

Submitter : Mr. William Yates
Organization : The Medicine Shoppe
Category : Pharmacist

Date: 01/18/2007

Issue Areas/Comments

GENERAL

GENERAL

I do not understand why this administration has targeted independent pharmacies as a useless business community in which can be done away with. You first asked us to teach seniors about your Medicare Part D plan while at the same time cutting our profits. Now you are going to continue cutting our profits with AMP pricing for Medicaid. My family has been dispensing medicine over 50 years in this small town we live in. I personally went to seniors houses so I could explain Medicare Part D to them. And the thanks we get for our hard work is continued reimbursement cuts. This might be the last cut our pharmacy can take before we have to close the doors. And when that day comes it will be felt through the community.

CMS-2238-P-2

Submitter : Ms. susan maddox
Organization : Sharp HealthCare
Category : Health Care Provider/Association
Issue Areas/Comments

Date: 01/22/2007

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 : susan maddox

Date: 01/22/2007

Organization : Sharp HealthCare

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-3-Attach-1.DOC

January 22, 2007



Michael Sullivan
Centers for Medicare and Medicaid Services
75 Hawthorne
San Francisco, CA 94105

SUBJECT: Proposed Requirement to use National Drug Codes (NDC) on Medi-Cal Hospital Outpatient Claims (File Code: CMS-2238-P)

- **Any effort by the state to collect rebates may drive drug manufacturers to completely eliminate 340B pricing in order to avoid duplicate discounts. Should this occur, hospitals stand to lose significant savings achieved through the 340B program. At Sharp HealthCare, this amounts to approximately \$3 million.**
- **The proposed rule is based on the Deficit Reduction Act of 2005 which requires state Medicaid programs to begin using NDCs to secure rebates for multiple- and single-source *physician-administered* drugs. Sharp HealthCare is not convinced of the feasibility to comply with the NDC requirement but have estimated the start up costs at \$5,500,000. The application has not been tested and would not be workable for compounded intravenous solutions and medications.**

Dear Mr. Sullivan:

Sharp HealthCare, San Diego's largest health care provider, consists of four acute-care hospitals, three specialty hospitals, three affiliated medical groups, and a health plan, along with many other health care facilities, appreciates the opportunity to discuss our concerns regarding the California Medicaid program (Medi-Cal) proposed requirement that all outpatient claims use National Drug Codes (NDCs) for drugs billed.

This proposal is based on the Deficit Reduction Act of 2005 which requires state Medicaid programs to begin using NDCs to secure rebates for multiple- and single-source *physician-administered* drugs. Unlike other state Medicaid programs, California's Department of Health Services (CDHS) has interpreted this provision to apply to all health care provider-administered drugs in the outpatient setting. Sharp urges CMS to provide guidance to CDHS that the language *physician-administered* is not subject to a more expansive interpretation. Imposing this requirement on our hospitals would have serious negative implications as discussed below.

Hospitals participating in the 340B Program are entitled to receive 340B discounts on all covered outpatient drugs. One condition of participation is that a drug purchased under Section 340B shall not be subject to both a 340B discount and a Medicaid rebate. To avoid these duplicate discounts,

340B hospitals are to bill Medi-Cal at acquisition cost (plus dispensing fee) for 340B drugs or "carve out" Medi-Cal patients altogether from the 340B program. Sharp has opted for the latter; that is medications dispensed to Medi-Cal patients are not replaced using 340B pricing. As such, Medi-Cal should be collecting rebates on the outpatient drugs we dispense today. Any effort by the state to collect rebates in addition to 340 B pricing may drive drug manufacturers to completely eliminate 340B pricing in order to avoid duplicate discounts. Should this occur, hospitals stand to lose significant savings achieved through the 340B program. **At Sharp HealthCare, 340 B savings related to non Medi-Cal outpatients amounts to approximately \$3 million dollars.**

A far more daunting challenge is the implementation of outpatient claims to use National Drug Codes (NDCs) for drugs billed. Unlike outpatient retail pharmacies, hospitals fill medications dispensed in their outpatient departments using their inpatient dispensing system which is generally not based on NDC. The NDC requirement therefore would necessitate additional labor to track the ongoing data base and the purchase, application, and maintenance of additional software. Additionally, the interface with our information systems and automated drug dispensing would not detect changes in NDC codes. This may be overcome by the implementation of point of service bar coding for unit dose medications. The problems still remain with intravenous medications that are compounded in the pharmacy. The intravenous solution will be associated with two or more NDCs which cannot be scanned at the point of service. We are not convinced of the feasibility to comply with the NDC requirement but have attempted an estimate of the start up costs as listed below:

Pharmacy Technicians to track the NDC codes at each of seven hospitals:	\$ 500,000
Interface of Information Technologies	1,000,000
Point of Service bar code application	2,000,000
User training	<u>2,000,000</u>
Estimated Start up Costs:	\$ 5,500,000

These costs do not reflect additional hardware or ongoing maintenance and education.

Sharp HealthCare leadership in the Pharmaceutical areas would welcome a site visit to Sharp Hospital(s) to walk through the potentially unfeasible challenge of meeting this requirement. I would be happy to coordinate a visit, perhaps by the CDHS Chief of Pharmacy, Kevin Grospe, at his convenience. I am at (858) 499-4594. Thank you for your consideration of our concerns.

Sincerely

Susan Maddox
Vice President, Legislative and Governmental Affairs

cc: Stan Rosenstein, Deputy Director, Medical Care Services, CDHS
Toby Douglas, Assistant Deputy Director, Medical Care Services, CDHS
Kevin Grospe, Chief, Pharmacy Policy, CDHS
Cindy Garrett, PRO Project Office, EDS

Submitter : Mr. Brad Houck
Organization : Valley Apothecary
Category : Pharmacist

Date: 01/23/2007

Issue Areas/Comments

Background

Background

CMS and Medicaid plans to use AMP vs AWP in determining reimbursement to pharmacies for prescription drugs starting July 1st (pushed back from January 1st 2007)

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

This rule shows a fundamental lack of understanding of the marketplace, it is going to require a substantial amount of education of Congress and the Administration. Pharmacies have already been squeezed to the point where many independent drugstores are having to close due to the poor and slow reimbursements from Medicare Part D plans. The AMP model, atleast as I have read it and tried to understand it, will further cut reimbursements. Maybe the place FDA should be focusing their attention on reducing drug costs is with the manufacturers who operate on much larger margins, as compared to independent drugstore owners such as myself and my wife. Forcing small businesses to shut down across the United States because of ill conceived plans such as this is surely no the intent of our blessed Food and Drug Administration. I will be writing my Congressmen as often as necessary to have the FDA's actions closely looked at. If you want to save money , look to where the money is being made (the drug manufacturers and PBM's) and don't kill out small businesscs in an effort to make your agency look like heros. Because when the facts are finally revealed, it will be the FDA with egg on it's face

Submitter : Mr. Tad Gomez

Date: 01/26/2007

Organization : Medical College of Georgia Health System

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-5-Attach-1.DOC

January 26, 2007

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



To Whom It May Concern:

On behalf of the Medical College of Georgia Health System, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. The Medical College of Georgia is a 632 bed hospital located in Augusta, GA, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. [Insert here a summary of the burdens your hospital would experience and how they would affect the hospital. If possible, please quantify the estimated cost to your hospital if final federal regulations impose the NDC reporting requirement on your outpatient clinic or department. You may wish to supplement this discussion with points or arguments extracted from the attached talking points.]

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

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

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

Sincerely,

Tad A. Gomez, M.S., R.Ph.
Director of Pharmacy
Medical College of Georgia Health System

Submitter : Mrs. Valerie Rinkle
Organization : Asante Health System
Category : Hospital

Date: 01/29/2007

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Asante Health System includes physician offices and hospital providers.

We are concerned about the NDC billing requirements in this rule.

Physician offices and hospitals do not operate pharmacies like retail pharmacies. We do not track NDC numbers for each drug administered to a patient and we do not have information systems to track the NDC number with a patient account and place the NDC number on the claim.

This applies to physician offices billing on HCFA 1500 claims and to hospitals billing on UB92/UB04 claims.

The administrative burden to physician offices and to hospitals would be immense. Note that initially, HIPAA transaction sets planned to use NDC numbers for drugs, but this idea was eliminated once they noted the operational burden on hospitals and physician offices.

NDC numbers only work for retail pharmacies. Tracking NDC numbers for drugs administered to patients is not possible with technology and physician office and hospital processes at this time.

Response to Comments

Response to Comments

The regulatory impact is understated. Physician offices do not have the systems to track and bill by NDC numbers. The timeframe of January 2007 is impossible.

Submitter : Mr. Vivek Bhatt

Date: 01/29/2007

Organization : Target

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

How does the government decide to pay less than the cost of the medicine to retail pharmacies????? Is the government BLIND to consider there are Manufacturers who sell to Wholesalers who in turn sell to Retailers!! UNDER THIS NEW GUIDELINE, PHARMACISTS WILL LOSE (BELOW COST) 3 TO 4 DOLLARS PER EACH PRESCRIPTION...HAVE YOU EVER GONE TO DUNKIN DOUNUTS AND THE GUY SOLD THE COFFEE AND BAGEL FOR LESS THAN THE MATERIALS IT COSTS HIM TO MAKE, LET ALONE ANY MARKUP????? Is there no value for America's Pharmacists who save lives every day? PLEASE consider a different formula for reimbursement (atleast pay the cost that wholesalers like McKesson sell the product at) AND INCORPORATE A DISPENSING AND EDUCATION FEE, as Pharmacists are liable for mistakes and should be compensated for Drug Utilization Review (DUR, the checking for interactions with medicines and food, and educating the patient)!! PLEASE don't make the mistake that will result in DISASTER for my profession, CMS, and Medicaid beneficiaries. You want to send how much...10 billion dollars to Iraq for reconstruction, another 5 billion to Afghanistan, BUT CUT 8.6 billion dollars to America's Pharmacists in Medicaid (America's Poor)...It's completely UNFAIR, UNJUST, AND SHOULD NOT TAKE PLACE!!!! PLEASE CONSIDER ANOTHER SOLUTION.

