Submitter : **Miss. Annalise Jencson** **Date: 02/16/2007**

Organization : **University of Toledo Pharmacy Student**

Category : **Individual**

Issue Areas/Comments

Background

Background

he proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.
Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.
Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

CMS-2238-P-711

Submitter : **Mrs. Martha Renfro** **Date: 02/16/2007**

Organization : **Mountain States Health Alliance**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

My comment is in an attachment. Please See Attachement.

CMS-2238-P-711-Attach-1.PDF

Johnson City Medical Center
400 N. State of Franklin Road
Johnson City, Tennessee 37601

Mountain States Health Alliance

February 16, 2007

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

Dear Sir or Madam:

I am replying with comments to your proposal in the proposed rule dated December 22, 2006 on file code CMS-2238-P. This is the proposed rule in the Federal Register to implement certain provisions in the Deficit Reduction Act of 2005 that would require hospitals to provide an 11-digit unique NDC number on the billing submission to State Medicaid agencies for outpatient drug administration to enable the state to bill manufacturers for rebates.

This requirement would create a massive and expensive undue hardship on our organization. We have no electronic mechanism to provide this information at the current time and do not foresee any development of one in the future, so this would be a manual process. This manual process would add many more steps to our already massive and complex medication ordering, dispensing, and administrating process. In adding these steps, patient safety would be impacted in a negative way. This would occur because our hospital workflow would be disrupted. Also, we do not have the financial and staffing resources to implement workflow changes that would be required to do this manual process. This would greatly slow down pharmacist order entry and would decrease patient safety.

We do not have separate billing systems for outpatients and inpatients. We have an integrated inpatient and outpatient pharmacy billing system and pharmacy dispensing system. This system relies on the same drug product inventories that may include multiple generic supplies (each with a separate NDC number) of the same medication.

At any one time any of our pharmacies could have several generic and the brand NDC of the same generic entity product on the shelf and/or in our automated dispensing system cabinets (pyxis). Our order entry pharmacists do not know what NDC of the product the specific patient will actually receive from the pharmacy or pyxis. When we order drug products from our wholesaler and a product is out of stock at the wholesaler, they automatically substitute another NDC item for that product. This also creates different NDC numbers in our stock. We do dose by dose dispensing and billing. We do not dispense by prescription in multiple quantities like a retail pharmacy does.

Our current pharmacy information system has no way of sending the NDC number to patient accounting to be placed on the bill. Our current financial system and charge master have no place to enter the NDC number associated with the drug charge on the financial side. We have no room in pyxis or on the pharmacy shelves to divide all products up by NDC number.

We believe trying to implement this process and managing it would cause a great financial cost to our facilities. At rough estimate, we believe it would cost at least $1 per dose dispensed. This would translate to millions of dollars per year for our alliance. Our Johnson City Medical Center facility alone has dispensed about 3.8 million doses during the last year. The financial burden on this one facility would be around 3.8 million dollars per year. The impact on workflow, staffing and financial resources of our hospitals is unrealistic and not justifiable given current fiscal and workforce constraints. We therefore ask you to reconsider this proposal. Thank you for your time and consideration in this matter.

Mountain States Health Alliance is a multiple hospital entity which includes hospitals in Northeast Tennessee and Southwest Virginia. These hospitals are Johnson City Medical Center Hospital, Northside Hospital, Johnson City Specialty Hospital, Johnson County Community Health Center, Indian Path Medical Center, Kingsport Surgery Center, Sycamore Shoals Hospital, Smyth County Community Hospital, Dickenson County Hospital and Norton Community Hospital.

Sincerely,

Martha M. Renfro, DPh
Charge Master Coordinator, Pharmacy Services
Mountain States Health Alliance
400 N. State of Franklin Road
Johnson City, TN 37604
1-423-431-5370
renfromm@msha.com

Submitter : **Larry Wagenknecht** **Date: 02/16/2007**

Organization : **Larry Wagenknecht**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

Centers for Medicare & 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

I am submitting comments today regarding the Centers for Medicare & Medicaid Services (CMS) December 20, 2006, proposed regulation that would provide a regulatory definition of average manufacturer s price (AMP) and implement the new Medicaid federal upper limit (FUL) program for generic drugs. As a pharmacist in Haslett, MI, the proposed regulation, if adopted, would have a significant negative economic impact on the patients in my community. Pharmacists are critical to the care of patients in my community and your consideration of these comments is essential.

