGE THE REIMBURSEMENT FORMULA ON THE GA MEDICAID PROGRAM TO THE NEW DEFINITION OF AVERAGE MANUFACTURER'S PRICE (AMP). I AM THE OWNER OF PORTER PHARMACY AND IF THIS CHANGE IS MADE I WILL NOT SERVE THE MEDICAID POPULATION ANYMORE. I CAN NOT ACCEPT THE TERMS OF REIMBURSEMENT PROPOSED BECAUSE IT WOULD RESULT IN ME LOSING MONEY TO FILL THIS POPULATION'S PRESCRIPTIONS AND WOULD PUT ME OUT OF BUSINESS. I FEEL THAT THERE HAS GOT TO BE A BETTER ALTERNATIVE TO SOLVE THE STATE'S BUDGET PROBLEM WITH THIS PROGRAM.

Submitter : Mr. Benjamin Loy
Organization : PDX, Inc.
Category : Health Care Industry

Date: 02/20/2007

Issue Areas/Comments

Background

Background

PDX, Inc., a major provider of retail pharmacy software to pharmacy chains, was established in 1985 in Granbury, Texas and was preceded by pci, Inc., a software application provider primarily for independent pharmacies. PDX is the most widely distributed single code-based pharmacy application used in North America. PDX and its affiliated companies provide pharmacy technology to a customer base of approximately 1,000 independent pharmacies and over 60 chains comprising in excess of 10,000 retail pharmacies. PDX has software installations in all 50 states, District of Columbia, Puerto Rico and the U.S. Virgin Islands. As such, we have a good understanding of the technology issues facing the retail pharmacy industry. We are writing to provide comments on the proposed implementation of the Average Manufacturer's Price (AMP) as the federal upper limit for reimbursement. PDX appreciates the opportunity to submit written comments to the Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS) concerning the impact of the proposed changes on the retail pharmacy industry.

Collection of Information Requirements

Collection of Information Requirements

We are concerned that, under the current definition of AMP, this data will not reflect anything that approaches the actual prices paid by retail pharmacies for brand and generic medications. As a result, this could provide a misleading picture to states, private plans and consumers about the true acquisition costs of medications for retail pharmacies. The disclosure of incorrect cost information could have a devastating effect on retail pharmacy and could potentially result in losses that would not be sustainable either forcing pharmacies to drop out of certain programs and possibly close all together in other cases. Therefore, the highest care must be employed to ensure that any prices published are fair and equitable and allow the retail pharmacy industry to receive a reasonable return on their investment in the medication and services that are required by the citizens of these great United States of America including the beneficiaries of the various state and federal prescription assistance programs.

GENERAL

GENERAL

Retail pharmacy is a highly compassionate industry that goes to great lengths to assist in times of need. The near catastrophe that followed the implementation of the Medicare Part D program was only averted by the willingness of individual pharmacies to provide the needed medications to recipients often with no assurance of repayment what so ever. These Heroes (not my term but Speaker of the House Nancy Pelosi's in a May 23, 2005 speech) were tanked by having to bill and rebill and rebill and sometimes even rebill these claims again and again to processors who were unable to adequately process them. Now these same Heroes are being asked (actually being told) that they will have to take an across the board 36% 3 reduction in reimbursement. If anything could chill the warm spot in the collective hearts of pharmacies and pharmacists this may just do the job.

Therefore, we urge that great deliberations be taken over this process and that it be implemented with the full understanding of its potential consequences to the fabric of the U.S. Healthcare System. If pharmacies find that they are unable to provide services for the reimbursement provided and either drop out of the government sponsored programs or discontinue business what benefit will this bring to the recipients covered by these programs? As a voting block seniors are the largest and most likely group to cast their votes. Pharmacists telling these voters that they are sorry but they are no longer able to fill prescriptions for them because the programs under which they are enrolled will not even cover the costs of buying the medications much less providing the services required of pharmacies could be a potent message.

Retail pharmacy has shown over the years a willingness and an ability to adapt and implement cost saving processes to allow acceptance of the necessary price constraints implemented by state, federal and private programs. Retail pharmacy could rightly be called the poster entity for the HIPAA Transactions and Code Sets Rule because this industry had already implemented a real-time on-line process for claim billing that allowed providers to remain in business and some to even flourish with reduced levels of reimbursement. Retail pharmacy continues to render quality care on what can only be classified to be razor-thin margins. It would seem only fair and even prudent to work with pharmacy to find an equitable reimbursement plan.

In closing, we will borrow a phrase from the oath of our colleagues in the medical profession and ask that you strive to do not harm in implementing this process to a lower cost allowances for retail pharmacy. The retail pharmacy industry and the health of the nation itself may hang in the balance. We thank you for the opportunity to provide these comments.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Data from the Centers for Medicaid and Medicare show that prescription medications as a percentage of total healthcare costs was relatively stable over the past 40 years between 1960 and in 2004 remained around 10% in 2004.1

Prescription as a Percentage of Total Health Care Costs was Relatively Stable Over the past 40 years.

Prescription Drug spending increased 5.8 percent in 2005 compared to growth of 8.6 percent in 2004. Factors contributing to this slowing trend were a sharp deceleration in Medicaid drug spending and a shift in use toward generic drugs. The broader slowdown between 2000 and 2005 was driven by the proliferation of tiered-copayment benefit plans, which slowed growth in brand-name drug use, and a decrease in the number of new drug introductions. In contrast to the overall trend, growth in out-of-pocket spending for drugs has outpaced private health insurance spending growth for drugs since 2003. 1

These numbers somewhat conflict with those provided by the GAO to Chairman Barton in their letter dated December 26, 2006 with the subject of Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, although they are from the same source but reflect general healthcare instead of only Medicaid expenditures. With many of the Medicaid beneficiaries that were under Medicaid in 2004 moving to Medicare Part D in 2006 and beyond the assumptions by the GAO may simply not be correct.

Numerous studies have shown that the most effective treatment method for chronic health conditions is a well regulated, self medicating, ambulatory patient who receives regular medical and pharmaceutical care. Maybe this is one of the reasons that most of the industrialized nations of the world spend a greater portion of their healthcare dollars, yen, Euros, etc. on prescription medications than does the United States. Only Norway, of the 10 largest economies, spends a smaller portion of total healthcare on pharmaceuticals. 2 While it is true that spending on pharmaceutical products increased from 8% to 13% of health care spending since 1980, that change occurred as total spending on health increased from 10% of GDP to 15%. Pharmaceutical spending increased from a bit less than 1% of GDP to a bit under 2% of GDP. That 1% of GDP is a lot of money, but it accounts for at most a fifth of the increase in health care costs in the US over the two and a half decades and arguably has provided the greatest beneficial impact. Therefore, if the intent is to significantly reduce health care costs and that by totally eliminating the pharmaceutical component would only produce a 13% reduction why not instead look at the remaining 87% of healthcare costs.

1 Office of the Actuary at the Centers for Medicare and Medicaid Services 2005 accessed on www.cms.gov February 16, 2007.

2 Pharmaceutical Pricing a Global Perspective, September 2004

Regulatory Impact Analysis

Regulatory Impact Analysis

However, at best the information provided by the GAO is only half of the story as the differential between the actual cost and the amount allowed under Medicaid is also used, in part, to compensate for the woefully inadequate professional fees allowed under many of these programs.

