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> Summary: Subject: Medicaid Program: Prescription Drugs; AMP  
> Regulation CMS 2238-P RIN ...  
> Product Level 1: Regulations & Guidance  
> Product Level 2: Policies  
> Product Level 3: e-Rulemaking  
> Date Created: 02/20/2007 12:11 PM  
> Last Updated: 04/05/2007 11:15 AM  
> Status: Reassigned  
> Assigned: Annette Pearson  
> State:  
>  
>

>Discussion Thread

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>Customer - 02/20/2007 12:11 PM  
>CMS 2238-P RIN 0938-AO20  
>

>I am pleased to submit these comments to the Centers for Medicare and  
>Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed  
>regulation that would provide a regulatory definition of AMP as well as  
>implement the new Medicaid Federal upper limit (FUL) program for  
>generic drugs. My name is William Thompson and I own 3 retail  
>pharmacies and 1 long-term care pharmacy in Altoona, PA. We are a  
>major provider of pharmacy services in the community and your  
>consideration of these comments is essential.  
>

>1. Definition of "Retail Class of Trade" - Removal of PBMs and Mail  
>Order  
>Pharmacies: Excluding PBMs and mail order pharmacies recognizes that  
>these are not community pharmacies where the vast majority of Medicaid  
>clients have prescriptions dispensed. These organizations do not

>dispense to the "general public". The more extensive comments  
>submitted by Pennsylvania Pharmacists Association have addressed  
>differentiation, consistency with federal policy, and the benefits of excluding these  
>data elements.  
>  
>2. Calculation of AMP - Removal of Rebates, Concessions to PBMs and  
>Mail Order Pharmacies: AMP should reflect prices paid by retail pharmacies.  
>Including these elements is counter to Congressional intent.  
>  
>3. Removal of Medicaid Data: Including these data elements is  
>"bootstrapping" the AMP calculation and does not recognize that  
>Medicaid pricing is heavily regulated by the state and federal governments.  
>  
>4. Manufacturer Data Reporting for Price Determination - Address  
>Market Lag and Potential for Manipulation: The actual implementation  
>of the AMP Regulation could create an avenue for market manipulation.  
>The risk of both price fluctuations and market manipulation, due to  
>timing of manufacturer reporting and the extended ability to revise  
>reported data, are amplified under the proposed structure. In order to  
>address these concerns, Pennsylvania Pharmacists Association proposes a  
>"trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS.  
>Furthermore, we comment on the lack of clarity on "claw back" from  
>manufacturer reporting error.  
>  
>5. Use of 11-Digit NDC versus 9-Digit NDC: We believe that CMS should  
>use the 11-digit AMP value for the most commonly-dispensed package size  
>by retail pharmacies to calculate the FUL for a particular dosage form  
>and strength of a drug. The prices used to set the limits should be  
>based on the most common package size dispensed by retail pharmacies.  
>Current regulations specify that the FUL should be set on package sizes  
>of 100 tablets or capsules or the package size most commonly dispensed  
>by retail pharmacies. These entities can only be captured if the  
>11-digit package size is used.  
>  
>In conclusion, I support the more extensive comments that are being  
>filed by Pennsylvania Pharmacists Association regarding this proposed regulation.  
>I appreciate your consideration of these comments and ask that you  
>please contact us with any questions.  
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>  
>Sincerely,  
>  
>William D. Thompson, III R.Ph.  
>  
>Auto-Response - 02/20/2007 12:11 PM  
>Title: Which DESI drugs do not satisfy the definition of a Part D drug?  
>Link: [http://questions.cms.hhs.gov/cgi-  
>bin/cms\\_hhs.cfg/php/enduser/popup\\_adp.php?p\\_faqid=8053&p\\_created=1165343](http://questions.cms.hhs.gov/cgi-bin/cms_hhs.cfg/php/enduser/popup_adp.php?p_faqid=8053&p_created=1165343)  
>011  
>  
>Title: What changes can Part D plans make to their formularies during  
>the plan year?  
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>bin/cms\\_hhs.cfg/php/enduser/popup\\_adp.php?p\\_faqid=7941&p\\_created=1159886](http://questions.cms.hhs.gov/cgi-bin/cms_hhs.cfg/php/enduser/popup_adp.php?p_faqid=7941&p_created=1159886)  
>692  
>  
>Title: Does the practice of "post-consumption" billing in  
>long-term-care pharmacies have to be accommodated by Part D plans under  
>the Medicare Prescription Drug Benefit?  
>Link: [http://questions.cms.hhs.gov/cgi-  
>bin/cms\\_hhs.cfg/php/enduser/popup\\_adp.php?p\\_faqid=6486&p\\_created=1135359](http://questions.cms.hhs.gov/cgi-bin/cms_hhs.cfg/php/enduser/popup_adp.php?p_faqid=6486&p_created=1135359)  
>686  
>  
>Title: How will CMS interpret the provision of the final regulation  
>that allows retail pharmacies to dispense a 90 day supply of drugs at  
>retail with any higher cost sharing paid by the beneficiary?  
>Link: [2](http://questions.cms.hhs.gov/cgi-</a></p></div><div data-bbox=)