Submitter : Dr. Sapna Bhatt

Date: 01/29/2007

Organization : A&P

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

PLEASE UNDERSTAND THE SHORT AND LONG TERM CONSEQUENCES OF SLASHING PHARMACY REIMBURSEMENTS TO AVERAGE MANUFACTURER'S COST...THE REVIEW DOES NOT CONSIDER THAT RETAIL PHARMACIES DO NOT BUY DIRECTLY FROM MANUFACTURERS IN BULK, AND ARE NOT GIVEN REBATES. SHORT TERM CONSEQUENCE: MEDICAID PATIENTS WILL BE TURNED AWAY FROM PHARMACIES BECAUSE NOBODY WILL WANT TO LOSE MONEY. LESS TIME WILL BE SPENT ON PROVIDING SERVICES TO MEDICAID PATIENTS BY PHARMACISTS. MEDICAID PATIENTS WILL END UP IN HOSPITALS!!!! LONG TERM CONSEQUENCE: CMS WILL GO BROKE FROM PAYING FOR HOSPITAL BILLS AND MORE FREQUENT DOCTOR VISITS BY MEDICAID PATIENTS. TAX PAYERS WILL BE ADVERSELY EFFECTED. SOLUTION: FIX THE DEFINITION OF AVERAGE MANUFACTUER'S COST (AMP) TO INCLUDE MARKUPS BY WHOLESALERS AND RETAILERS TO A FAIR AMOUNT. SECONDLY, INCLUDE A COUNSELING FEE FOR THE PHARMACIST TIME TO TEACH, EXPLAIN, CHECK, AND EDUCATE. LETS PREVENT HOSPITAL VISITS AND STAY HEALTHY...PHARMACISTS ARE KEY HEALTHCARE PROVIDERS AND PARTNERS IN BETTER HEALTH...LETS KEEP IT THAT WAY.

Regulatory Impact Analysis

Regulatory Impact Analysis

SOLUTION: FIX THE DEFINITION OF AMP TO INCLUDE A FAIR WHOLESALE AND RETAIL MARKUP.

Submitter : Mr. Roger Gurnani
Organization : Mr. Roger Gurnani
Category : Individual

Date: 01/29/2007

Issue Areas/Comments

Background

Background

THE ANSWER IS SIMPLE: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee.

GENERAL

GENERAL

As I see it: WITHOUT PROPER REIMBURSEMENTS TO PHARMACY PROVIDERS, MEDICAID PATIENTS WILL BE LEFT WITHOUT THE BEST AND HONEST ADVICE IN HEALTHCARE...PHARMACISTS. Mail Order pharmacies are a night mare...try using one through all the prompts, nobody to speak to, and medicines not coming on time. Please reimburse Retail Pharmacies: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee. IF this does not happen, disaster will. CMS and Healthcare professionals have to come together, because politicians don't know diddly. Save money by cutting the fraud, abuse, and corruption by politicians...not taking fair reimbursements from America's Pharmacists.

Regulatory Impact Analysis

Regulatory Impact Analysis

THE ANSWER IS SIMPLE: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee.

Response to Comments

Response to Comments

THE ANSWER IS SIMPLE: AMP + (Actual COST of Wholesale Markup) + (Fair cost of Retail Markup) + Counseling Fee.

Submitter : Dr. Wesley Cowell
Organization : South Florida Baptist Hospital
Category : Pharmacist

Date: 01/30/2007

Issue Areas/Comments

GENERAL

GENERAL

Please clarify that hospital outpatient (clinic) administered drugs are excluded from the definition of "physician administered drugs".

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Few facilities have the capability of passing a drug's NDC number from the pharmacy system to the Medicaid claim. The inclusion of the "top 20" multisource drugs complicates this significantly. Most inpatient pharmacy systems utilize unit-dose dispensing and without an electronic point of care documentation system (RFID or barcoding that INCLUDES the NDC# of the unit dose product) would not be able to bill accurately. The reason for this is that FDA approved, generically equivalent drugs are interchanged frequently in this environment based on availability, contracts, cost fluctuations.

Response to Comments

Response to Comments

If the states begin to request manufacturer rebates on hospital outpatient clinic administered drugs, this will cause problems for the PHS/340B program due to the statutory protection that the manufacturer has against double discounts because they will no longer be required to offer 340B pricing.

Submitter : Agnes Kolodziej
Organization : Agnes Kolodziej
Category : Other Health Care Professional

Date: 01/30/2007

Issue Areas/Comments

**Collection of Information
Requirements**

Collection of Information Requirements

The proposed definition of "retail pharmacy" does not allow for adequate analysis of the costs related to operating such a pharmacy. What normally qualifies as a retail pharmacy are independently owned, grocery, or chain pharmacy locations. Mail-service and hospital outpatient pharmacies do not incur the same costs as the retail pharmacies. These practice sites are able to purchase drugs at a lower cost than retail pharmacies. Any definition of pharmacy that is used in calculating costs must adequately differentiate between various practice settings so that reimbursement can properly cover the true costs associated with each setting.

Submitter : Jeff Sikes
Organization : Georgia Pharmacist
Category : Pharmacist

Date: 01/30/2007

Issue Areas/Comments

Background

Background

Community pharmacist (owner) for 28 years

Collection of Information Requirements

Collection of Information Requirements

AMP pricing regarding medicaid reimbursement rates

GENERAL

GENERAL

We have been successfully teaching and training medicaid recipients on how to take their medicines correctly, what side effects to consider important enough to contact either us or the doctor, what to avoid, etc. etc. for 28 years in South Georgia. If the federal government isn't willing to pay us a reasonable profit to take our time to teach and train this special class of recipients, we will not participate in the program period. You pay defense contractors, paving contractors, housing contractors, etc. a reasonable profit for their services, and you should do the same or better for the people who look after the health and well being of our medicaid recipients. The government can either pay now for good quality care which has been and would continue to be provided from community pharmacists, or you can pay later when the system has failed and the emergency rooms are filled with simple questions and problems we have been handling for decades.

I find it offensive that the government is going to cut reimbursement to pharmacists for the most cost efficient drugs being used (Generics) while paying the full price for brand name medications which are bankrupting our medicaid system.

Will somebody please do the math and quit rewarding the brand name manufacturers for their unending contributions to our legislators? Of all the errors the government has been accused of making, this is the most egregious and in southern vernacular "Just Plain Stupid" move I have ever witnessed a supposedly educated body make. I'm usually a lot more diplomatic than this, but this only makes sense if the government is using false logic and listening to the wrong people.

I beg our government to consult community pharmacists for cost saving measures. Instead of the \$8.5 billion this measure purports to save, we can lend advice which saves this much EACH YEAR, but nobody seems to be listening. We are speaking plain English, the other side is speaking political contributions. Your department has a chance to stop this lunacy before you play a part in destroying the best drug distribution system in the world, not only for our medicaid patients, but others too.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Information gathered from GAO reports

Submitter : Mr. William Dudewicz
Organization : Borden's Pharmacy, Inc.
Category : Pharmacist

Date: 01/31/2007

Issue Areas/Comments

Background

Background

The Federal Government is proposing a new formula to reimburse Medicaid-Medicare generic prescription drugs, utilizing a formula that is 250% of AMP. This will not provide sufficient reimbursement to pharmacies dispensing prescriptions to their Medicare-Medicaid patients. We (pharmacists) are already fighting to survive under current reimbursement policies. The GAO has already stated that this proposal will not adequately reimburse pharmacies. This is a study that the Federal Government has already done.

Collection of Information Requirements

Collection of Information Requirements

This bill would require pharmacies to lose between 30-40% on the cost of generic drugs dispensed. This is totally unfair, what other business is expected to lose money on every transaction that occurs. The impact of this legislation is that pharmacies will have to stop filling these prescriptions, if they are to survive. What does this do to our patients, and their health? We cannot be expected to carry the burden of the federal governments budget wocs. The dispensing fee, averaging \$4.00/Rx, is not capable of making up for the difference. Numerous studies have shown that the dispensing fee should be \$10-12/Rx, yet no-one is paying that.

GENERAL

GENERAL

Community pharmacy is already reimbursed at too low a level, reducing this would only force the closure of many pharmacies, restricting patient access. My business is 97% third party, which means I'm already subject to reimbursement levels set by Insurance companies. I have no control of my mark-up, profit margin, costs, etc. These numbers are already set by Blue Cross, Medicaid, Medicare, etc. Pharmacy profits are already too low, we should be allowed to pay our bills, our employees, our taxes, etc., and still make a profit at the end of the year. I know of no other business that has to deal with this sort of thing. No one can stay in business under the proposed reimbursement formula. Please reconsider, and properly study the impact of this legislation before in is enacted. Thank You, William Dudewicz, RPh.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I'm not sure what this sections means, but obviously the people in charge have not studied what the implications of this bill would be. My pharmacy, an Independant pharmacy in Michigan, is probably 30-40% medicare/medicaid business. This bill would effectively ruin my business, and place 27 people out of work. Reimbursement levels are inadequate now, and many studies by non-pharmacy organizations have proven this time and time again, all one has to do is properly research the issue.

Regulatory Impact Analysis

Regulatory Impact Analysis

All of the comments I have read, is that this legislation will only harm the patients, restricting their access to medications. The profit margins in community pharmacies are already so low, that they can't be reduced any farther without dire consequences.

Response to Comments

Response to Comments

I cannot see anything good coming from this legislation.