An analysis by a national pharmacy provider for the first four weeks of 2007 showed that the average fee paid by seven of the ten largest states in which they provided services (the other three were not calculable) was on average only \$3.52 and averaged \$3.71 for brand named drugs and \$3.33 for generic products with a range from a low of \$1.75 to a high of \$8.20. In contrast to these amounts the 2005 NCPA Digest found that the cost of dispensing was \$9.24 and The University of Texas at Austin (Summer 2005) found that the cost of dispensing within a chain pharmacy was \$9.62 mean (average) and \$9.46 median (middle point). Estimates for high cost of living areas such as California show costs of dispensing in the range of \$12 to \$13. An analysis of the Discount Drug Card programs compiled by PAAS National in July 2004 (see attached) shows an average professional fee allowed of less than \$2.00.

As noted in the GAO's letter & 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. Basing a reimbursement schema on a process that may have no relationship to what the pharmacy pays (Average Manufacturer's Price vs. Pharmacy Wholesale Price) for a product does not appear to even approach an equitable system. In addition to the pending AMP reimbursement, pharmacies are faced with a number of lower of measures such as MAC (maximum allowable cost) or Usual and Customary price. Why would the Medicaid program think that it has a right to the same fee as someone paying cash on the spot? The Medicaid program exposes the pharmacy to administrative overhead, transmission fees, carrying costs (sometimes as great as 180 days), liability under state and federal regulations that apply to these programs and subjects the pharmacy to funds recalls that do not apply to cash paying customer. This is obviously not the same class of trade and due to these factors cash prices should not reasonably apply.

Response to Comments

Response to Comments

Retail pharmacy is a business and is entitled to a reasonable return on its investment for the product, labor and professional services provided. The professional services component of pharmacy consists of a highly trained registered pharmacist who may be assisted by one or more certified pharmacy technicians. If companies cannot obtain a reasonable return for their investment in pharmacy they could take the billions of dollars currently invested in buildings, product, professional and non-professional staff and simply put this in a prime money market fund where they would be assured of a 5% net profit at today's rates. It is unconscionable that a company can make a 25% gross profit on a product that is sold over the counter when a medication for a life treating condition that requires a prescription under state and federal law and requires the pharmacist who provides such medication to perform prospective and retrospective drug utilization review, allergy checks for frank or potential allergies, drug disease checks to determine if other medical conditions of the patient would interfere with or be adversely affected by the prescribed drug, provide the patient with written instructions and counseling for taking such medication may not even be compensated for the cost of the product dispensed and have to wait 30 to 60 days or more to receive this inadequate reimbursement. Pharmacies should never be required to sell a medication at a loss to a beneficiary under a public program. Reimbursement must include the cost of the medication, cost to have the medication on-hand, overhead such as building, computer systems, networks and utilities, labor costs, professional services and a reasonable return on the investment in product, labor and professional services.

MEDICARE DISCOUNT DRUG CARD PROGRAMS

Assembled by PAAS National®

program	contact	reimbursement	details	Deadline	Addendum?
AARP/ Express Scripts, Inc. Medicare Approved Drug Discount Card Program	Provider Relations 866-296-9943 Fax 800-789-1867	<u>Brand:</u> AWP-13% + \$2.50 or U&C <u>Generic:</u> AWP-13% + \$2.50 or ESI Consumer MAC + \$2.50 or U&C	<ul style="list-style-type: none"> • Effective June 1, 2004 • Addendum to ESI Pharmacy Network Agreement • This program not applicable to PCA card. • Provider cannot mix AARP materials with other Medicare Approved Cards. 	• Sign and Fax by April 22, 2004	Yes
AdvancePCS, Inc. Amendment to CCPO2 Network Addendum & Network Enrollment Form	866-488-4708 Fax 480-314-8205	<u>Option2 (Default)</u> <u>Brand:</u> AWP-14% + \$1.50 <u>Generic:</u> nonMAC AWP-14%+\$2.00 <u>Option1</u> <u>Brand:</u> AWP-15% + \$1.50 <u>Generic:</u> nonMAC AWP-15%+\$1.75 <u>Option3</u> <u>Brand:</u> AWP-13% + \$2.50 <u>Generic:</u> nonMAC AWP-13%+\$2.50	<ul style="list-style-type: none"> • Amendment to CCPO2 Network • If Pharmacy does not decline or select Option 1 or 3; Pharmacy automatically in Option 2. • Pharmacies in Option 1 given preference on AdvancePCS website. • Larger percent of Manufacturer Rebates passed to Patients at Option 1 Pharmacies. 	Decline or Select Option 1 or 3 by February 27, 2004 Effective March 16, 2004	YES and Network Agreement
Anthem Prescription Management, LLC Pharmacy Program Conditions for the Anthem Medicare Discount Card Retail Pharmacy Network	Provider Network Department 800-230-8635 M-F 8am-4pm EST Fax 513-770-7693	<u>Brand:</u> AWP-13% + \$2.00 or U&C <u>Generic:</u> AWP-40% + \$2.50 or U&C	<ul style="list-style-type: none"> • Amendment to current Contract. • If Pharmacy does not decline this offer by March 6, 2004 the Program Conditions automatically become effective June 1, 2004. 	Decline by March 6, 2004.	Amendment
Argus Health Systems, Inc. Regulatory Addendum to include Medicare Drug Discount Cards	Help Desk 800-522-7487 Fax 816-435-7440	<u>None Listed</u>	<ul style="list-style-type: none"> • Generally binds Pharmacies to Federal and State laws/regulations. • Changes Argus ability to amend to passive, without Pharmacy approval. 	None	Yes
Caremark Advantage, Inc. Medicare Prescription Drug Discount Card Program Participating Pharmacy Agreement	Caremark Retail Services 800-421-2342	<u>Brand:</u> AWP-13% + \$2.50 or U&C <u>Generic:</u> AWP-13% or CMS MAC + \$2.50	<ul style="list-style-type: none"> • Caremark Advantage, Inc. is a different company from Caremark, Inc. • This is an entire contract and the language should be very closely reviewed. • 10¢ Administrative Transactional Fee. • 50¢ Network Administration Fee/Rx 	• Sign & Return by February 20, 2004	NO This is a New Contract