>bin/cmshhs.cfg/php/enduser/popup\_adp.php?p\_faqid=4379&p\_created=1112217  
>978  
>  
>Title: Can patient assistance programs (PAPs) provide assistance with  
>Part D drug costs to Part D enrollees outside of the Part D benefit and  
>without counting towards TrOOP?  
>Link: [http://questions.cms.hhs.gov/cgi-](http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/popup_adp.php?p_faqid=7942&p_created=1160159)  
>bin/cmshhs.cfg/php/enduser/popup\_adp.php?p\_faqid=7942&p\_created=1160159  
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>[http://questions.cms.hhs.gov/cgi-  
>bin/cmshhs.cfg/php/admin/launch.php?p\\_launch=1](http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/admin/launch.php?p_launch=1)

>Reference #070214-000088

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> Summary: JOSE MARCO, R.Ph. February 11, 2007 MARCO'S  
> FARMACIA 4762 E. WHITTIER BLVD. L...  
> Product Level 1: Regulations & Guidance  
> Product Level 2: Policies  
> Product Level 3: e-Rulemaking  
> Date Created: 02/14/2007 07:40 PM  
> Last Updated: 04/05/2007 10:40 AM  
> Status: Reassigned  
> Assigned: Annette Pearson  
> State:

>Discussion Thread

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>Customer - 02/14/2007 07:40 PM  
>JOSE MARCO, R.Ph.  
>February 11, 2007  
>MARCO'S FARMACIA  
>4762 E. WHITTIER BLVD.  
>LOS ANGELES, CA. 90022  
>TEL: 323.269.7958  
>FAX: 323.269.1312