Submitter : Dr. Ken Nelson
Organization : Luck Pharmacy
Category : Pharmacist

Date: 01/31/2007

Issue Areas/Comments

Background

Background

The proposed CMS-2238-P plan with reimbursement rates that don't even cover cost of most drugs (not to mention costs associated with dispensing) will make it impossible for our rural pharmacy to continue to participate in the medicaid program. The idea of transparent reimbursement for services is welcomed but reimbursement has to be set at a realistic rate which allows us to remain has viable healthcare providers. A recent national survey using data from over 23,000 pharmacies indicated the average cost to a pharmacy to dispense a prescription was roughly \$10.50. This current CMS proposal needs to adjust dispensing rates such that the true cost of providing the service is covered. At that point, an adjustment in actual drug cost could be entertained. Please make adjustments to this plan so that pharmacies can continue to participate in the medicaid program

GENERAL

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The proposed CMS-2238-P plan with reimbursement rates that don't even cover cost of most drugs (not to mention costs associated with dispensing) will make it impossible for our rural pharmacy to continue to participate in the medicaid program. The idea of transparent reimbursement for services is welcomed but reimbursement has to be set at a realistic rate which allows us to remain has viable healthcare providers. A recent national survey using data from over 23,000 pharmacies indicated the average cost to a pharmacy to dispense a prescription was roughly \$10.50. This current CMS proposal needs to adjust dispensing rates such that the true cost of providing the service is covered. At that point, an adjustment in actual drug cost could be entertained. Please make adjustments to this plan so that pharmacies can continue to participate in the medicaid program

Submitter : Harry Lipschultz
Organization : Max-Well Pharmacy Services
Category : Pharmacist

Date: 01/31/2007

Issue Areas/Comments

GENERAL

GENERAL

Community Pharmacies do NOT receive products (read medications) at cost levels comparable to other organizations; as such they should NOT be included in the same definition of "pharmacy" as mail order, clinics, etc.

Fee schedules for prescriptions dispensed to not come close to our actual cost of dispensing. Those fees need to be adjusted to be more in line with our actual production costs.

Submitter : Dr. Allen Nichol
Organization : Ohio Department of Health/BCMHH
Category : State Government

Date: 01/31/2007

Issue Areas/Comments

Background

Background

I am the Pharmacist in charge of a medication program for about 20,000 children with special needs for the Ohio Department of Health the Bureau for Children with Medical Handicaps.

Our Data Base for medications that we pay for is shared with the Ohio Department of Job and Family Services (Medicaid for Ohio).

If this proposed AMP is implemented, Ohio Medicaid will be forced to comply and therefore we will, by virtue of the data base pricing, also be forced into the AMP proposed program. In the past CMS ignored comments surrounding the MTM portion of the Medicare Reform Act, hopefully this will be different. The methodology proposed to further reduce generic drug reimbursement, may have the effect of having pharmacies dispense more branded products, which by nature, are infinitely more expensive. Drugs that are in a therapeutic classification may be more often used, merely to sustain the pharmacy's ability to stay in business. At the same time the patient potentially may end up consuming medications, more expensive and not necessarily the more prudent choice, because of economic restraints put into play, via government interdiction.

Collection of Information Requirements

Collection of Information Requirements

Because the provisions of this proposed regulation will not affect mail order pharmacies, it will by nature, allow the profit structure to stand in place for mail order pharmacies. This will more than likely negatively impact on community pharmacy. Access of local pharmacies may become limited to our fragile (ODH/BCMHH) population.

To date Mail order pharmacies have refused to participate as providers to our insured children with special needs population. If this AMP program eliminates community access for these children, and mail order pharmacies continue to refuse to participate in our program, then access is a serious issue. More of these children will be hospitalized because medication compliance will become an issue, and the health care dollars expended will rise disproportionately to the proposed savings on the reimbursement of generic drugs. This movement is ill conceived and should not be moved forward.

GENERAL

GENERAL

CMS again fails to see the forest from the trees. The only parties that control drug cost are the manufacturers. If CMS, allows Congress to create an opportunity for CMS to directly negotiate with manufacturers, just as the current VA system is afforded, then CMS will be able to negotiate best price. This proposal of AMP will in effect, diminish participation of pharmacy vendors and decrease access for patients. The only net effect will be putting the patients who are frail in some nature, in harms way.

I suggest the entire AMP idea be put on hold until CMS has a realistic approach to this process. Our special needs program will become more at risk, because of mail order's refusal to participate.

Without community pharmacy participation the care of children with special needs, will be at an increased risk.

Regulatory Impact Analysis

Regulatory Impact Analysis

The mail order pharmacies continue to receive significant discounts from manufacturers because of this artificially created trade class distinction. Manufacturers were sued in class action by community pharmacies in 1994 for violations of Robinson Patman/Sherman antitrust violations. All manufacturers as of 2006 have settled the Robinson/Patman portion of the suit. The Sherman antitrust portion is pending Federal District Court Review. CMS needs to look at the pricing disparity and realize that the real issue is with Manufacturers establishing class of trade and not for CMS to be punitive to the pharmacy retail class that pays the most dollars to service the vast majority of the patients.

PBM rebates should not be considered in AMP because in most cases that have been litigated, it illuminates the fact that this rebates are held by the PBM and are never shared with the pharmacies that do the community dispensing of medications to the patients. Thus again CMS is being unreasonable by even considering the PBM rebate to establish AMP. This is by your query, not operationally feasible.

Your comment that chargebacks or rebates provided to PBMS are passed on to the purchaser, meaning the community pharmacies, is totally inaccurate. No such rebating from PBMS to the community pharmacies (that are not a corporate component of the PBM) exists today.

PBM's do not act as wholesalers-another inaccurate statement.

Mail order in general, should not be considered a factor in determining the AMP, especially in the definition of Retail Pharmacy Class of Trade. Mail order is a restricted vehicle for the delivery of prescription drugs, not available to all patients.

I am also of the opinion that prompt pay discounts, if included in AMP, will have a negative impact back to the wholesale drug distribution system, which needs that cash flow. The incentive for prompt pay will be eliminated, therefore the impact will be negative to the economy of the industry. If wholesale distribution is negatively impacted, it will have direct consequences for drug availability at the patient level.

The statement of including Medicaid sales in AMP determination is equally inappropriate. Supplemental rebates with the state Medicaid programs are not disclosed, never are shared with pharmacy vendors and may be significant in their negative impact on those vendors participating in the Medicaid program. This statement also is similarly reflective with regard to Medicare D, MA-PD, being included in AMP calculation. This should not be included.

CMS-2238-P-17 Prescription Drugs

Submitter : Mrs. Heidi Snyder

Date & Time: 01/31/2007

Organization : Drug World Pharmacies

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-17-Attach-1.DOC



Pharmacies & Home Care Centers

P.O. Box 1107
New City, New York 10956
(845) 639-4952
(845) 639-4955 FAX

February 21, 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**

Drug World Pharmacies 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 6 pharmacies in New York State. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by \$8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.
- **Require that States Increase Pharmacy Dispensing Fees:** CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

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

Sincerely,

Heidi Snyder, R.Ph., MBA
President/CEO

Submitter : Kyle McHugh
Organization : H&M Healthcare
Category : Pharmacist

Date: 01/31/2007

Issue Areas/Comments

GENERAL

GENERAL

As an independent pharmacy owner in 3 small towns in SC I cannot see how you can ask me to sell drugs to patients for less than I pay for them. The information we have received states that you are going to require reimbursement at or below my cost with no regard for the fact that it costs me \$10 to dispense that prescription and I have to pay for the drug before I dispense it and will not get paid until 3 weeks after I dispense it. I will not be able to participate in the medicaid program in my rural towns if this measure is past. It may not seem like much to you but for the patients I care for it means they will have to drive over 20 miles 1 way to get their medicine (if they can find someone who agrees to operate at a loss).

Please reconsider this act that does nothing to address the real problem with high drug prices (the pharmaceutical companies) Every time there has been a cut in Medicaid drugs costs it has come from local small pharmacy owners and never from the drug companies who increase their profits each year but do not release new drugs at the same rate. I would rather see an expanded 340B program than the current suggestion. If you must pass the AMP limits then you must also REQUIRE a \$15 dispensing fee to cover my costs of filling the prescription and keeping the medicine on hand. Please think of all the patients and small businesses you will be affecting with this decision.

Sincerely
Kyle F McHugh, RPh
803-247-2133

Submitter : Mr. Brad Nall
Organization : Samford University student
Category : Pharmacist

Date: 01/31/2007

Issue Areas/Comments

Background

Background

I am a P2 pharmacy student at Samford University in Birmingham, AL and will graduate in 2009. I am very involved at my school and stay up to date with anything pharmacy related.

Collection of Information Requirements

Collection of Information Requirements

Way Average Manufacturer's Price is calculated and states being allowed to set dispensing fees.

Response to Comments

Response to Comments

The proposed definition of retail pharmacy, which will be used to calculate AMP, includes mail-service pharmacies, hospital outpatient pharmacies, and outpatient clinics. These pharmacies may have access to rebates and price concessions that may not be accessible to community pharmacies. Consequently, I believe that AMP may be set at a rate lower than what community pharmacy can purchase generic drug products.

The proposal does not address dispensing fees and continues to let States determine the "reasonable" dispensing fee they are required to pay pharmacists. I believe that this lack of guidance allows State Medicaid programs to continue to underpay pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a \$4 dispensing fee when studies indicate that the average cost to dispense a medication is approximately \$10.

Submitter : Mr. Thomas Healy

Date: 01/31/2007

Organization : Healy's Edward Campus Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am concerned that the proposed AMP pricing to be used on Medicaid prescriptions will not fairly reimburse our costs. The GAO's study shows that this cost basis is about 20-40% below the average acquisition cost to pharmacies. Obviously we can not stay in business and sell for under our cost.

A margin of profit OVER our cost is in fact required since dispensing fees alone do not accurately reflect the cost of providing this service. The state of Illinois has a very poor record of adjusting fees (none I am aware of in over a decade).

In my situation only about 5% of my business is Medicaid. I could therefore stop servicing medicaid patients if required. For pharmacies with higher levels of Medicaid populations, they will simply cease to operate.