4. Manufacturer Data Reporting for Price Determination,Address Market Lag and Potential for Manipulation

Reporting of AMP data by the manufacturers on a quarterly basis versus a monthly or weekly basis does not address the issue of price fluctuations when they occur. CMS needs to address this concern and create an 'exceptions' and 'appeals' process, similar to Medicare Part D, which would allow any provider, including a pharmacy, a mechanism to request a redetermination process for a FUL. The redetermination process should include a toll-free number that would be monitored by CMS and include a specific timeframe in which the redetermination process must occur and a procedure by which a redetermined FUL would be updated. This process would mitigate the risk of pricing lag and create a fair reimbursement mechanism for community pharmacy that is timely.

1. Definition of 'Retail Class of Trade' - Removal of PBMs and Mail Order Pharmacies

CMS should exclude pharmacy benefits managers (PBMs) and mail order pharmacies from the definition of 'retail pharmacy class of trade.' PBMs and mail order pharmacies are not community pharmacies, which is where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the 'general public.' The definition of 'retail pharmacy class of trade' should include independent pharmacies, independent pharmacy franchises, independent chains, chain pharmacies, mass merchandiers and supermarket pharmacies.

2. Calculation of AMP - Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

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. Nursing home pharmacies, PBMs and mail order pharmacies receive discounts, rebates, and price concessions that are not available to the community retail pharmacies, making them a fundamentally different class of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacy for medications. Including these elements is counter to Congressional intent.

3. Removal of Medicaid Data

Including Medicaid data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. Medicaid, like the PBMs, does not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Inclusion of Medicaid data would have an artificial impact on market prices. Medicaid should be treated consistently with other federal payor programs and, therefore, be excluded from AMP calculations in the proposed regulation.

Collection of Information Requirements

Collection of Information Requirements

5. Use of 11-Digit NDC Versus Nine-Digit NDC

We believe that CMS should use the 11-digit NDC in the calculation of AMP since this is package size most commonly dispensed by retail pharmacies. The prices used to set the FUL should be based on the most common package size dispensed by retail pharmacies, not quantity sizes that would not be purchased routinely by a community pharmacy. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

I appreciate your consideration of these comments and support the more extensive comments that are being filed by the Michigan Pharmacists Association

regarding this proposed regulation. Please feel free to contact me with any questions.

Sincerely,

Larry Wagenknecht, Pharmacist
6097 Partridge St.
Haslett, MI 48840
email: amylarryw@comcast.net

Copy: Members of Congress

Submitter : **Mr. BILL ALLEN** **Date: 02/16/2007**

Organization : **AMERIMED PHARMACY**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

CMS-2238-P-713-Attach-1.TXT

CMS-2238-P-713-Attach-2.PDF

02/15/2007

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.

I am going to speak to you from the heart. I own an independent pharmacy in a rural town of 1800. I know I can compete every day with chains, mail order and any other delivery system out there if I have a level playing field because my overhead is so much lower than theirs. If you look at the average prescription costs between idependents and the mail orders and chains, you will find we are the lowest because every day we help patients cut costs. We have been the ones promoting generics because we have never had the back in deals that the chains and mail orders and PBM's get paid because of the lack of transparentcy in our system. And we have done this while at the same time paying more for medications than practically anyone in the world. Higher than countries like Canada, Mexico and even Switzerland, higher than chains, higher than mail orders (who are owned or have financial ties to PBM's, chains or drug manufacturers).

And now the goverment wants to add AMP to the unlevel playing field. As a small independent, we will always be on the wrong side of any average formula. This will do more to put us out business than all the decreases that have happened to us in just the last two years, decreased Medicaid reimbursemnets, Medicare Part D, Discount Cards given to everyone. No industry I know has more cost controls on the despensing side. And has this hepled? NO, it hasn't, because the problem is not the despensing side, it is the cost of the product. Even if you negotiate discounts, the manufactures just go up on the costs so in 2 years the prices are right back where they were or higher.

In the past, generics were where a drugstores profit came from. Take that away and you will see less and less generics being used. If a stores average cost of doing business if between $9-10.00 and you are paid less than half that to dispense a "cheap generic" then there is no incentive to dispense that generic. You will see larger costs on the drug side of the equation.