MEDICARE DISCOUNT DRUG CARD PROGRAMS

Assembled by PAAS National®

program	contact	reimbursement	details	Deadline	Addendum?
Community Care Rx/ MemberHealth, Inc. Network MH4 Agreement for Medicare Discount Network Supported by NCPA (National Community Pharmacists Association)	MemberHealth 888-868-5854	<u>Brand:</u> AWP-13% + \$2.50 or U&C <u>Generic:</u> CCRx MAC + \$2.50 or U&C MAC set at HCFA MAC or 125% of Actual Acquisition Cost	<ul style="list-style-type: none"> • CCRx is a not for profit LLC controlled by Community Pharmacists. • Payment for Enrolling Members of \$12.00; additional \$12 payment if patient re-enrolls • Dispense up to 100 Day Supply • Plan does NOT contain a mail order option • Has Long Term Care option which allows pharmacies to enroll patients from nursing homes and other long-term care facilities 		Network Agreement
Express Scripts, Inc. Addendum to Pharmacy Network Agreement Medicare Discount Card	Provider Relations 866-296-9943 Fax 877-782-3164	Not noted in addendum.	<ul style="list-style-type: none"> • Applies to all ESI Medicare Discount Programs other than PCA. 	• March 10, 2004	YES
First Health Group Corporation Medicare Discount Card Network	Kirsten Sanderson 916-374-3756 Geneva Rattliff 916-374-3713	<u>Brand:</u> AWP-10% + \$5.00 or U&C <u>Generic non-TA:</u> AWP-20% + \$5.00 or U&C <u>Generic TA:</u> MAC + \$5.00 or CMS FUL MAC + \$5.00 or AWP-10% + \$5.00 or U&C	<ul style="list-style-type: none"> • Primary Target State Senior Pharmaceutical Assistance Programs. • \$1.00 Administrative Fee deducted from Pharmacy Reimbursement, lowering the Professional Fee to \$4.00. 	April 1, 2004	Amendment
HealthPartners/Pharmacare Medicare Drug Discount Card	Mark Clancey Senior Contracting Analyst 800-237-6184 x7555	<u>Brand:</u> AWP-12% + \$2.50 or U&C <u>Generic:</u> MAC or AWP-20% + \$2.50 or U&C (MAC is Pharmacare Managed Care MAC value)	<ul style="list-style-type: none"> • If Pharmacy does not decline this offer they will automatically be added to the Network. 	• Decline by January 29, 2004 or Pharmacy will be automatically included.	Amendment
Medco Health Solutions, Inc. Consumer Program Pharmacy Network Schedule YRX-100 Addendum, Amended to add Medicare Drug Discount Card	800-523-6389	<u>Brand:</u> AWP-13% + \$2.25 or U&C <u>Generic:</u> AWP-13% or MAC + \$2.25 or U&C	<ul style="list-style-type: none"> • If Pharmacy does not decline this offer they will automatically be added to the Network. 	Effective February 1, 2004	Amendment
MedImpact Healthcare Systems, Inc. Medicare Drug Discount Card & Transitional Assistance Program—Retail Network & Choice 90-Option Network	Questions 800-788-2949	<u>Retail Network</u> <u>Brand or Generic:</u> AWP-15% or CMS MAC + \$3.50 or U&C. <u>Choice 90-Option (>84 Days)</u> <u>Brand or Generic:</u> AWP-20% or CMS MAC + \$1.00 or U&C.	<ul style="list-style-type: none"> • Choice 90-Option for 84 Days Supply or Greater in lieu of Mail Order Pharmacy. • MedImpact does not own Mail Order facility. • \$1.00/Claim Fee PAID BY PHARMACY 	• Return by February 15, 2004	Yes

MEDICARE DISCOUNT DRUG CARD PROGRAMS

Assembled by PAAS National®

program	contact	reimbursement	details	Deadline	Addendum?
PacifiCare/Secure Horizons RxSolutions, Inc. (Prescription Solutions) Medicare Drug Discount Card	Contracting Department 800-613-3591 Fax 714-825-3608	<u>Brand:</u> AWP-13% + \$2.75 or U&C. <u>Generic:</u> AWP-13% + \$2.75 or MAC + \$2.75 or U&C.	<ul style="list-style-type: none"> • RxSolutions does business as Prescription Solutions 	Effective June 1, 2004	Amendment
Pharmacy Care Alliance/ Express Scripts PCA Medicare Approved Drug Discount Card Program <u>Version 2</u> Supported by NACDS (National Association of Chain Drug Stores)	Questions 800-332-5455 Fax 877-387-5800	Lesser of U&C minus \$1.00 or < 60 Day Supply <u>Brand:</u> AWP-13% + \$2.00 <u>Generic:</u> ESI Retail Medicare MAC or AWP-13% + \$2.50 > 60 Day Supply—Select ONE #1- <u>Brands:</u> AWP-18% + \$2.00 <u>Generics:</u> MM MAC or AWP-18% + \$2.50 #2- <u>Brands:</u> AWP-20% + \$2.00 <u>Generics:</u> MM MAC or AWP-20% + \$2.50 #3- <u>Brands:</u> AWP-23% + \$0.00 <u>Generics:</u> MM MAC or AWP-23% + \$0.00	<ul style="list-style-type: none"> • Payments for Co-Marketing and Enrollments up to \$12.00. • Provider will NOT promote any other Medicare Approved Drug Discount Card. • Most Favored Nations Provision—if Pharmacy accepts a lower paying Medicare Discount Card they will bill ESI at the lower rate less 50¢. • MM MAC is ESI Medicare Maintenance MAC and is valued at 2.5% of AWP less than ESI Retail Medicare MAC. 	Effective on date of signing.	YES
Pharmacy Care Alliance/ Express Scripts PCA Medicare Approved Drug Discount Card Program <u>Version 6</u> Supported by NACDS (National Association of Chain Drug Stores)	Provider Relations 866-296-9943 Fax 877-782-3164	Lesser of U&C minus \$1.00 or < 60 Day Supply <u>Brand:</u> AWP-13% + \$2.00 <u>Generic:</u> ESI Retail Medicare MAC or AWP-13% + \$2.50 > 60 Day Supply—Select ONE #1- <u>Brands:</u> AWP-18% + \$2.00 <u>Generics:</u> MM MAC or AWP-18% + \$2.50 #2- <u>Brands:</u> AWP-20% + \$2.00 <u>Generics:</u> MM MAC or AWP-20% + \$2.50 #3- <u>Brands:</u> AWP-23% + \$0.00 <u>Generics:</u> MM MAC or AWP-23% + \$0.00	<ul style="list-style-type: none"> • Payments for Co-Marketing and Enrollments up to \$12.00. • Provider will NOT mix PCA Materials with any other Medicare Approved Drug Discount Card. • Most Favored Nations Provision—if Pharmacy accepts a lower paying Medicare Discount Card they will bill ESI at the lower rate. • MM MAC is ESI Medicare Maintenance MAC and is valued at 2.5% of AWP less than ESI Retail Medicare MAC. 	Return by March 10, 2004 Effective on date of signing.	YES
PharmaCare Medicare Prescription Drug Discount Card and Transitional Assistance Network	Mark Clancey Senior Contracting Analyst 800-237-6184 x7555	<u>Brand:</u> AWP-13% + \$2.00 or U&C <u>Generic:</u> AWP-25% + \$2.50 or CMS MAC x 105% + \$2.50 or U&C	<ul style="list-style-type: none"> • If Pharmacy does not decline this offer they will automatically be added to the Network. • 3¢ per Transaction Administrative Charge to the Pharmacy. 	• Decline by February 29, 2004 or Pharmacy will be automatically included.	Yes