Submitter : Mr. Conrad Banks, RPh
Organization : Responsive Solutions, Inc
Category : Pharmacist

Date: 01/31/2007

Issue Areas/Comments

Background

Background

Our organization is a closed shop home infusion (IV) pharmacy with a small retail component. I am a pharmacist, with retail, hospital \institutional , and home infusion pharmacy practice since 1980 in South Carolina. We service the Pee Dec area of South Carolina and are located in Myrtle Beach, in Horry County.

Collection of Information Requirements

Collection of Information Requirements

This proposed CMS-2238-P poses a great concern for both aspects of our pharmacy and the pharmacy business in general and our ability to sustain or maintain business at the proposed reimbursement levels as indicated in CMS-2238-P in AMP.

The proposed AMP in CMS-2238-P for prescription drugs does not adequately reimburse the pharmacist or pharmacy.

This could potentially change the landscape of pharmacy as the American people know it, controlled by an elite few companies. This proposed change also targets the small home town independent pharmacy which will be gone because they cannot maintain their practice.

GENERAL

GENERAL

AMP is as ambiguous as AWP or ASP. It can be interpreted many ways and does not consider business overhead requirements of drug wholesalers and distributors as applied to AMP for retail practices. If closure and change of access to prescription medication is the intent of CMS then CMS-2238-P will accomplish this end. Only a few large mail order houses and large pharmacy chains will be able to survive this most recent attack on pharmacy reimbursement in the private sector.

I do understand this feedback collection tool and apologize if the format or information is not in proper order. Thank you.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I am not sure this section applies.

With striking reimbursements and the biased or inaccurate AMP, pharmacy cannot provide service levels that are expected by CMS or the American people.

The continued squeeze on pharmacy reimbursement only adds insult to injury as experienced by all when Medicare Part D was introduced.

Retail pharmacy is not sustainable at AMP reimbursement levels. There is currently a shortage of pharmacist in the US and that will continue with AMP making pharmacy a money losing business model.

Regulatory Impact Analysis

Regulatory Impact Analysis

Is the intent of CMS to eliminate retail pharmacy the purpose of this bill by using AMP reimbursement levels.

Who will define AMP and based on what industry reports indicate most all pharmacist will be dispensing below their acquisition cost. We currently do this a present with certian prescriptions under Medicare Part D.

Response to Comments

Response to Comments

The impact of this is the closure of many pharmacies across the US or the unwillingness of pharmacy to accept AMP based on the losing business model CMS-2238-P proposes.

Submitter : Greg Hines
Organization : Hines Pharmacy Inc.
Category : Pharmacist

Date: 01/31/2007

Issue Areas/Comments

GENERAL

GENERAL

I own and operate an independent retail pharmacy in Bowling Green KY and have very serious concerns about the change to AMP pricing due to take effect on July 1, 2007. The definition and examples of this pricing have not been established yet, but according to everything I hear, the reimbursement for retail pharmacies will be anywhere from 25% to 65% below our cost. These figures are based on what mail-order and non-profit hospital pharmacies can purchase their prescription drugs, and retail pharmacies can not purchase items at these prices.

Implementation of this rule will put many independent pharmacies out of business or at least cause them to quit accepting Medicaid patients. Pharmacies should not be expected to lose money when filling a prescription. We spend 6-7 years studying to become a pharmacist, which is one of the most trusted professions, but yet

we are expected to work for nothing or at a loss. This is not fair and very short-sighted. Many retail pharmacies in low income rural areas are totally dependent on Medicaid prescriptions for their income. When they close their doors, what will these patients do?

Will they end up in the hospital at a greater cost to our health care system or maybe just die. I understand the need to reduce costs, but the prescription drugs which our country uses are very cost effective, preventing many deaths and unnecessary hospitalizations. Sometimes you have to spend some money to save money.

According to this rule these reimbursement cuts only apply to generic drugs which are already saving the government and consumers billions of dollars each year. This rule will encourage pharmacists to dispense more expensive brand name drugs as opposed to the cheaper generic drugs. Does this make any sense? If anything pharmacist should be paid more to dispense generic drugs, because they reduce costs for the entire health care system.

If this change in reimbursement is implemented then the law must also mandate the all pharmacies are allowed to purchase the the lowest possible prices so that a reasonable profit is obtainable. If this is not done then this law effectively put thousand of retail pharmacies out of business. I do not think this was the intent of the law. Can you tell me any other industry which has price mandates like this. If the government wants to save money they should mandate prices from the brand name drug industry, because this is where 90% of the dollars are spent in the drug industry. This regulation is a disaster waiting to happen. Remember which profession stepped up and saved the day during the first month of Medicare Part D! The pharmacist. What reimbursement did we get for this service. Nothing. I hope you will reconsider this planned switch in reimbursement based on AMP until you can measure the effects on retail pharmacy. Thank you for your time and attention to this matter.

Submitter : Dr. Kara Carruthers

Date: 01/31/2007

Organization : Dr. Kara Carruthers

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I oppose the change to AMP for several reasons. A 36% reduction in reimbursement will hurt independent pharmacies, already struggling to meet costs. Our pharmacy has already had to stop dispensing some Medicare covered items b/c they reimburse below our cost, adding a formula that takes into account reimbursements and mail order pricing that retail pharmacies are denied access to will only make this list grow. Some of these medications include nebulizer medications such as Xoponex, Duoneb, Pulmicort, other meds such as MyFortie, Cell-cept, Xeloda, to name a few. The CMS's statement that OTC/front end sales are twice the dispensing sales and that we should be able to mitigate losses in this arena is absurd. An independent pharmacy does not do twice the OTC or front end sales, at least not an independent, and this area is not mitigating losses already felt in the pharmacy as CMS so "expertly" proposes. As Health Professionals who by law are mandated to perform certain services we are already not reimbursed for I have to question why pharmacies have to absorb these costs. Research has shown actual cost associated with dispensing a prescription to be \$10 and actual reimbursement dispensing rates are around \$4, another place we are already asked to take a loss. This change, in my opinion, will drive Medicare patients to more mail order services, this is a population with a high number of medications, medical conditions, physicians, and confusion. In a word, high risk for adverse events, they do not get adequate counseling, education, and monitoring from a mail order pharmacy. These are patients who do not use on-line/phone services well and need one to one interaction for safe drug use. To create a pricing scheme that undercuts retail/independent pharmacies, places retail at a disadvantage, and more importantly places our patients at a disadvantage.

Submitter : Mr. Allan Davies

Date: 02/01/2007

Organization : Expert-Med, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

The proposed AMP pricing for medicaid prescriptions.

GENERAL

GENERAL

Please reconsider your proposed AMP pricing model. It is not fair. Even the GAO agrees.

Response to Comments

Response to Comments

You will drive independent pharmacies out of business. I believe you will impact smaller chains also that do depend on prescriptions for as a revenue stream. Who will take care of the patients who depend on delivery, special needs, consultation. You are creating the end of the superior health care in this country.

Submitter : Mr. Michael Whitfield

Date: 02/01/2007

Organization : MedWorks Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

I recognize the difficulty of establish a cost basis for prescription drugs and that some basis needs to be used. None of the current methods using AWP are accurate in reflecting cost. However, the proposal for using AMP is just as convoluted and inaccurate as AWP. Neither AWP or AMP are a good choice for basing payment.

Also, regardless of what method is used, the payment formula needs to be fair to all providers and to adequately reimburse pharmacies for their true costs of dispensing and a reasonable profit.

Collection of Information Requirements

Collection of Information Requirements

I recommend that no changes be made until a better cost basis and an accurate cost of dispensing can be determined. Pharmacy computers are sophisticated and can track actual cost of goods. I recommend the government programs use a cost of goods basis provided by the pharmacy. The pharmacy could be required to maintain invoices for goods purchased that could show the last cost paid prior to dispensing a particular prescription. These would be subject to audit. The payment mechanism would then reflect a dispensing fee that adequately reflected the cost of dispensing from studies conducted in that area of the nation, and a profit margin consistent with the historical levels for the industry.

GENERAL

GENERAL

Pharmacists are very understanding of the need to control costs in government prescription programs. As evidenced by the significant role pharmacists played in the successful implementation of Medicare part D, often at personal expense, we will work with CMS to develop and implement a fair payment system. Please do not proceed with the AMP cost basis as it is no better than the current methodology and threatens to reduce the number of pharmacies and limit access to those most in need. Let's work harder together to devise a payment mechanism that saves money for CMS but also is fair to pharmacies.

Response to Comments

Response to Comments

It is clear from the GAO's own studies that using AMP will force pharmacies to sell prescriptions below cost or decide not to participate in government programs. Neither of these is acceptable.

CMS-2238-P-27 Prescription Drugs

Submitter : Mr. Richard Robinson

Date & Time: 02/01/2007

Organization : Harps Food Stores, Inc.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-27-Attach-1.DOC

February 1, 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**

Harps Food Stores, Inc. 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 21 pharmacies in two states. We are a major provider of pharmacy services in the communities in which our stores are located.

This proposed regulation, if adopted, would have a significant negative economic impact on our 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. We ask that CMS please do the following:

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by \$8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.
- **Require that States Increase Pharmacy Dispensing Fees:** CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

We 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,

Richard Robinson
Director of Pharmacy
Harps Food Stores, Inc.
P.O. Drawer 48
Springdale, AR 72765-0048

479-751-7601

Submitter : Dr. Suzanne Light
Organization : Northern Montana Pharmacy - Retail
Category : Pharmacist

Date: 02/01/2007

Issue Areas/Comments

GENERAL

GENERAL

I do not believe those involved in making the decisions for this proposal really know what kind of impact it will have on community pharmacy in general. Ever since managed care has rolled into pharmacy, pharmacy owners have continually been asked to take less and less reimbursement from the insurance industry. The cost of drugs continue to go up (including generics) and reimbursement continues to go down. Not only do we contend with decrease reimbursement we also have watch managed care organization merge with "mail order" pharmacies again driving community pharmacists out of business. The competition is not even competition because the large corporate managed care-pharmacy organization are not trying to run all aspects of patient care and pharmacy services.