So how do you cut cost? Pay more on the dispensing side so patients will have face to face contact with pharmacists to guide then and consul them on the medications. Look at what PBM's are paid. When CVS which has a book valvue of 27 billion tries to buy a

PBM for 27 billion, then something is wrong. The PBM is making way to much now compared to the 10 to 20 cents a claim when they first started out and make them transparent. Look at the drug manufactures. I have a bottle of 90 generic Zocor for $9.78 then have the same tablet that Merck sells me for $388.52. The same tablet. Pass laws to allow my co-op to negotiate for the same prices that VA, and mail order do. Do away with class of trade laws that have put us on an unlevel playing field. Pass laws to make PBM's transparent. Pass laws that make PBM's pass savings on to the companies that have hired them to look out after their interest. Pass laws that give us the right to negotiate rates with PBM's. Now it is take it or leave it. Come up with a viable reimbursement formula for the despensing of prescriptions tied to the true cost of despensing a prescription not mainly to the cost of the medication. Pass laws that allow the federal goverment to negotiate the price of drugs for the medicare part D patients. We can fill these prescritions and give face to face consultation at a less cost if we have access to the same cost of goods. AMP is not the answer without change the rest of the formulas. One can not come before the other.

Sincerely,

Bill Allen, RPh
AmeriMed Pharmacy
117 West Main St
Hahira, Ga 31632
ballen31632@yahoo.com

Submitter : **Miss. Wendy Marek** **Date: 02/16/2007**

Organization : **Wilkes University Nesbitt School of Pharmacy**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. I am a pharmacy student attending Wilkes University Nesbitt School of Pharmacy and I also work at CVS Pharmacy #1325 in Nesquehoning, PA.

1. Remove PBM and Mail Order from the Retail Class of Trade

(i) Creates consistency in the Regulation

(ii) Conforms definition with market reality

2. Implement a Trigger Mechanism

(i) Addresses severe price fluctuations

(ii) Reduces risk of Market Manipulation

(iii) Mitigates Risk of Pricing Lag

3. Use of 11-Digit NDC versus 9-Digit NDC

(i) Represents the most common package size dispensed by retail pharmacies

I support the more extensive comments that are being filed by Pennsylvania Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Wendy Marek
Student Pharmacist

Submitter : **Mr. John McCorkle** **Date: 02/16/2007**

Organization : **Mr. John McCorkle**

Category : **Pharmacist**

Issue Areas/Comments

Background

Background

We are the only pharmacy in a small low income town and closest pharmacy to us is ten miles away. On average 25% of our business comes from Medicaid patients and 40% from Medicare part D patients. Our total volume is a little over 100 prescriptions per day.

Collection of Information Requirements

Collection of Information Requirements

If the following provisions of AMP take place our cash flow will come to an end. We will have to most likely close the doors to our only pharmacy in town.

Response to Comments

Response to Comments

We will have to close the door to our pharmacy!

Submitter : **Mr. John Heffernan** **Date: 02/16/2007**

Organization : **Massachusetts Pharmacists Association**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-716-Attach-1.PDF

MPhA
MASSACHUSETTS PHARMACISTS ASSOCIATION

February 16, 2007

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

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

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

Summary

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

§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of

500 West Cummings Park, Suite 3475, Woburn, MA 01801 Phone (781) 933-1107 Fax (781) 933-1109

trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

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

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless states were to mandate mail order pharmacy. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general

public." The following paragraphs will further address the unique contractual arrangements that distinguish mail order and PBM pharmacies from community retail pharmacies.

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

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

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

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

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29." Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to 1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of

AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which ultimately reduces the amount that manufacturers receive. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On

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

§447.510 Requirements for Manufacturers.

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

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer chooses to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[2] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.
[3] §447.510(d)(2)

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

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

Record Keeping

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

Additional Comments

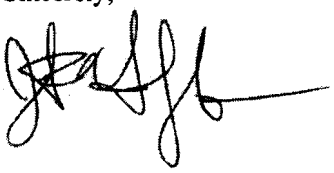
Use of the 11-Digit NDC Rather Than the 9-Digit NDC

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

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

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

Sincerely,



John F. Heffernan
Executive Vice President

cc: Senator Edward M. Kennedy (D-MA)
Senator John F. Kerry (D-MA)
Representative Michael Capuano (D-MA 8th)
Representative William Delahunt (D-MA 10th)
Representative Barney Frank (D-MA 4th)
Representative Stephen F. Lynch (D-MA 9th)
Representative Edward J. Markey (D-MA 7th)
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Representative Marty Meehan (D-MA 5th)
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Submitter : **Dr. Joni Cover** **Date: 02/16/2007**