MEDICARE DISCOUNT DRUG CARD PROGRAMS

Assembled by PAAS National®

program	contact	reimbursement	details	Deadline	Addendum?
Prime Therapeutics, Inc. PrimeRx Card Network	Alan Van Amber Sr. Director. Pharmacy Services 800-821-4795	<u>Brand:</u> AWP-13.5% + \$2.00 or U&C <u>Generic:</u> AWP-20% or CMS MAC + \$2.00 or U&C.	<ul style="list-style-type: none"> Pharmacy must sign and return this Amendment to be included in the Network. 	February 16, 2004	Amendment
RESTAT Medicare-Approved Prescription Drug Discount Card & Transitional Assistance Program	Provider Relations 800-926-5858 x4249	<u>Brand:</u> AWP-13% + \$2.25 or U&C <u>Generic:</u> AWP-20% (or MAC) + \$2.25 or U&C	<ul style="list-style-type: none"> \$30 Enrollment Fee Split w/Pharmacy Enrolling Patient. Mail-Order Offered/not Promoted. RESTAT does not Operate Mail Order Pharmacy. No Limit on Days Supply 	Return by January 27, 2004.	Yes
Sav-Rx Medicare-Approved Prescription Drug Discount Card and Transitional Assistance Program	800-228-2181 402-727-9798	<u>Brand:</u> AWP-13% + \$.200 or U&C <u>Generic:</u> Sav-Rx MAC + \$2.50 or AWP-30% + \$2.50 or U&C	<ul style="list-style-type: none"> 3¢ per Transaction Administrative Charge to the Pharmacy. 	Return by January 26, 2004	Yes
ScriptSave/MSC Amendment & CMS Endorsed Network Exhibit C	Marc A. Bralts 800-347-5985 x3131 Fax 520-887-7670	<u>Retail:</u> Lesser of U&C <u>Brands:</u> AWP-13.5% + \$2.00 <u>Generics:</u> AWP-32% or CMS MAC + \$2.50 <u>Maintenance:</u> Lesser of U&C <u>Brands:</u> AWP-18\$ + \$1.50 <u>Generics:</u> AWP-55% or CMS MAC + \$2.00	<ul style="list-style-type: none"> Maintenance Schedule is Optional. MSC Administrative Fee up to \$2.00/Rx charged to patient. Payment within 30 days after the end of the month. 	Return by February 19, 2004	Amendment
Scrip Solutions Medicare Funded Transitional Assistance and Medicare Discount Drug Card	Professional Relations 800-230-8187	<u>Brand:</u> AWP-12% + \$2.25 <u>Generic:</u> HCFA MAC or AWP-25% + \$2.25	<ul style="list-style-type: none"> Administrative fee paid by Patient. Confusing language for pharmacy to collect and remit the administrative fee. 	Respond by January 26, 2004 or Pharmacy will be automatically included.	No Network Agreement
UnitedHealthcare/Medco Health Solutions, Inc. UnitedHealthcare Premier Pharmacy Network to add Medicare Drug Discount Card Program	NONE	<u>No Change in Reimbursement</u>	<ul style="list-style-type: none"> Passive Acceptance—no action required automatically goes into effect. To Decline Pharmacy must notify Medco Health Solutions. To include Medicare+Choice enrollees who qualify for Transitional Assistance w/Medicare Drug Discount Program to Premier Network. 	Effective April 1, 2004	Amend Participating Pharmacy Agreement with Addendum to UnitedHealthcare Premier Network
WellPoint Pharmacy Management Medicare Discount Card Program	Network Department 800-962-7378 x5118 or x5120 or x5116	<u>Brand:</u> AWP-13.5% + \$1.75 or U&C <u>Generic:</u> MAC + \$2.00 (MAC average AWP-25%) or U&C	<ul style="list-style-type: none"> 25¢/Claim Patient Access Fee Most Favored Nations Provision—if Pharmacy accepts a lower paying Medicare Discount Card they will bill WellPoint at the lower rate. 	Respond by January 25, 2004	Yes

MEDICARE DISCOUNT DRUG CARD PROGRAMS

Assembled by PAAS National®

program	contact	reimbursement	details	Deadline	Addendum?
WellPoint Pharmacy Management Medicare Discount Card Program - -REVISED	Network Department 800-962-7378 x5118 or x5120 or x5116	Brand: AWP-10% + \$4.41 or U&C Generic: MAC + \$4.41 (MAC average AWP-25%) or U&C	<ul style="list-style-type: none"> • 25¢/Claim Patient Access Fee • Most Favored Nations Provision—if Pharmacy accepts a lower paying Medicare Discount Card they will bill WellPoint at the lower rate. • May only be offered in Georgia. • Pharmacy Agrees not to offer Competitive Alternatives to Patient 	<ul style="list-style-type: none"> • Respond by March 10, 2004 	Yes
WHP Health Initiatives, Inc Medicare Discount Card Program	Member Services Department 800-207-2568	Rates as set forth in each Pharmacy's Pharmacy Network Agreement	<ul style="list-style-type: none"> • Pharmacy Agrees not to offer Competitive Alternatives to Patient 	<ul style="list-style-type: none"> • Return by January 30, 2004. 	Amendment

All pharmacies are cautioned to carefully review each plan and its impact on their pharmacy's business before accepting or rejecting the plan. Non-participation in a Medicare Network should not affect participation in any other network from that entity. For a detailed Contract Review contact PAAS National® at 888-870-7227 or info@paasnational.com.

Submitter :

Date: 02/20/2007

Organization : plannedparenthood, alamosa

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attachemnt

CMS-2238-P-1414-Attach-1.DOC

February 20, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the manager of Planned Parenthood of the Rocky Mountains' Alamosa health center, a non-profit outpatient clinic in Alamosa, Colorado. We provide reproductive health care services including breast and cervical cancer screenings, treatment for abnormal pap smears, birth control (including birth control pills, intrauterine devices and condoms), annual exams, STD testing, and pregnancy options education to uninsured and underinsured women. My health center serves over 900 patients each year, many of whom could not otherwise afford the health services—particularly oral contraceptives—that we provide. As an agency, Planned Parenthood is committed to providing quality care to the low and moderate-income women and men of the Alamosa community.

For nearly 40 years, the Alamosa health center has

- Provided health education, contraception, pregnancy options education, breast cancer screening and cervical cancer screening.
- We provide menopause and midlife services.
- We provide comprehensive testing for sexually transmitted diseases, including HIV/AIDS. We refer those with positive tests for treatment to our partners in the reproductive health community.
- More than 93% of our surveyed clients are at 200% of poverty or below.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Planned Parenthood of the Rocky Mountains is not federally funded. Therefore, we do not have access to the guaranteed pricing under the 340B program.

At the same time, Planned Parenthood of the Rocky Mountains, and our Alamosa health center, serves as a key safety net provider to our community. Our ability to continue to do so rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define "safety net provider" or apply the ability to purchase

nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, we do not qualify for the three categories listed above.

The Alamosa health center has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. Our ability to serve clients at below market rates is completely dependent on our ability to provide them with low cost contraceptives. Indeed, the majority of our clients simply cannot afford to purchase contraceptives at market rate that is why they come to Planned Parenthood. They trust us to provide them with quality, honest reproductive care at an affordable cost. It is critical that we continue to provide them with the health care they seek at an affordable price, or they may not seek any reproductive health care at all.

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

Respectfully submitted by,

Ernestine Martinez
Planned Parenthood of the Rocky Mountains, Alamosa Health Center
Alamosa, Colorado

CMS-2238-P-1415

Submitter :

Date: 02/20/2007

Organization : Planned Parenthood, Granby

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1415-Attach-1.DOC

February 20, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the manager of Planned Parenthood of the Rocky Mountains' Granby health center, a non-profit outpatient clinic in Granby, Colorado. We provide reproductive health care services including breast and cervical cancer screenings, treatment for abnormal pap smears, birth control (including birth control pills, intrauterine devices and condoms), annual exams, STD testing, and pregnancy options education to uninsured and underinsured women. My health center serves over 550 patients each year, many of whom could not otherwise afford the health services—particularly oral contraceptives—that we provide.