With a continuing behavior of managed care organizations trying to monopolize the pharmacy industry, we do not have a chance to compete nor continue to serve the public.

Maybe it is time for those decision makers to look once again at the problem, which is not at the pharmacy level, but the manufacturing (drug company) level. Is it not enough that managed care organization restrict what doctors can prescribe and pharmacies can dispense....What happen the "what is best for the patient".

Those of you making decision really need to understand how the managed care system works and ever since it's inception it has continually decreased pharmacy reimbursement. We can not serve our patients if we can not pay our bills because you rules and regulations cut our profits. At this point reimbursement is minimal and we are forced to increase our volumes to make up for the terrible reimbursement, which then takes a away from our ability to take care of our patients - AGAIN!!!

This proposal is a bad thing and if you want to see small community pharmacies go out a business then go ahead, but I beg of you to reconsider this new pricing structure. Get help from the professionals who know something about pharmacy.

Submitter : Mr. Warren Bryant

Date: 02/01/2007

Organization : Longs Drug Stores

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-29-Attach-1.DOC

#29

Longs Drugs

Live healthy. Live happy. Live Longs.



General Offices: 141 North Civic Drive, P. O. Box 5222, Walnut Creek, CA 94596

Telephone: (925) 210-6360
Fax: (925) 210-6883

WARREN BRYANT
Chairman, President and CEO

February 1, 2007

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

Via: [HTTP://WWW.CMS.HHS.GOV/ERULEMAKING](http://www.cms.hhs.gov/erulemaking)

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

Longs Drug Stores 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 509 pharmacies in six states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by \$8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.
- **Require that States Increase Pharmacy Dispensing Fees:** CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

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

Sincerely,

LONGS DRUG STORES CALIFORNIA, INC.



Warren F. Bryant
Chairman, President and CEO

Submitter : Mr. Steve Love
Organization : Lillian Pharmacy
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

Background

Background

The AMP based FUL's will not cover my acquisition cost. Even the GAO has said on average AMP will be 36% below my cost. The use of a faulty AMP calculation of the FUL will force me to discontinue service to my Medicaid patients, denying them access to prescription drugs since it is 10 miles to the next pharmacy. For this to work CMS must define AMP to reflect my actual cost, excluding all rebates and price concessions not available to my pharmacy, then allow a dispensing fee that covers my cost to dispense, currently \$9.52 per prescription.

Collection of Information Requirements

Collection of Information Requirements

AMP was never intended to serve as a basis for reimbursement. If it is to serve this purpose it must reflect the actual cost paid by retail pharmacy, excluding rebates and prices not available to retail pharmacies. These price concessions and rebates should be included in "best Price" but not in AMP. An accurate definition of AMP will increase state rebates and encourage the use of more affordable generics saving the system money and promoting effective patient care.

GENERAL

GENERAL

Define AMP correctly.
 Define dispensing fee Correctly.
 Update weekly
 Use 11-digit NDC for reporting.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

CMS correctly excludes hospital and nursing pricing. Both are extended pricing that is not available to retail pharmacy and both are not publicly accessible. PBM mail order facilities should be added to this because they meet both criteria. They are extended special pricing and are not publicly accessible. Sales to mail order facilities should not be included in AMP. "Retail class of trade" should include community pharmacies, independent, franchises, chains, mass merchants, and supermarkets. This includes 55,000 pharmacies now open to the public.

AMP must differ from best price if it is to represent the price of drugs for retail class of trade. AMP must reflect our true cost!
 Rebates to PBMs are not available to retail pharmacy and should be excluded as should Direct to Patient Sale prices.

PBMs are not regulated at the state or Federal level, therefore there is no way to audit rebates, discounts, and price concessions. No transparency! To use these figures in the net drug price would be inappropriate. Due to lack of regulation their true information remains hidden and they are allowed to self refer which no other health care entity is allowed to do.

AMP must be reported weekly! We have to pay our suppliers either weekly or bi-weekly and AMP must be current to prevent further losses.
 AMP must be reported using the 11-digit NDC to ensure Accuracy. All of our systems and reimbursements are based on this.

Regulatory Impact Analysis

Regulatory Impact Analysis

AMP as defined will not cover our cost!
 AMP was never intended to reflect actual cost to my pharmacy!
 For this to work AMP must reflect my actual cost!!
 AMP calculation should exclude all rebates and price concessions not available to retail pharmacy including those from PBM mail order facilities.
 AMP must be reported using the 11-digit NDC level to ensure accuracy!

Response to Comments

Response to Comments

The GAO findings should be sufficient! Your are asking us to accept a reimbursement that is proven to be below our actual cost. No business can accept this. If and accurate definition of AMP is not used with a dispensing fee that reflects our true cost (currently \$9.52 for me), we will be unable to accept Medicaid. This could put many pharmacies out of business.

Submitter : Dr. RICHARD LOGAN
Organization : L & S PHARMACY
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

GENERAL

GENERAL

The implementation of AMP as currently defined as a reimbursement model will have a devastating effect on my Community Pharmacy Practice. AMP is not now clearly defined and should not be published or used until correctly defined. AMP should reflect the true cost of generics to Community Pharmacy. Pharmacies such as mine do not have access to manufactures rebates, or preferred pricing. The GAO projects a 36 to 65 percent shortfall in cost coverage for the generics I dispense. I cannot continue to serve the 26% of my patients who are medicaid eligible if I am reimbursed below cost. When enacted, AMP should be accompanied by a mandate to State Governments to increase dispensing fees to cover expenses, and encourage generic dispensing. AMP should not be a disincentive for dispensing cost effective generic medications.

Submitter : Mr. Marshall Davis

Date: 02/02/2007

Organization : Davis Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Reports from the GAO suggest that reimbursement for medications will be approximately 36 percent less than many retail pharmacy acquisition costs. If this report is accurate, I and many of my colleagues, as independent retail pharmacists, will be forced to stop service to this portion of the community. We as a group cannot continually absorb this reduction in reimbursement. I have already lost a significant portion of business due to CMS freezing of insulin reimbursement to 95% of 2003 AWP. Thank-you for your consideration of this matter.

Submitter : Ms. Gerald Besiner
Organization : Wilkinson Pharmacy Inc
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-33-Attach-1.WPD

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 : Jeff Scott

Date: 02/02/2007

Organization : Cheek and Scott Drugs Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to voice a concern regarding the reimbursement of retail prescriptions. I would like to factually add the cost of dispensing a prescription. In 2006 it cost \$9.79 per prescription in operational cost. With your new reimbursement method we will be filling many prescriptions at a loss. I am sure you do not want pharmacies to flop but if this continues as proposed many will have to close their doors.

Submitter : Mr. George Warren Jr
Organization : Bay and Lake Pharmacies
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

GENERAL

GENERAL

I have a hard time understanding how CMS can set the AMP based reimbursement model in place when the GAO reports that community pharmacies would LOOSE money on every Medicaid generic medication dispensed!

My father and I have owned and operated Bay and Lake Pharmacies for 43 years. In this time, we have seen many issues that have threatened our ability to take care of our less fortunate patients.

This issue is like no other. The initial impact will be devastating and force us to stop serving these patients. The longterm care facilities we serve (around 1800 beds) will have to find another provider. Finding a provider that is prepared and willing to accept unprofitable business will be impossible.

After the initial impact, should CMS recognize it's mistake and modify AMP based reimbursement, it may be too late for community pharmacies that have closed.

I also have issues with the classes of trade which are used to determine AMP. Mail order pharmacies are allowed rebates from manufacturers that retail pharmacies are not allowed to collect. This difference, when factored into AMP, skews the values. AMP should be MY aquisition price at the retail class of trade. Do not include mail order pharmacy in the AMP model. If mail order pharmacy is included; eliminate the rebates mail order pharmacies are able to receive.

Level the playing field. We have been asking for this for over 20 years!

Do the right thing and do not proceed till you can be assured the reimbursement model is fair and allows community pharmacies to serve the patients most in need.

Historically, third party payers follow the CMS lead. Don't be a bad leader!

Submitter : Dr. Robert Beeman
 Organization : Pharmacy service inc
 Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

Background

Background

I am a pharmacist in a poor area and 95% of my sales are derived from prescription drug sales. (point A) Can not afford to treat poor patients. Example A My gross sales exceeded 12 million in 2005 and our gross profit from these sales was 26%. With the advent of medicare part D our sales were reduced by 2.5 million due to unfair competition created by medicare part D and my gross profit was reduced to 18%. The only senior medicare part D patients left to do business at our store are the extremely loyal and the ignorant. (Point B) Predatory pricing and unfair marketing (Example B) Recently predatory pricing by Sam's Club has further reduced our patient volume because they are charging patients reduced copays on brand drugs \$9.00 vs the \$30 copay generated by Blue Cross-D. (Point C) Denied and unaffordable care for the people who need it most. Example C Since the 1980's our store has served the mentally ill county and state dependent patients. It is impossible to deal with the part D for authorizations for homeless patients when the insurance companies refuse to provide help based on wrong address information (hence the word homeless), drug formularies, and wrong copays. Point D Unequal access to medication. Example D A patient came to our store with an expensive chemo therapy drug and we received authorization to fill the medication from the insurance company. The \$1000 profit generated by billing the account offset the \$12,000 cost. However this Bayer drug had restricted sales to specialty pharmacies. Increasingly our access is being denied to profitable drugs by PMB's, Wholesalers, and manufactures. It is my belief they are collaborating behind closed doors to cherry pick more profitable drugs under the guise of specialty pharmacy. What is a specialty pharmacy anyways? It is not on my state application for my pharmacy license.

Collection of Information**Requirements**

Collection of Information Requirements

Reducing the cost to AMP will cause the extinction of many independent retail pharmacies in poor locations. Our family store has already been forced to reduce staff and due to the aforementioned points and examples. Homeless and mentally ill people do not increase retail sales but they do increase theft. Most chain stores do not cater to these people and are often removed from the property prior to entering the establishment. I would also argue many independents exist in areas where chain stores have closed do to lower retail sales. Many people will have to travel further distances to get there medication.