Organization : **Nebraska Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-717-Attach-1.PDF

CMS-2238-P-717-Attach-2.PDF

Nebraska Pharmacists Association

February 16, 2007

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

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

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

Summary

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

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NPA

§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

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

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do

not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

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

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

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

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

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29." Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to 1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

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

Market Manipulation

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

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

'Claw-back'

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

Pricing Lag

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

[3] §447.510(d)(2)

Severe Price Shifts

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

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

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Additional Comments

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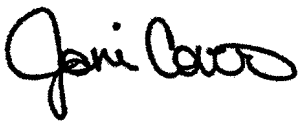
We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,



Joni Cover, JD
Executive Vice President

cc. Senator Chuck Hagel
Senator Ben Nelson
Congressman Jeff Fortenberry
Congressman Adrian Smith
Congressman Lee Terry
Governor Dave Heineman

Submitter : **Linda Jones** **Date: 02/16/2007**

Organization : **NYS Department of Health**

Category : **State Government**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-718-Attach-1.DOC

STATE OF NEW YORK
DEPARTMENT OF HEALTH
Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany New York 12237

February 16, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Electronic Submission: www.cms.hhs.gov/erulemaking

Re: File code CMS-2238-P, Comments on the Deficit Reduction Act (DRA) of 2005, pertaining to prescription dugs under the Medicaid program (42 CFR, Chapter IV, Part 447 – Payments for Services).

To Whom It May Concern:

The New York State Department of Health has reviewed the draft proposed rule to amend 42 CFR, Chapter IV, Part 447 – Payment for Services, under provisions of the DRA 2005.

We would like to provide the following comments to the proposed rule:

I. Background

- CMS should consider including customary prompt pay discounts extended to wholesalers in the Average Manufacturer Price (AMP) calculation since these discounts are required to be reported to the Secretary. Currently, customary prompt pay discounts are included in the calculation of best price (BP); removing them from the AMP calculation would result in inconsistencies in the two variables which are used to determine the unit rebate amount (URA) for single source drugs under the Medicaid Rebate Program. Also, removing customary prompt pay discounts from the AMP calculation may artificially inflate the AMP and new federal upper limit (FUL).

- We strongly support the requirement of manufacturers to include the lowest price available to any entity for a drug sold under a New Drug Application (NDA) approved under section 505c of the FFDCA when determining best price.

- We also strongly support the amendment to section 1927k to require all drugs sold under an NDA (approved under section 505c) and paid for by wholesalers and subsequently distributed to the retail pharmacy class of trade, be included in the AMP calculation.

II. Provisions of the Proposed Regulations

- CMS is encouraged to analyze the relationship between AMP and pharmacy acquisition costs and provide guidance to State Medicaid programs in the development of appropriate reimbursement amount under the estimated acquisition cost (EAC) or other methodology. State Medicaid programs do not have access to actual pharmacy acquisition costs, making it impossible to ensure fair and equitable reimbursement for prescription drugs under the EAC methodology. With CMS guidance in developing an accurate reimbursement methodology that most closely represents the pharmacy's actual acquisition cost, State Medicaid programs would be more willing to adjust pharmacy dispensing fee (based on appropriate criteria) to ensure adequate payment for professional pharmacy services.

- CMS should provide clarification or reasoning for its proposal to revise the definition of AMP to exclude customary prompt pay discounts to wholesalers. We believe excluding customary prompt pay discounts will artificially increase the AMP.

- The availability of AMP is described in the proposed rule to serve two purposes: 1) drug rebate liability and 2) payment. The rule further describes that "while there is no requirement that States use AMPs to set payment amounts, we (CMS) believe the Congress intended that States have drug prices data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices of sale to the retail pharmacy class of trade". AMP, based on a reliable methodology, will provide States with a more accurate estimate of prices available to wholesalers and, to a lesser extent, retail pharmacies. However, the availability of AMP and it's use in new EAC reimbursement methodologies (i.e. non-FUL drugs), will not affect manufacturers from continually pricing drugs at a premium. Manufacturers will continue to set prices without respect to ingredient costs. We believe that the intent to use AMP for payments may significantly disadvantage pharmacies while holding manufacturers relatively harmless.