As an agency, Planned Parenthood is committed to providing quality care to the low and moderate-income women and men of Granby, a quiet town with amazing views of the jagged Rocky Mountains.

The Granby health center has been able to serve women in need of low-cost reproductive health care services because we have historically been able to purchase oral contraceptive drugs from manufacturers willing to provide them at nominal prices. Our ability to serve clients at below market rates is completely dependent on our ability to provide them with low cost contraceptives. Indeed, the majority of our clients simply cannot afford to purchase contraceptives at market rate that is why they come to Planned Parenthood. They trust us to provide them with quality, honest reproductive care at an affordable cost. It is critical that we continue to provide them with the health care they seek at an affordable price, or they may not seek any reproductive health care at all.

For decades the Granby health center has

- Provided health education, contraception, pregnancy options education, breast cancer screening and cervical cancer screening.
- Provided comprehensive testing for sexually transmitted diseases, including HIV/AIDS. We refer those with positive tests for treatment to our partners in the reproductive health community.
- More than 68% of our surveyed clients are at 200% of poverty or below.

As you know, effective last month, only three kinds of providers are allowed to purchase drugs at nominal prices: 340B covered entities, intermediate care facilities for the mentally retarded and state owned or operated nursing homes. Planned Parenthood of the Rocky Mountains is not federally funded. Therefore, we do not have access to the guaranteed pricing under the 340B program.

At the same time, Planned Parenthood of the Rocky Mountains, and our Granby health center, serves as a key safety net provider to our community. Our ability to continue to do so rests with our ability to purchase contraceptive drugs at a nominal price. Therefore, we were deeply disappointed when CMS did not define "safety net provider" or apply the ability to purchase nominally priced drugs to other safety net providers in the proposed rule. Unfortunately, like many other small safety net providers, we do not qualify for the three categories listed above.

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

Respectfully submitted by,

Aimee Quadri
Planned Parenthood of the Rocky Mountains, Granby Health Center
Granby, Colorado

Submitter :

Date: 02/20/2007

Organization : Planned Parenthood, Glenwood Springs

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

continued below

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

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

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

Submitter :

Date: 02/20/2007

Organization : Planned Parenthood, joplin

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

attached document

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

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

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

Submitter :

Date: 02/20/2007

Organization : Planned parenthood La Junta

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

see attached letter

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

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

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

Submitter :

Date: 02/20/2007

Organization : Security Planned Parenthood

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

Planned Parenthood

1419

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

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

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

Submitter :

Date: 02/20/2007

Organization : Salida

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

attached letter on this issue

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

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

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

Submitter : Shelley Bailey
Organization : Central Drug
Category : Other Health Care Provider

Date: 02/20/2007

Issue Areas/Comments

Background

Background

February 20, 2007

Central Drug
538 SW 4th Ave.
Portland, OR 97204
503-226-2222
(f) 503-223-2439
centralportland@hotmail.com

Center for Medicaid/Medicare Services:

My name is Shelley J. Bailey and I am contacting you on behalf of Central Drug (an independent retail pharmacy in Portland, Oregon operating since 1903) to comment on the definition of AMP currently being purposed by CMS. According to the Government Accountability Office (GAO), with the proposed AMP reimbursement structure defined by CMS, pharmacies will be forced to accept payment for generic medications that is 36 percent below acquisition cost.

I am writing to you today to request that 1) the definition of AMP only include rebates available at the retail pharmacy level (excluding all rebates and price concessions only available to mail order pharmacies) 2) that AMP differs from Best Price 3) that AMP data is reported and updated weekly. Best Price is a calculation that was created as a contrasting measure to AMP for states to receive a rebate benefit more closely matching the marketplace; manufacturers must pay states either a percentage of AMP of the difference between AMP and Best Price, whatever is greater. In regards to the time frame for AMP updating, under the proposed rule, manufacturers supply CMS pricing data 30 days after the month closes, meaning that published pricing data will be at least 60 days behind market place pricing. In order for pharmacies to be reimbursed correctly, AMP data must be reported weekly (providing retail pharmacies sufficient time to re-run claims after the AMP data has been reported).

If the definition of AMP includes rebates available to mail order pharmacies in its definition, does not differ from Best Price, and is not reported weekly, retail pharmacies will be encouraged to not dispense generic medications, AMP as it is now defined discourages generic dispensing by retail pharmacies. For every generic medication dispensed for Medicaid or Medicare members, pharmacies save the United States taxpayer approximately \$94.00 per month (the difference between the average cost of brand name medications and similar generics). For Central Drug, a financial disincentive to dispense generics will encourage us to have our customers change to therapies where there are brand name equivalent medications still covered by Medicaid. For Central Drug, assuming we fill 130 Medicaid generic medications per day it will cost the United States Taxpayer approximately \$3,812,640 (312 operating days per year * 130 Medicaid generic dispensed/day * \$94 lost generic dispense savings to taxpayer) to have our customers on therapies which consist of brand name medications rather than similar generic therapies.

The appropriate definition of AMP to reflect the true acquisition cost of medications purchased by retail pharmacies ensures not only that retail pharmacies are in a financial position to remain open and continue to serve the public, but also results in a savings to the United States taxpayer with the financial incentive for pharmacies to continue to dispense generic medications to Medicaid members.

Please feel free to contact me at any time to discuss how the AMP definition affects retail pharmacy.

Regards:

Shelley J. Bailey, SPHR, GPHR

Submitter : Mr. William Vaughan
Organization : Consumers Union
Category : Consumer Group

Date: 02/20/2007

Issue Areas/Comments

Background

Background

February 20, 2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Washington, DC 20212

Re: CMS-2238-P

Dear CMS:

We submit these comments on behalf of Consumers Union, the independent, non-profit publisher of Consumer Reports.

Consumers Union strongly supports greater transparency and clarity in determining the true cost of prescription drugs paid for under various HHS programs. As the January, 2007 McKinsey Global Institute report, *Accounting for the Cost of Health Care in the United States*, makes clear, although they use fewer drugs per capita, Americans pay about 70 percent more for prescription drugs than the citizens of other peer nations. Drug rebates and other complicated payment arrangements account for billions of dollars of that extra expense:

We also analyzed the drug distribution and retail pharmacy system in the United States and peer countries. We found that distribution systems are overall quite similar, except for two distinctions. The first is the use of pharmacy benefit managers (PBMs), an entity unique to the United States, which adds 1 to 3 percent to the total cost of drugs to the system. The second is the use of rebates negotiated between pharmaceutical companies and payors or PBMs. Although in extreme situations rebates can reach 50 percent, they generally average 10 percent. [MGI, page 14]

We believe that increased public transparency of the true, net average manufacturing price will help more purchasers, especially smaller buyers, obtain lower prices.

Consumers Union promotes the use of the safest, most effective prescription drugs through its www.crbestbuydrugs.org program. We are continually surprised by public and private pharmaceutical plans that include on their formularies drugs which are not particularly safe, or effective, or which are among the higher cost drugs in a class. We assume that some of these anomalies in the marketplace are due to hidden rebates and other opaque payments that can cause a less safe, less effective, or a more expensive drug to be included in a plan's formulary. The more CMS can bring clarity and transparency to the Average Manufacturer Price, the more it will help drive plans toward prescription drugs which have the maximum efficacy and safety. Therefore, for the sake of patients, consumers, and taxpayers, we urge you to take the strongest possible position in support of netting out all exchanges of value in calculating the true AMP.