GENERAL

GENERAL

In general under the guise of reducing cost which I understand the federal government has allowed legislation to pass which will ultimately cause the extinction of many independent pharmacies. The small special interest groups that have stolen our profits now wish to finish us off and this is what reducing prices to below market prices will eventually cause. I hope you take the time to evaluate all I have said and not call me a criminal as the president has in the past. I have been audited and not convicted like Medco (large PBM), sponsor our local childrens events unlike most chain stores, I do not divert drugs from canada like Walmart, Amerisource Bergen, and Cardinal. I provide health insurance to my employees unlike Walmart. So why am I called a criminal when the federal government deals with convicted felons every day. Patient care is a joke when you refuse to help the patients who need it most. However it does reduce cost.

CMS-2238-P-37 Prescription Drugs

Submitter : Mr. Dennis Galluzzo

Date & Time: 02/02/2007

Organization : Pharmacists' Association of Western New York

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern;

I am a pharmacist in WNY, I own Family Medical Pharmacy.

If Congress allows Medicaid to only reimburse us the proposed amounts tauted by CMS and ignores the comments from the GAO, we as pharmacists will be faced with yet another cut in reimbursement from Third Party sources that will tighten our Gross Margins to levels which will not sustain our business. I know I am a pharmacist but I am learning very quickly what it means to be a businessman in an atmosphere filled with draconian predators seeking to drain off the last remnants of my patient base to Mail Order, Internet and Fast below cost cash providers. And, now CMS is willing to undercut our business and offer us reimbursements that would be 36% below our cost!

Please have mercy!

Sincerely Dennis C. Galluzzo R.PH.

Submitter : Mr. tHOMAS VANHASSEL
Organization : YUMA REGIONAL MEDICAL CENTER
Category : Hospital

Date: 02/02/2007

Issue Areas/Comments

Background

Background

THE SUBMISSION OF NDC NUMBERS OF INDIVIDUAL PRESCRIPTION TO MMEDICAID WOULD BURDEN THE STYTEM TREMONDOUSLY.IT WOULD BE MUCH BETTER IF THE AGGREGATE DATA WAS GELAMED FOR PURCHASE RECORDS.

Collection of Information Requirements

Collection of Information Requirements

NDC NUMBER SUBMISSION NOT FEASIBLE

GENERAL

GENERAL

i AM THE PRESIDENT OF THE ARIZONA STATE BOARD OF PHARMACY AND FEEL THIS REQUIREMENT WQOULD PLACE UNDO STEEE ON THE PHARMACIES AND RSULT IN HIGHER ERROR AND UNSAFE PRACTICES. THE COST COULD BE HUGE IN BOTH MANPOWER AND REPORTING TIME FROM COMPUTERS ETC. I STRONGLY RECCOMMEND THAT AGGREGATE DAT ABE COLLECTED FROM PURCHAS EHHSITORIES WHICH ARE MUCH EASIER TO GET AND MORE ACCURATE

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

i DIRECT AN EXTREMLEY AUTOMATED PHARMACY AD THIS WOULD BE DIFFICULT EVEN FOR MY HOSPITAL TO COMPLY. MUCH OF THE DATA YOU GET WILL BE HIGHLY INACCURATE FROM MANY HOSPITALS

Response to Comments

Response to Comments

HUGE TIME BURDEN ON AN ALREADY BURDENED SYSTEM

Submitter : Gill Abernathy
Organization : Gill Abernathy
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Dear CMS,

Currently hospital information systems are not set up to collect NDC information on each drug that we use. A typical 900 bed hospital would administer 10,000 doses per day. Many hospitals are currently focused on trying to meet existing JCAHO Patient Safety Goals which require additional resources as well as USP 797 standards.

These are important for patient safety and yet finding the resources is a challenge. To add on another requirement at this point in time would set us up for failure. In another four years, I believe most hospitals will have bedside bar coding in place; by the end of 2008, I believe the # will go from < 10% to more like 40-50%. This would allow capture of NDC number information. Billing systems would then have to be reconfigured to get that information out of clinical information systems into financial ones, but if the data is captured it should somehow be possible. I have no issue with the valid concept of NDC # capture, we simply need to have time to budget for, acquire, implement and refine the technology needed to do so. A deadline of April 1, 2009 would be more feasible.

Submitter : Mr. Duane Szymanski
Organization : St. Joseph Health System
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

Background

Background

regarding submission of NDC number with the use of drugs

GENERAL

GENERAL

this proposed regulation would add an undo burden to a bureacracy that continues to put the safe medication management at risk. this proposal would shift already limited professional resources to a function that is likely intended to save the government money but will likely cost the government more money in health care resource needs and injured patients.

Submitter : Dr. David Arrington

Date: 02/02/2007

Organization : Dr. David Arrington

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I believe this would create an undue hardship since institutions would have to provide this information manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources.

CMS-2238-P-42 Prescription Drugs**Submitter :** Mr. STEVEN PERKINS**Date & Time:** 02/02/2007**Organization :** COLDWATER PHARMACY**Category :** Pharmacist**Issue Areas/Comments****Background**

Background

2/02/07

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

Ms. Norwalk,

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

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

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medication. This does not consider the recently released report from the accounting firm Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies in which it is reported that the median cost of dispensing a prescription for a pharmacy is \$9.86.

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

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

Sincerely,

STEVEN PERKINS R.PH

Submitter : Dr. Joseph Huff
Organization : Columbia Pharmacy
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

GENERAL

GENERAL

I am a pharmacist in a rural area, Columbia KY. Our customer population is about 60% medicaid recipients. I am confused as to why CMS is cutting the reimbursement on generic medications. It is the high priced brand drugs that are costing the state the money. There are few if any drugs that do not have generic substitutes. I have always tried to switch my patients to the lower cost drug. Now I feel that in order to have enough money to pay our bills, that I may be asking physicians to change back to the brand name drugs. Since we will be reimbursed a significant enough amount to pay for our cost. I am also confused on how politicians can take money from major private insurance companies which continually interrupt the flow of health care in America and they are simply a self-created middle man. They are the only people in the United States benefiting from health care, and they do nothing but manage it. And manage it poorly at that. You can't shut down all the pharmacies by under paying us for drugs that people need, and allow major chains who can "take the hit" to thrive. If you really want to save CMS and the states some money, make medical billing online also. So that you can see when a drug-seeker is going from ER to ER looking for controlled medication prescriptions. Please do not undercut local pharmacies or pharmacies in general. After all if Wal-Mart continues the way it is I am sure we will soon be the United States of Sam. I also am sure that you will do nothing about that because I am sure they donated plenty to certain political parties. Call me at 270-315-6732

Submitter : JOSEPH GOODMAN
Organization : NDS PHARMACY
Category : Pharmacist

Date: 02/02/2007

Issue Areas/Comments

Background

Background

WE HAVE BEEN IN BUSINESS IN AN INNER CITY AREA OF PROVIDENCE, R.I. FOR 35 YEARS. WE HAVE SURVIVED HURRICANES, BLIZZARDS, COMPETITION OF ALL TYPES. AND REIMBURSEMENT RATES LOWER THAN 25 YEARS AGO. LAST YEAR MEDICAID PATIENTS WHO WERE AUTOMATICALLY TRANSFERRED TO MEDICARE PART D COST MY SMALL PHARMACY NEARLY \$70,000 IN RX REIMBURSEMENT THE NEWEST PROPOSALS WILL IN ALL PROBABILITY FORCE ME TO CLOSE OUR DOORS. I SIMPLY CANNOT COMPETE AGAINST THE FEDERAL GOVERNMENT.

Submitter : Mr. Alfred Gagliardi
Organization : Southern Chester County Pharmacy
Category : Pharmacist

Date: 02/03/2007

Issue Areas/Comments

Background

Background

I am an Independent Pharmacy owner for 33 years.

Collection of Information Requirements

Collection of Information Requirements

CMS and AMP

GENERAL

GENERAL

Frankly, I can not understand why my government has to be involved with free enterprise and an industry that I have served for 33 years. If my government desires to be involved with regulating sales and profits (AMP) in the retail pharmacy business then why not also get involved with every other Industry and regulate how they must sell their product and regulate how much profit they are going to make. I am tired of paying the high fees or prices for autos, life insurance, home owners insurance, professional insurance, health insurance, clothing, food, school taxes, real estate taxes, how about just going to a ball game, etc. The American dream of being an entrepreneur, being your own boss, owning your own business working hard for yourself is being destroyed by our own government. It is just common sense that one can not sell a product for less money then it cost. I love what I do, otherwise I wouldn't have been in retail pharmacy for 33 years, but what CMS is currently trying to do with AMP and its regulations will prove to be the downfall of independent pharmacy if we can not make a reasonable profit.

Submitter : Dr. Larry Clark
Organization : St. Mary's Hospital
Category : Pharmacist

Date: 02/03/2007

Issue Areas/Comments

Background

Background

This comment is in reference to file code: CMS-2238-P.

On December 22, 2006, The Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the Federal Register to implement certain provisions in the Deficit Reduction Act of 2005 (DRA).

Collection of Information Requirements

Collection of Information Requirements

Under the DRA, hospitals would have to provide NDC information on a billing submission to State Medicaid agencies to enable them to bill manufacturers for rebates due to the states under the Medicaid program.

GENERAL

GENERAL

The impact on workflow, staffing and financial resources of the hospital is unrealistic and not justifiable given current fiscal and workforce constraints.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered to the patient.

Regulatory Impact Analysis

Regulatory Impact Analysis

I believe this would create an undue hardship since institutions would have to provide this information manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources.