>CMS

>  
>  
> SUBJECT: CMS ASKS FOR SPECIFIC EXAMPLES FROM THE PUBLIC ON THE  
> PROPOSED MEDICAID AMP RULE BY THE DEFICIT  
> REDUCTION ACT WILL IMPACT COMMUNITY RETAIL  
> PHARMACY COMING JULY 1, 2007 ON GENERIC DRUG REIMBURSEMENT  
>  
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>  
> HISTORY: ON JANUARY 22, 2007 THE GOVERNMENT ACCOUNTABILITY OFFICE  
> (GAO) RELEASED A STUDY THAT FOUND THAT BASING  
> REIMBURSEMENT ON A NEW AVERAGE MANUFACTURER  
> PRICE FORMULA, AS DICTATED BY CMS, WILL RESULT IN  
> PHARMACISTS BEING PAID, ON AVERAGE, 36 PERCENT  
> LESS (BELOW) THAN THEIR "ACTUAL" ACQUISITION COST ON  
> MEDICAID PRESCRIPTIONS.  
>  
>  
>  
>  
>  
> MY FOLLOWING THREE TRUE COMMENTS ARE REAL AND NOT  
> ANY FABRICATION OF FALSE REPRESENTATION THAT  
> CMS WILL BE DOING TO ME, A COMMUNITY PHARMACIST,  
> AS WELL AS TO ALL AMERICAN TAXPAYER COME JULY 1, 2007.  
>  
>  
>  
> EXAMPLE 1. THE PRESENT IS THE FUTURE COME JULY 1, 2007 COURTESY OF CMS  
>  
> CMS PROPOSED \$8.4 BILLION DOLLARS IN MEDICAID  
> CUTS OVER THE NEXT FIVE YEARS FOR GENERIC  
> PRESCRIPTION MEDICINES TO MEDICAID PATIENTS.  
> BUT, BUT, NOT FOR "BRAND NAME MEDICATIONS".  
> CASE IN POINT: ON FEBRUARY 07, 2007, AT MARCO'S  
> FARMACIA, I TRIED TO PROCESS A PRESCRIPTION FOR  
> A GENERIC PRESCRIPTION FOR ZOCOR 40MG  
> (THIRTY) TABLETS BUT THE STATE  
> COMPUTER REJECTED THIS: 'ONLY'  
> REIMBURSEMENT!!!! DRUG" WAS ACCEPTED FOR  
> WHY????? DOES THE AMERICAN TAXPAYERS KNOW THAT THE COST  
> FOR 30 (THIRTY) GENERIC TABLETS COST JUST \$3.00 (THREE DOLLARS)  
> PLUS A PHARMACIST'S DISPENSING FEE, WHICH INCLUDES A  
> PROTOCOL OF PHARMACIST'S CARE CONSULTATION ON  
> TAKING ANY MEDICATION, BUT THE CALIFORNIA MEDICAID PROGRAM  
> WILL ONLY PAY THE BRAND NAME ZOCOR FOR 30 TABLETS AT A COST OF  
> \$143.00 (ONE- HUNDRED FORTY-THREE DOLLARS). AS WELL AS  
> HEALTH NET 2/5/07.  
> SAYS MR. BOSS MAN OF CMS, "I AM GLAD YOU WERE NOT  
> COVERING 'MAY BACK' IN THE MID 1960'S WHEN I WAS IN THE U.S.  
> ARMY SINCE YOU ARE DEMONSTRATING AMAZINGLY NO COMMON SENSE. "  
>  
>  
>  
>  
>  
> EXAMPLE 2. WHO'S TO BLAME?  
>  
> ON JANUARY 02, 2006 WITH THE NEW MEDICARE PART D  
> PROGRAM STARTING, I ASKED FOR \$13.00 DOLLARS CO-PAY  
> FROM A POOR AMERICAN SENIOR CITIZEN FOR HER 8  
> (EIGHT) PRESCRIPTIONS. THEN SHE REFUSED 3 (THREE) OF  
> HER  
> HYPERTENSIVE MEDS., 1 (ONE) CHOLESTEROL MED., 1  
> (HEART MED.), 2 (TWO) DIABETIC MEDS. BUT SHE WAS WILLING TO  
> PAY FOR HER PAIN MED. A NARCOTIC.  
> AT THIS POINT, I DECIDED TO NOT ASK ANY MEDICARE