Thank you for your consideration.

Sincerely,

William Vaughan
Senior Policy Analyst

Submitter : Mr. Leroy Dinslage
Organization : PacNSave Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Discounts, rebates, and price concessions in 447.504(g)(6)AND (9) should not be included in the AMP calculation. Price concessions provided by drug companies to PBMs and mail order pharmacies are not available to the average community retail pharmacy, and thus are not available to the general public. AMP should reflect the price paid by retail pharmacies.

GENERAL

GENERAL

My general comment is geared to the effect this legislation will have on my business. I am 57 years old and have been in pharmacy for 35 years. I have watched as profit margins have shrunk to the point that I am worried the profit margin and the expense margin will not allow me to continue to do business. I am within 8 years of retiring, so it will not affect me as much as others that have 30 years of their future and are just starting out.

I don't see the reason that the government wants to have pharmacy bear 90% of the burden of the 8.5 billion that the government hopes to cut out of the Medicaid budget. Why is this pharmacy's burden? This needs to be shared by the drug manufactures and the PBM's as well. Caremark is being sold to the highest bidder for billions of dollars, and their profit is reported to be one billion dollars a year. How do they get by without sharing in this burden? They are just one of many PBM's.

I want to see that my business continues after I retire, but there needs to be enough profit in it to be worthwhile. Many small towns are going to loose their pharmacies, causing people to drive long distances to get their prescriptions filled. The government is going to save money, but force undue burden on the general public.

Leroy Dinslage RP

Submitter : Travis Rusch

Date: 02/20/2007

Organization : Milburn Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Just wanted to let you know how I feel about all of this AMP reimbursement investigation. First of all I would like to see the list of drugs that were used in the study and secondly why do pharmacies have to take such a large cut in reimbursements when the services we provide are so valuable to our patients. Everyday I deliver meds to the elderly and give them advice that keeps them out of the doctor's office, hospital, and nursing homes. It is time we are given credit for what we do and not looked at as an expense that does not return anything of any value. If AMP pricing comes to be it could be devastating to us and place a larger amount of problems on other parts of the healthcare system costing even more money. One final thought, we are not a government agency or charity so why are we experiencing such drastic cuts in reimbursement that our profit margins look like we are? Thank you for your time

Submitter : Mr. ALAN BARLING
Organization : FLANAGAN PHARMACY
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

LESLIE NORWALK,
I HAVE A BS IN PHARMACY & HAVE BEEN IN THE PROFESSION 32 YEARS WITH 26 AS A PHARMACIST 21 AS AN INDEPENDENT
PHARMACY OWNER.(FLANAGAN PHARMACY, FLANAGAN, IL. 61740

GENERAL

GENERAL

LESLIE NORWALK, THE WAY AMP IS SCHEDULED TO WORK WILL BE DEVASTATING TO MY PHARMACY & PHARMACY IN GENERAL! TO
CALCULATE THE AMP USING MAIL ORDER PRICES & PBM REBATES IN RETAIL PRICING IS LIKE COMPARING APPLES TO ORANGES. THE
PREFERENTIAL PRICING THEY RECEIVE IS & ALWAYS HAS BEEN UNFAIR. IN THE 21 YEARS AS A PHARMACY OWNER I HAVE NEVER
RECIEVED A PRICE INCREASE ON ANY OF MY DISPENSING FEES. THEY HAVE BEEN CUT YEAR AFTER YEAR ALL
THE WHILE MY EXPENSES KEEP GOING UP! THIS CUT WOULD PROHIBIT MY STORE FROM PATICIPATING IN MEDICAID PROGRAM &
COULD EVENTUALLY CLOSE MY STORE. MEDICAID IS NOW LATE ON PAYMENT OF 90-100 DAYS MAKING CASH FLOW VERY DIFFICULT
AS IT IS! THIS STORE SERVES A RURAL COMMUNITY WITH A POPULATION OF 1000. IT WOULD BE NICE IF FOR ONCE THE GOVERNMENT
COULD POSSIBLY SEE WHO IS REALLY MAKING ALL THE PROFITS. ITS NOT RETAIL STORES LIKE MINE! TAKE A LOOK AT PBM'S WHICH
DICTATE PRICE & REIMBURSEMENT MAKING PROFITS FOR MANUFACTURES, INSURERS AND RETAIL PHARMACIES.IE 30-50% INCREASE
IN PROFITS. THEREFORE IF I HAVE TO DROP MEDICAID I WILL ALSO HAVE DROP SERVICE TO A NURSING FACILITY. THIS WILL
ULTIMATELY CUT SALES 30-35% & WILL CLOSE MY STORE!

THANK YOU,

ALAN W. BARLING RPh.
FLANAGAN PHARMACY, INC.
FLANAGAN, IL. 61740

Submitter : Dr. Bruno Tching
Organization : Inland Pharmacy Inc
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

Implementation of this reimbursement model will ultimately result in the closure of many pharmacies. These closures will limit the access of patients to care and ultimately end up costing the healthcare system more. Traditional pharmacies are stakeholders in the health of their communities and for that they are trusted. We simply provide not only more care, but a higher quality of care. Community pharmacies are a front line defense in keeping healthcare cost down. Medication cost accounts for far less than a tenth of health care cost. All the while, pharmacy bears the grunt of all healthcare reimbursement cuts. The dispensing of generic medication has been a staple to reducing medication cost. The question which keeps running through my mind is& How does discouraging the dispensing of generic drugs reduce medication cost?

As a community pharmacist I oppose cuts to pharmacy reimbursement in the Medicaid program, such as those proposed in the President s budget. The implementation of Medicare Part D has already resulted in problems with reimbursement and daily disruptions to pharmacy operation. I am extremely concerned about the potential impact that such an additional proposal may have on my patients and community.

The U.S. Government Accountability Office recently reported that on average the federal upper limits under the new Average Manufacturer Price (AMP) were 36% lower than average retail pharmacy acquisition costs for the medications they reviewed. What business model allows someone to sell a product for 36% less than they are able to purchase it?

It is important to keep in mind that the GAO s findings were based on a reimbursement model of 250% of AMP, because the President s Fiscal Year 2008 budget proposes to further reduce reimbursement to pharmacists to 150% of AMP. This would be another \$1.2 billion in cuts from federal reimbursement, or over \$2 billion when combined with the corresponding state match. How are we supposed to continue to serve our patients with such devastating cuts to our reimbursement?

The calculation of AMP is based on the definition of retail survey price (RSP). The RSP inaccurately reflects the purchase price of traditional retail pharmacies. Including mail order and nursing home pharmacies into this calculation distorts the accuracy of prices paid by traditional pharmacies. Traditional community pharmacies do not have the bulk purchasing capability of these larger pharmacies and therefore do not get the rebates or discounts that these types of pharmacies acquire.

While multiple studies have demonstrated that the average cost to dispense a medication is approximately \$10, the typical reimbursement for pharmacist services provided by Medicaid is \$4. Previously higher margins for product reimbursement helped to make up for the inadequate reimbursement of pharmacist services. But now, what do we do? How do we continue to meet the needs of those in our community who need our help the most while keeping our pharmacy doors open?