Response to Comments

Response to Comments

The cost to implement this change for my institution would be approximately \$5.00 per medication charged. CMS stated in their proposed rule hospitals would need to provide the NDC manually or implement a one-time systems change in our statements software. They are unable to estimate the cost of this manual activity or system change. Unless a hospital has bar-coding at the point of patient administration in the ambulatory setting, the hospital information system will not yield an 11-digit unique and correct NDC number to submit to the State Medicaid agency. The only alternative would be to manually submit these claims. The care giver would have to record the specific NDC number at the time of their encounter. 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. And we do not currently print NDC numbers on our self-packaged medications.

Submitter : Mr. Roger Cole
Organization : Moundsville Pharmacy
Category : Pharmacist

Date: 02/03/2007

Issue Areas/Comments

Background

Background

I am a community pharmacist and would like to share these comments.

GENERAL

GENERAL

see attachment

CMS-2238-P-47-Attach-1.DOC

To: Acting Administrator
Leslie Norwalk

Subject: AMP

My name is Roger Cole and I have been a pharmacist for 30 years and have been a community pharmacist owner for 26 years now. AMP pricing policy is the biggest challenge that I have seen community pharmacy face in my career. The current deficiencies with the AMP pricing scheme will be a financial burden to my pharmacy. Moundsville WV is a small town in WV and we have a high number of Medicaid patients, without a better definition of AMP we will be unable to serve those patients, reducing their access to care and quite possibly cause my pharmacy to become unprofitable and go out of business.

PLEASE REVIEW THESE AREAS OF THE AMP POLICY

Inclusion of mail order pharmacy prices with pharmacy class of trade Page 29

Mail order pharmacies are extended special prices and are not publicly accessible and therefore sales to mail order pharmacies should not be used in AMP calculations. The retail pharmacy should include, independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarkets.

AMP must differ from Best Price

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

How PBM price concessions should be reported to CMS page 33.

PBM transparency is necessary to access manufacturers rebates. PBMs are not regulated by state or federal standards and therefore to accurately calculate those rebates without transparency would be improper.

Allowing the use of 12 month rolling average estimate for all lagged discounts for AMP Page 70.

AMP must be reported weekly. My pricing changes daily, monthly reporting will cause too long a delay in updated AMP prices

Use of 11 digit NDC to calculate AMP page 80

Only the 11 digit NDC number can be used for accurate pricing. Inventory control is vital for a pharmacy to control it's costs, larger bottles would cause the pharmacy to over inventory and therefore be at a financial disadvantage.

Assessment of the impact on small pharmacies, particularly those in low income and high volume of Medicaid patients page 110

The GAO findings clearly demonstrate the devastating effects the ruling will have on small independent pharmacies. No pharmacy can stay in business experiencing a 36% loss on such transactions. The deficit cannot be overcome by aggressive purchasing, rebates, generic rebates or even adequate dispensing fees. It is unlikely that states would be willing to adjust their dispensing fees to \$10.50 per prescription as determined by a national cost of dispensing study has found.

CMS must employ a complete definition on the cost to dispense.

The definition of "dispensing fee" does not reflect the true costs to pharmacists and pharmacies to dispense medication to Medicaid patients. This definition must include valuable pharmacist time doing all the activities needed to provide prescriptions and counseling such as communicating by phone, fax and email to Medicaid agencies and PBMs regarding the patients needs as well as other real costs to dispense such as rent, utilities and labor costs.

All calculations should be independently verifiable with a substantial level of transparency to assure accuracy. **An AMP-based policy that underpays pharmacies will have dire consequences for patient care and access.**

Medicaid patients in Moundsville WV will lose access to my pharmacy as I cannot keep my doors open with the deficiencies in the current AMP-based policy. Medicaid patients, more than many others need that extra attention to get full benefit from their prescription drugs.

I will leave you with one story about one of my Medicaid patients. This patient has been in and out of the local mental health units several times over the past few years. To say she can be difficult to deal with is an understatement. We fill weekly pill reminder containers to help her manage her medication so she can remain independent. She calls the pharmacy almost daily, sometimes to ask about her diabetes, sometimes to ask about side effects or her blood pressure. We are on call 24 hours and I have been called at home in the middle of the night to answer questions about her low blood sugar or really high readings, "What should I do?" she will ask. We give her the best information and advice we can and she is able to "remain on her own at home". **Pharmacists provide CARE and services far beyond the net net cost of a drug and some small "dispensing fee"**. In the considerations of AMP based policy I ask for your diligent consideration of the points I have tried to make.

Thank-you

Roger Cole RPh
Moundsville Pharmacy
Moundsville WV
304-845-0390

Submitter : Mr. walter toole
Organization : Liberty Family Pharmacy
Category : Pharmacist

Date: 02/03/2007

Issue Areas/Comments

Background

Background

I am the owner of a independent community pharmacy in a rural area of South Carolina with a substantial medicaid population. I offer excellent pharmaceutical services to this population and have saved the government funds by being available 24 hours a day and preventing this population from using expensive emergency rooms by calling physicians and helping patients to determine that most of their medical needs are not life threatening.

Collection of Information Requirements

Collection of Information Requirements

The GAC analysis of generic drug costs dated Dec. 22, 2006 which was based on a sample of the most prescribed and highest cost prescriptions used by medicaid recipients estimated AMP-based FULS were on average 36 percent lower than average retail pharmacy acquisition costs. If this regulation goes into effect it will discourage the use of generic drugs and force pharmacies like mine to opt out of the medicaid program. to be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This should exclude all rebates and price concessions made by manufacturers which are not available to retail pharmacy. Exclude all mail order facilities and PBM pricing from AMP calculations since they are not publicly accessible in the same way that community pharmacies are publicly accessible.

GENERAL

GENERAL

Dear leslie Norwalk, Acting Administrator

I would like for you to reconsider the AMP-based FULS pricing methodology so it will be based on more realistic market pricing. Pharmaceutical manufactures have tier pricing and independent community pharmacies pay the highest tier so this pricing model should be based on wholesale pricing to community pharmacies and not mail order or PBM's or non-profit entities like hospital pharmacies.

If this is allowed to be implemented , within 30 days there will be very few independent pharmacies who will serve the medicaid population because it will be unprofitable.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Response to Comments

Response to Comments

If this regulation is allowed to be implemented, the medicaid population will have fewer pharmacies, fewer generic drugs will be used and hospital and emergency room costs will increase dramatically.

Submitter : Ms. Craig Tetreau
Organization : Scheurer Family Pharmacy
Category : Pharmacist

Date: 02/04/2007

Issue Areas/Comments

Background

Background
2-4-2007

To Whom it May Concern,

I have been a pharmacist for more than 24 years, in both the retail and hospital settings. In this time I have seen many changes, and unfortunately the majority of them have impacted community pharmacy in a negative way. Some of these changes, such as mandatory mail order impedes my ability to positively have an impact on the patients I care for; because I am not allowed to fill their prescriptions. When pharmacists are taken out of the equation, these patients are left at the mercy of the mercenary pharmacies for profit which is exactly what mail order is. Because of this I have seen many of my former patients go without medication or have to pay a higher price, because of mail order screw ups and the for profit insurance companies don't care and don't police the mail order pharmacies because all they care about is the pocket books.

I am afraid that the AMP Pricing issue is going to be another example of government mismanagement and misplaced trust in private insurers.

The proposal before you is flawed, no body can even identify the amp price. To say that mail order pharmacies and Dispensing hospital inpatient pharmacies prices should be included will skew the price to a lower level that retail outlets will never be able to purchase the medications for. Furthermore, to allow the states such as my state to determine the dispensing fee, will allow the states with financial problems to arbitrarily cut or not pay any dispensing fee just so they can make up budget shortcomings. On the average a retail pharmacy spends roughly 9.00 to dispense a prescription. This amount does not reflect the cost of the medication being dispensed.

The current AMP proposal as it stands will force more retail pharmacies out of business. This will limit access to the poorest of our population. The retail pharmacies that do manage to survive, more than likely will not be accepting medicaid prescriptions, which will have the same result.

What should you do? Take a look at the profits of the major pharmaceutical Companies. The answer should be self-evident, 1. CAP THE COST OF THE MEDICATIONS FROM THE PHARMACEUTICAL COMPANIES. 2. CHARGE ALL PHARMACIES THE SAME PRICE AND DO NOT ALLOW PREFERENTIAL TREATMENT OR PRICING OF ONE TYPE OF PHARMACY OVER ANOTHER. 3. SET ALL MEDICAID DISPENSING FEES THE SAME BASED ON THE NATIONAL ASSOCIATION OF RETAIL DRUG STORES SURVEYS ON THE COST TO DISPENSE A PRESCRIPTION.

I feel doing this will help us to serve our patients to the fullest because there will be no restricted access. The pharmacist is the last person to see a patient before they get their meds; having a policy that does not take this ability away will assure more positive patient outcomes, and therefore less healthcare cost down the road.

Thank-you for your time.

Craig Tetreau R.Ph.
Scheurer Family Pharmacy
Pigeon, MI 48755
e-mail ctetreau@yahoo.com

GENERAL

GENERAL

See Background field

Submitter : Mr. Michael Rubino

Date: 02/04/2007

Organization : American Society of Health System Pharmacists

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The requirement to include NDC numbers with the billing information for prescription drugs is an unreasonable mandate. The hospital pharmacy purchases many generic products and may have to vary the brand and or manufacturer based on availability. This results in the purchase of drugs with many different NDC numbers. The hospital will not know which drugs are associated with rebates. Attempting to determine which drugs for which patients require NDC and then submitting the information will cause delays in providing patient care and will add to the cost of care for this accounting/clerical procedure. Manufacturer's have the information on purchases of their products and CMS knows the drugs that the covered patient's received. This should allow for rebate data to be obtained without the requirement of NDC's.

Submitter : Mr. Michael Delpiere

Date: 02/04/2007

Organization : Harbor Drug, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

Proposed Medicaid AMP Definition Won't Cover Costs: GAO

Community pharmacies will be paid on average 36% below their acquisition cost for every Medicaid generic drug prescription they fill under a reimbursement formula proposed by the Centers for Medicare & Medicaid Services (CMS), a report by the Government Accountability Office (GAO) has determined. CMS proposed definition is effectively putting community pharmacies out of the Medicaid business, said NCPA Executive Vice President and CEO Bruce Roberts, RPh.