>PART D PATIENT FOR CO-PAYMENT SINCE I COULD NOT LIVE WITH  
> MYSELF KNOWING, AS A PHARMACIST, THAT THESE  
>PATIENTS, LIVING ON A VERY LOW MONTHLY INCOME, WOULD  
>EVENTUALLY, .  
> IF NOT SOONER, BE HOSPITALIZED, CRITICALLY ILL,  
>BLIND, OR JUST DIE. FOR FURTHER INFORMATION, I REFER READER TO  
>READ  
> THE LOS ANGELES TIMES FRONT PAGE IN THE BUSINESS  
>SECTION ON WEDNESDAY APRIL 5, 2006.  
> THEREFORE, MR. BOSS MAN OF CMS, "ANY PHYISCAL  
>HARM THAT COMES TO MY PATIENTS IN THE MEDICAID PROGRAM  
> BEGINNING JULY 01, 2007 DUE TO YOUR 36 %  
>LESS (BELOW) FLUS ON GENERIC DRUGS, AS THE GAO SAYS IN ITS  
>REPORT, THAT  
> MAKES ME GO OUT OF BUSINESS, IT WILL BE ON YOUR  
>CONSCIENCE IN THIS PRESENT LIFE AND BEYOND; BUT NOT ON MY  
>SOUL.  
>  
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>  
>EXAMPLE 3. WHO LET TO DOGS OUT!!!  
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>  
> ACCORDING TO THE PHARMACEUTICAL CARE MANAGEMENT  
>ASSOCIATIONS (PCMA) AND THIER PRICEWATERHOUSE  
> COOPERS REPORT SUGGEST THAT "TRANSPARENCY" WOULD  
>RAISE PRICES BY PROMPTING DRUG COMPANIES TO REDUCE  
> THIER DISCOUNTS.  
> CASE IN POINT: ONE PCMA MEMBER CEO OF CAREMARK  
>RX, EDWIN M. (MAC) CRAWFORD, MADE ALMOST \$6  
>MILLON DOLLARS  
> IN 2005 AND ANOTHER  
>DAVID B. SNOW JR. CEO OF MEDCO HEALTH SOLUTIONS MADE  
>\$4.9 MILLION DOLLARS  
> IN 2005, ACCORDING TO  
>DRUG BENEFIT NEWS, FROM DRUG TOPICS APRIL  
>2006, PG 22S.  
> THEREFORE, SAY MR. BOSS  
>MAN AT CMS, WHY ARE YOU PROTECTING THE  
>SALARIES OF THE PCMA CEOs  
> AT THE EXPENSE OF THE  
>POOR AND THE AMERICAN TAXPAYER?????  
> AND YOU STILL WANT TO  
>PUNISH THE ONE PERSON THAT HELPS THE POOR AND TRYs TO  
>SAVE THE TAXPAYER MONEY, ME,  
>THE PHARMACIST.  
>  
>P. S. THE ONLY PLACE IN THE U.S.A. THAT I KNOW THAT SHOULD  
>NOT HAVE "TRANSPARENCY" IS IN RACHEL, NEVADA ----- A R E A 5  
>1 ----- BUT NOT IN A BUSINESS!!!  
>  
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>  
> IN CONCLUSION, FREEDOM, LIBERITY,  
>ACCOUNTABILITY AND QUALITY OF LIFE ARE FOR ALL AMERICAN CITIZENS, POOR  
>, SENIOR, AND THE TAXPAYER BUT NOT FOR JUST PCMA CEOs AND THEIR AGENTS AT CMS!!!!!!!!!!!!  
> SAY MR. BOSS MAN AT CMS, YOU ARE EITHER DEMONSTRATING NO KNOWLEDGE OF  
>MATHEMATICS OR BEING COERSED BY THE PCMA AND THEIR CEO MEMBERS SINCE  
>THERE IS NO BUSINESS THAT CAN FUNCTION WITH THEIR PRODUCT COST LESS 36  
>%; OH, OH, IF THE BUSINESS ORIGINATES FROM CHINA, WHICH HAS AN ILLEGAL  
>LABOR FORCE, AND THEIR WORKERS LOSE FINGERS ON THE JOB, TO GAIN PROFITS

>FOR THE FEW IN THE CONTROL OF THE COUNTRY!!  
>THEREFORE, I AM FORWARDING THIS LETTER TO MY POLITICAL REPRESENTATIVES  
>TO SEE IF THEY CAN MAKE SENSE OF YOUR FLUS PRODUCT COST AT LESS 36%  
>PAYMENT OR CORRECT THIS MADNESS THAT THE GAO STATED ON JANUARY 22, 2997.  
>  
>CC REP. GRACE FLORES NAPOLITANO  
>CC SEN. BARBARA LEVY BOXER  
>CC SEN. DIANE FEINSTEIN  
>CC. SEN. RONALD S. CALDERON  
>CC. REP. CHARLES M. CALDERON  
>  
>Auto-Response - 02/14/2007 07:40 PM  
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>011  
>  
>Title: What is CMS's position on continued payment of  
>access/performance rebates by pharmaceutical manufacturers to long-term  
>care (LTC) pharmacies that participate in Part D plan LTC pharmacy networks?  
>Link: [http://questions.cms.hhs.gov/cgi-](http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/popup_adp.php?p_faqid=6326&p_created=1133205)  
>[bin/cmshhs.cfg/php/enduser/popup\\_adp.php?p\\_faqid=6326&p\\_created=1133205](http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/popup_adp.php?p_faqid=6326&p_created=1133205)  
>396  
>  
>Title: Why did CMS wait until so late in the year to clarify its policy  
>to prohibit LTC access/performance rebates?  
>Link: [http://questions.cms.hhs.gov/cgi-](http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/popup_adp.php?p_faqid=6688&p_created=1139856)  
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