1427

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

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

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

Submitter : Mr. Bob Brown

Date: 02/20/2007

Organization : Best Discount Pharmacy

Category : Pharmacist

Issue Areas/Comments

Response to Comments

Response to Comments

My cost to fill a prescription is \$9.26.

Submitter :

Date: 02/20/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

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

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

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

Submitter : Mr. Santiago Munoz
Organization : University of California, Office of the President
Category : Academic

Date: 02/20/2007

Issue Areas/Comments

Background

Background

See Attachment

Collection of Information Requirements

Collection of Information Requirements

See Attachment

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-1432-Attach-1.PDF

UNIVERSITY OF CALIFORNIA

BERKELEY • DAVIS • IRVINE • LOS ANGELES • MERCED • RIVERSIDE • SAN DIEGO • SAN FRANCISCO



SANTA BARBARA • SANTA CRUZ

OFFICE OF THE PRESIDENT --
CLINICAL SERVICES DEVELOPMENT

OFFICE OF THE PRESIDENT
1111 Franklin Street
Oakland, CA 94607-5200
Phone: (510) 987-9071
Fax: (510) 763-4253
<http://www.ucop.edu>

February 20, 2007

Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services (CMS)
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

SUBJECT: Proposed Rule CMS-2238-P Medicaid Prescription Drugs

Dear Director Norwalk:

Thank you for the opportunity to comment on the Proposed Rule CMS-2238-P relating to Medicaid prescription drugs. These comments are submitted on behalf of the University of California (UC) Health System and its academic medical centers (AMCs) located in Davis, Los Angeles, Irvine, San Diego, and San Francisco. Our comments are related to the administrative and financial burden imposed by the proposed rule and the potential impact to the 340B drug program.

The UC Health System is California's fifth largest hospital system. It is comprised of five AMCs which share a mission of educating health professionals, conducting research, and providing high quality patient care. Annually, the medical centers provide patient care services valued at over \$3.8 billion. Eight acute care hospitals in the UC Health System house 3,217 licensed acute care beds and provide a broad array of specialized services that are often not available elsewhere. UC medical center services are essential to the health and well being of Medicaid beneficiaries; they include cancer centers, trauma and burn centers, geriatric and orthopedic centers of excellence, and world class primary and preventive care.

The AMCs owned and operated by the UC qualify as disproportionate share hospitals ("DSH") under the Medicare program and are enrolled as covered entities under the federal 340B drug discount program. Our health system plays a major role in serving a significant portion of California's Medicare and Medicaid beneficiaries.

February 20, 2007

Page 2

Our principal concerns with the proposed rule are as follows:

First, the proposed regulations will create an enormous administrative and financial burden by requiring the reporting of NDC information on drugs furnished as part of a physician service in hospital outpatient settings. The proposed rule fails to recognize the inherent complexity of efficiently administering pharmaceuticals in a hospital setting. Often, common drugs come in several different generic versions and are packaged in several different sized containers. Moreover, a particular drug may be filled with various generics kept in stock. These practical considerations, coupled with ensuring that the clinical care requirements remain the most important focus of our clinicians, make tracking the exact source of drugs enormously difficult, if not impossible, at the physician level.

In addition, the hospital patient accounting systems are simply not designed to handle the routine reporting of a drug manufacturer's NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS) to report a particular drug or biologic rendered to a patient.

Second, CMS's proposed rule would significantly decrease the savings our AMCs achieve through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. Although our hospitals constitute a small fraction of the 400 acute care hospitals in California and our physicians an even smaller fraction, our health system is a major referral center for vast regions of the state and plays a significant role in serving many of California's most medically vulnerable, including the Medicaid population. In short, the 340 B program was designed to provide assistance to mission-driven health systems such as ours. We are extremely concerned that the proposed rule could financially undermine our role, which is critical to the health and well-being of all Californians.

Third, the rules relating to computing the Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our health system pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. For a health system such as ours, which serves a significant number of medically indigent patients, increased drug prices will have serious financial impact, including the possibility of losing nominal pricing contracts in non-340B participating parts of our health system.

February 20, 2007
Page 3

While the UC Health System wholeheartedly endorses CMS's efforts to improve access for Medicaid beneficiaries, we believe the proposed rule is counter-productive to this goal. We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Thank you for the opportunity to comment on this proposed rule. If there are questions or if I can provide any additional information or input, please contact me at 510-987-9062 or santiago.munoz@ucop.edu.

Sincerely,

A handwritten signature in cursive script, appearing to read "Santiago Muñoz".

Santiago Muñoz, Executive Director
Clinical Services Development

Submitter : Dr. Dirk White
Organization : White's Incorporated
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attached

CMS-2238-P-1434-Attach-1.PDF

1434



**HARRY RACE
PHARMACY & PHOTO**
106 Lincoln Street
Phone: 907-747-8666
Fax: 907-966-2467

White's, Inc.

SITKA, ALASKA 99835



WHITE'S PHARMACY
705 Halibut Point Road
Phone: 907-747-5755
Fax: 907-966-2468

February 19, 2007

Leslie Norwalk
CMS
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms Norwalk,

Since I need my time to help my community stay healthy and continue to ensure they take their medications properly I will not waste any time coming up with all kinds of arguments why AMP should not be implemented. I will cut to the chase and give you the bottom line.

My community will loose the benefit of our professional medical counsel, they loose the ability to have us review their medications and OTCs for interactions and possible side effects that may be causing lose of quality of life, or cause them to seek much more costly means of care such as the emergency room and then hospitalization. They will loose timely delivery of critically needed medications. Mail order Pharmacy is not an option for us on our island in the pacific. UPS, FEDEX, DHL and even the USPS will not guarantee next day, overnight, or express delivery. I am currently waiting for a computer from Dell that shipped Friday the 16th on Priority overnight service from FEDEX; they say it might deliver tomorrow the 20th.

We are the only community pharmacies on Baranof Island to serve our community. The Federal Government considers the extra cost to live here when it pays each and every Coast Guard, Forest Service, Park Service, and any other Federal employee their paycheck. A COLA (Cost of Living Allowance), which amounts to 25% of the base pay tax free, is added to each of these paychecks. This being the case and the GAO having said that pharmacist's payments under AMP calculations would be on average 35% below the cost of the medication, then you may as well factor in the COLA for me and you can see that I would be paid 60% below my cost to dispense a prescription.

I think you can see why we would not be able to accept this level of payment and would have to refuse to participate in any program that would reimburse based on AMP. This will be a serious setback to the health and well being of our community here in Sitka, as well as to our 30 plus employees. This will only lead to more Federal and State monies spent on social programs and increased utilization of higher priced health care options.

Sincerely,

Trish White RPh
Dirk White RPh

Submitter : Mr. Todd Sondrup

Date: 02/20/2007

Organization : Medical Plaza Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am opposed to the use of the AMP or Average Manufactures Price as the formula for reimbursing pharmacies for thier Medicaid claims. This formula is ill defined and does not reflect the true cost of dispensing prescriptions in a community retail pharmacy setting. The inclusion of mail order pharmacies and hospital outpatient pharmacies in the definition of retail pharmacies is not fair to all the small independent pharmacies in the country. The large mail order houses have access to rebates and price concessions that individual small businesses do not have.

Also, the proposal does not address the issue of dispensing fees for pharmacies.

Until there is a fair and equitable definition for AMP I urge the CMS not to implement this regulation.