On July 1, CMS plans to begin reimbursing for generics with a Federal Upper Limit (FUL) based on a new definition of Average Manufacturers Price (AMP), which it proposed in a regulation released Dec. 15. As required by the Deficit Reduction Act, the FUL will be a ceiling of 250% of the AMP.

Community pharmacies will lose money on virtually every one of those transactions, the report by GAO, the investigative arm of Congress, confirmed last week. The GAO examined the AMPs of 27 high expenditure generics, 27 frequently used ones, and 23 that overlapped both categories.

For the high expenditure drugs, GAO calculated the new FULs were 65% lower on average than community pharmacies actual acquisition costs. For the frequently used drugs, acquisition costs were 15% lower. In the overlap category, acquisition costs were 28% lower. For all 77 drugs, the average acquisitions costs were 36% lower.

The complete report (GAO-07-239R) can be found on the GAO Web site.

NCPA supports a fair and transparent system to reimburse pharmacists under Medicaid, but not a system that penalizes pharmacists for participating in the program, said Roberts. No small business can be expected to operate at a loss, and pharmacies are no exception

Submitter : Anthony Czaplicki
Organization : Baptist Medical Center
Category : Pharmacist

Date: 02/05/2007

Issue Areas/Comments

Background

Background

Pharmacy Director

Collection of Information Requirements

Collection of Information Requirements

Requirement of NDC information on state Medicaid billing submission

GENERAL

GENERAL

This requirement would be a nightmare and increase hospital costs tremendously. The pharmaceutical industry has changed and product availability changes daily. It is very possible that a medicaid patient may receive the same chemical product with different NDC information on a daily basis. Patients receiving intravenous products will require multiple NDC information. The costs would far outweigh any savings

Submitter : Mr. Mitch G. Sobel

Date: 02/05/2007

Organization : Saint Michael's Medical Center Pharmacy Dept.

Category : Pharmacist

Issue Areas/Comments

Background

Background

Deficit Reduction Act of 2005 (DRA). Under the DRA, hospitals would have to provide NDC information on a billing submission to State Medicaid agencies to enable them to bill manufacturers for rebates due to the states under the Medicaid program. Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered to the patient.

GENERAL

GENERAL

Submission of an NDC number for CMS patients presents a hardship. The operations of a disproportionate share hospital (DSH) or 340B hospital pharmacy is based on acquisition of the cheapest drugs available on formulary from the wholesaler. The wholesaler often changes the generic product supply and prices. Items documented as given to patients should be identified by generic name or American Hospital Formulary Service (AHFS) code. The AHFS code designates drug by class which is more congruent to hospital pharmacy practice. Limiting medications to exact NDC codes will present tedious documentation issues. Most hospital pharmacy computer programs and systems do not track dispensations to patients by NDC number. The programs will track generic name, AHFS codes, strength, dose, quantity, and instructions for use. By limiting the drug dispensation documentation requirements to an NDC number will result in many claims to be submitted inaccurately and fraudulently. We currently use a 340B program that tracks our drug use by NDC number. Because of the aforementioned issues with the NDC number many potential savings have not been realized. These lost savings amount to \$100,000 to \$200,000 of legitimate 340B dispensations. Once the same generic drug but different NDC number is used, the hospital loses 340B purchasing rights or credits on the previously used NDC number. This is an unfair predicament because the hospital has dispensed a legitimate amount of drug to 340B qualified patients and can not receive credit for the dispensations once the NDC number changes. The NDC number requirement will also cause unfair competition and misrepresentation among drug suppliers and wholesalers. NDC numbers that are not changed because of the inherent system difficulties will cause inaccurate data submissions to CMS. The NDC number requirement is not a realistic expectation of compliance and will create a tremendous hardship to DSH and 340B institutions. This hardship will also create an unnecessary hardship for vulnerable patients. I urge CMS to reconsider the NDC requirement for 340B or DSH medication dispensation documentation.

Submitter : Dr. James Stevenson
Organization : University of Michigan Health System
Category : Pharmacist

Date: 02/05/2007

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Our current charge systems do not include NDC level data so this would need to be created. To obtain this capacity, our hospital will have to make significant changes to our billing systems, at considerable expense in terms of money, staff resources, and disruption of administrative operations. More importantly, this will have to be maintained in order to keep the data accurate. Given the many changes in manufacturer packaging, NDC numbers, and the substantial impact of needing to substitute product sizes due to manufacturer shortages and recalls, this will present a major burden to DSH hospitals trying to comply with this new requirement. My rough estimate is that this would cost the institution over \$200,000 annually in maintenance costs alone, on top of the one time effort and costs required to modify our charge systems to accept NDC information.

CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. In our case, this could amount to over \$1 million in savings for Medicaid patients annually.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price (AMP), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

GENERAL

GENERAL

I urge that this proposed change be reconsidered and some other, more efficient, mechanism be proposed as an alternative to achieve the desired ends. The proposed rule is a classic example of how administrative rules will drive up the costs of healthcare.

Submitter : Dr. Lori Brown
Organization : Kerr Drug
Category : Pharmacist

Date: 02/05/2007

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

The proposal does not address dispensing fees and continues to let States determine the "reasonable" dispensing fee they are required to pay pharmacists. This lack of guidance could lead to State Medicaid programs underpaying pharmacists for their dispensing-related services. For example, the average State Medicaid program pays a \$4 dispensing fee when studies indicate that the average cost to dispense a medication is approximately \$10.

Submitter : Dr. Fletcher Johnston
Organization : Medical Park Pharmacy West
Category : Pharmacist

Date: 02/05/2007

Issue Areas/Comments

Background

Background

Leslie Norwalk

As a community pharmacist which provides services for a large number of Medicaid beneficiaries. The proposed reduction in reimbursement for generic drugs will have a immediate and severe effect on my ability to service this population.

Many Medicaid beneficiaries use a large number of medications and do not have the ability to manage there therapies effectively. Also, a large number of beneficiaries do not have the ability to obtain their medications without the use of our delivery services. Without the management and delivery services that we provide, these patients will be the ones that suffer the most. The proposed reimbursement rates will force the discontinuation of our services to Medicaid beneficiaries.

We simply cannot offer services at a lose. Attached you will find specific comments about CMS 2238-P.

GENERAL

GENERAL

See Attachment

CMS-2238-P-56-Attach-1.PDF

CMS-2238-P-56-Attach-2.DOC

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

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

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

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

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

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

OVERVIEW

CMS's Costs Savings Estimates Ignore Increased Costs

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

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

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

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

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

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

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

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

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

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

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

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

Public Access Defines Retail Pharmacy Class of Trade

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

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

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

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

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

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

AMP Must Differ From Best Price

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

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

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

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

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

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

PBM Transparency Necessary to Assess Manufacturer Rebates

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

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

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

AMP Must Be Reported Weekly

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

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

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

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

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

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

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

CMS discusses impact on pharmacy:

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

Impact on small pharmacies demonstrated by GAO findings

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

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

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

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

CMS Must Employ a Complete Definition on Cost to Dispense

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

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

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

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

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

Summary of Key Points:

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

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

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.—pg. 29**Public Access Defines Retail Pharmacy Class of Trade**

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The 11-digit NDC must be used when calculating the FUL.

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national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation. 6 If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.

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

Summary of Key Points:

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

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

2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*
3. Reporting AMP at the 11-digit NDC level to ensure accuracy

Submitter : Mr. Roger Collins
Organization : Harps Food Stores
Category : Other Health Care Provider

Date: 02/05/2007

Issue Areas/Comments

Background

Background

The CMS proposed regulation on AMP and FUL which will determine reimbursement for generic prescription drugs under Medicaid and Medicare do not provide adequate reimbursement as currently proposed. In fact, according to the GAO, reimbursement will average 36% below pharmacy costs. Implementation of this regulation should be delayed until this problem is corrected and a fair reimbursement methodology is developed.

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See attachment.

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CMS-2238-P-57-Attach-1.DOC

CMS-2238-P-57-Attach-2.DOC

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

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This will reduce Medicaid generic payments to pharmacies by \$8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas. We ask that the implementation of these FULs be suspended because it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.
- **Require that States Increase Pharmacy Dispensing Fees:** CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

We 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,

Roger Collins
President
Harps Food Stores, Inc.
P.O. Drawer 48
Springdale, AR 72765-0048

479-751-7601

Submitter : Robert Stoneburner

Date: 02/05/2007

Organization : VSHP

Category : Pharmacist

Issue Areas/Comments

Background

Background

Under the provisions in the Deficit Reduction Act of 2005 (DRA), hospitals would have to provide NDC information on a billing submission to State Medicaid agencies to enable them to bill manufacturers for rebates due to the states under the Medicaid program. Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered to the patient.

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GENERAL

VSHP believes this would create an undue hardship since institutions would have to provide this information manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources.

Submitter : Mr. Mark Jacobs
Organization : Shopko Stores Operating Co., LLC
Category : Pharmacist

Date: 02/05/2007

Issue Areas/Comments

GENERAL

GENERAL

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

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

Our Corporation Shopko Stores LLC operates 134 pharmacies in 13 states. We are a major provider of pharmacy services in the communities in which our stores are located.

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

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

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

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

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

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I support the more extensive comments that are being files by the National Association of Chain Drug Stores (NACDS). I appreciate your consideration of my comments.

Sincerely,

Mark R. Jacobs RPh
Pharmacy Mgr.

Submitter : Mr. Dennis Dawiedczyk
Organization : Shopko Stores Operating co.,LLC
Category : Pharmacist

Date: 02/05/2007

Issue Areas/Comments

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

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

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

I support the more extensive comments that are being files by the National Association of Chain Drug Stores (NACDS). I appreciate your consideration of my comments.

Sincerely,
Dennis Dawiedczyk RPh
Pharmacist