Thank you.

CMS-2238-P-1436

Submitter : Mr. Sujay Jadhav

Date: 02/20/2007

Organization : Model N. Inc.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1436-Attach-1.RTF

Model N

Sujay Jadhav
Vice President of Life Sciences
1800 Bridge Parkway
Redwood Shores, CA 94065
Tel 650.610.4622
Fax 650.610.4699
E-Mail sjadhav@modeln.com
www.modeln.com

February 16, 2007

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

RE: FILE CODE CMS-2238-P (Medicaid Program; Prescription Drugs)

Dear Administrator Norwalk:

Model N appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding implementing provisions of the Deficit Reduction Act of 2005 (DRA) published in the Federal Register on December 22, 2006.¹

Model N provides a suite of Revenue Management applications for manufacturers of health care products to align their business processes of pricing strategy and execution, contract development and management, contract performance compliance, and payment of trade settlements, such as rebates, chargebacks, and fees. The suite shares a common platform that links the processes, people, and information involved in the entire revenue life cycle. In addition, to address specific life sciences regulatory exposures, Model N offers government pricing and Medicaid claims processing applications as part of the suite. By aligning revenue transactions with Medicaid and other government drug-pricing policies as well as with government best-price reporting requirements, the Model N regulatory applications eliminate the financial and brand name exposure to regulatory non-compliance.

As a part of Model N's continued support of the prescription drug manufacturing industry, we have solicited feedback and comments through our DRA portal² from our customers regarding implementation of rules and regulations resulting from the DRA. The comments below represent a summary of the views of our customers. The comments are not legal advice and do not necessarily represent details on past, present or future Model N products and solutions.

¹ 71 Fed. Reg. 77174.

² <http://dra.modeln.com/>

Model N

Continuation of the Quarterly Rebate Period. As stated in the proposed regulation, under statute, the rebate period is “a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under the national rebate agreement. The Medicaid Drug Rebate Program currently operates using a calendar quarter for the rebate period.”³

Comments: The feedback supports the CMS position that the rebate period continues to be based on a calendar quarter. In addition to the lack of legislative intent to change the period, changing the rebate reporting to a different or more frequent time period would place unneeded burdens on changing drug manufacturers’ government reporting systems without additional public benefit.

Exclusion of Returned Goods from AMP and BP Calculations. Returned goods are problematic to account for in AMP and BP calculations as these transactions, if not correctly handled, can cause large temporary fluctuations in the statistics that do not reflect market prices for the drugs involved. For this reason, CMS has proposed excluding transactions where “goods are being returned in good faith when they are being returned pursuant to manufacturer policies which are not designed to manipulate or artificially inflate or deflate AMP.”⁴

Comments: Comments generally supported the CMS decision to exclude returned goods from calculation of AMP and BP. Manufacturers have different return policies and returns within a calculation don’t provide an accurate result of weighted average pricing. Also, including returned goods is problematical for seasonal products where manufacturers experience a larger-than-sales return when the product is off-season. The returned goods transactions are usually easy to identify and their exclusion should provide more stable and accurate AMP and BP calculations.

Harmonization of PHS and CMS calculations. Based on the DRA, the CMS is proposing changes to how AMP and BP are calculated for future periods. Meanwhile, the Office of Pharmacy Affairs (OPA) has indicated⁵ that it will likely retain all or most of the prior AMP calculation methods going forward under its interpretation of section 340B(c) of the Public Health Service Act.

Comments: A common suggestion was for the Director of the CMS work with the Director of OPA to develop a unified method for determining and calculating terms held in common such as AMP. Wherever possible this should be done on an administrative basis and elsewhere by working with legislative leadership to introduce necessary amendments to existing statute. The current situation with multiple different AMPs can lead to manufacturers reporting up to 20 AMP values per year for each

³ Id. at 77177.

⁴ Id. at 77181.

⁵ Director of the Office of Pharmacy Affairs letter dated Jan 30, 2007.

Model N

product. The current dichotomy in rules places an unnecessary and unrealistic burden on manufacturers to calculate the multiple different AMPs with no clear public benefit.

Transmission of Authorized Generic Data. In response to requirements in the DRA to include data from authorized generics (AG) into the calculation of AMP and BP, the CMS has proposed rules for AG data inclusion. In the proposed rules, data from all sales for single source or innovator multiple source drugs for drugs marketed under brand manufacturer's original NDA but a different NDC must be aggregated for calculation of AMP and BP as reported by the brand manufacturer⁶.

Comments: The rules need to be clarified to specifically allow for the option of using aggregate data (at the NDC11 level) supplied by the authorized generic manufacturer to the brand manufacturer. While it might seem ideal to use all the transaction data from the AG manufacturer in the brand calculations of AMP and BP, there are several operational and legal issues that make this an impractical option for many situations. The first issue is that there is usually only 30 days to calculate the end of period results and report on them. The large amount of data required to be moved at the transaction level could impact manufacturer's data systems speed. Another issue raised by complete transaction level data transfer is inter system compatibility between the AG and branded manufacturer's reporting systems. Each manufacturer has somewhat unique methods of capturing and categorizing transactions which could easily lead to mishandling of AG raw transactional data in the branded manufacturer's system. A third issue is that of potential competitive and legal issues regarding transfer of sales data from one drug manufacturer to another. To minimize the impacts of all these factors, import of data at the highest aggregate level necessary for calculating an accurate AMP and BP should be specifically allowed. One example of this would be to take the AMP as reported by the AG manufacturer to the CMS along with net eligible units sold for that NDC by the AG manufacturer to be used to calculate the AG contribution to the branded manufacturer's blended AMP value for its related NDC.

Smoothing of Lagged Data in AMP. In the proposed rule, while the CMS does discuss the use of smoothing, it does not permit its use for lagged data in the AMP calculations. Instead, the proposed rule allows the use of estimation and assignment of lagged data for monthly AMP calculations.⁷

Comments: The consensus was that the CMS should be commended for identifying this issue and soliciting feedback. The CMS should specifically allow the use of smoothing for lagged data in monthly AMP calculations and should indicate as soon as possible what method of smoothing to use. Furthermore, it was recommended that the CMS specifically authorize the option of using either a 12 month or a 4 quarter rolling average smoothing method for this purpose. By allowing smoothing, a more accurate and less volatile AMP will result. A 12 month smoothing is what is currently used in

⁶ 71 Fed. Reg. 77198.

⁷ Id. at 77186.

Model N

ASP calculations and it would be consistent to have a similar methodology used for AMP. A 4 quarter rolling average has the added advantage of being easily understood and interpreted if applied uniformly to the monthly and quarterly AMP lagged data and would tend to yield more similar results between the monthly and quarterly values.

Conclusion. Model N appreciates the opportunity to provide comment on the Medicaid Prescription Drug Program. As always, we welcome any question or additional information that you may have, and look forward to working with you on implementation of this important new program.

Sincerely,

Sujay Jadhav
Vice President, Life Sciences

Submitter : Mrs. Frances Brown

Date: 02/20/2007

Organization : Brown Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

My cost for filling a prescription is \$10.53. I have been a registered pharmacist for many years...both in institutional and community pharmacy. I now am part owner of three community pharmacies who serve many medicare patients...many who are not able to drive 15 miles to the next town. Please consider the needs of these people before you pass regulations which will cause most of us to close our businesses.