  We encourage CMS determine reimbursement rates, based in EAC or some other methodology, for all single and multi-source drugs covered by State Medicaid programs. CMS is in a better position than any individual State to substantiate prescription drugs prices and reimbursement methodologies. CMS has already set precedence by setting reimbursement rates for drugs on a national level with the advent of average sales price methodology (106% ASP) for physician administered drugs under the Medicare Part B program.

- We encourage CMS to include mail order prices in the definition of retail class of trade. A majority of commercial third party payers, including those servicing Medicare Part D beneficiaries, encourage the use of mail order pharmacies. Many third party payers provide financial incentives to their beneficiaries in the form of reduced copays when using mail order services rather than the community pharmacy. It is well documented that mail order pharmacies are willing to accept lower reimbursement rates from third parties payers because of their purchasing power and ability to capitalize on economies of scale related to prescription volume. Since mail order pharmacies dispense to the general public, not including these prices would result in artificially inflated AMPs.

- We strongly support the inclusion of Pharmacy Benefit Manager (PBM) rebates, discounts and other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP. In general, there are very few pharmacy transactions/claims that are not processed by or paid through a PBM. Manufacturers provide PBMs with financial incentives associated with drug formulary development and these financial incentives must be included in the AMP calculation. Not including PBM rebates, discounts and other price concessions would significantly increase the AMP resulting in artificially inflated FULs. Also, there are well documented concerns with inadequate transparency regarding financial relationships between manufacturers and PBMs. Not including PBM pricing concessions would continue to compound the transparency issue.

- We are concerned with the financial impact that public access to AMP may or may not have on entities involved in the drug distribution and payment systems. Setting FULs too low will act as a disincentive for pharmacies to dispense generic drugs. If a pharmacy's profit margin is greater for a similar product not subject to a FUL, a pharmacy may be inclined to consult with a patient's prescriber to dispense a more expensive non-generic product. The proposed rule does not affect those drugs that have the greatest budgetary impact on State Medicaid programs. Generally, generic drugs account for a large percentage of pharmacy claims but smaller percentage of expenditures when compared to single source brand name drugs. We encourage CMS to use AMP and other prices available from the manufacturer, including those that are not publicly available, to provide a pricing construct for single source brand name drugs. Currently, each state Medicaid program uses a unique EAC based reimbursement methodology without having access to information submitted to CMS by manufacturers (i.e. BP). This not only limits the ability of states to ensure adequate reimbursement to pharmacies but has no affect on manufacturers setting premium prices for drugs that may not have any significant clinical impact when compared to drugs already in the marketplace.

- We support the proposal to exclude rebates paid to states under the Medicaid Rebate program from AMP calculations. We also support the

inclusion of price concessions associated with sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients in the AMP calculations. Medicaid sales could be a substantial portion of certain drugs classes, including drugs used in the treatment of mental illness and HIV/AIDS. Excluding Medicaid price concessions associated with sales could undermine the actual purpose of the DRA, as Medicaid programs are the predominate users of the FUL. Including rebates paid to States under the Medicaid Rebate program in the AMP calculation may result in AMPs and subsequently FULs that fall below the pharmacy acquisition cost. This would potentially result in accessibility issues for states' Medicaid programs and their beneficiaries.

- We strongly support the inclusion of Medicaid Part D sales, including rebates paid by manufacturers to Prescription Drug Plans (PDP) or Medicare Advantage – Part D Plans (MA-PD), in the AMP calculation to the extent that sales are to the retail pharmacy class of trade. Medicare Part D sales could be a substantial portion of certain drugs classes used by geriatric patients, including drugs used in the treatment of cardiovascular disease and diabetes.

- We request clarification regarding the treatment of sales associated with PBMs and how these differ from payment to PDPs. It is our understanding that PDPs are functioning as PBMs for the purposes of Medicare Part D beneficiaries. We strongly support the inclusion of PDP and PBM rebates, discounts and other price concessions for drugs provided to the retail pharmacy class of trade for the purpose of determining AMP.

- We strongly encourage CMS to include in the final rule the definition of "State Pharmaceutical Assistance Program (SPAP)", thereby eliminating existing inconsistencies between CMS policy releases and the "Qualified SPAP Checklist" used by SPAPs to attest to CMS.

- We very strongly encourage CMS to include in the final rule provision allowing state Medicaid programs to share with their SPAP the quarterly Unit Rebate Amounts (URA) provided by CMS for manufacturer invoicing purposes. SPAP access could be limited to URA's for which the SPAP has a rebate agreement with the manufacturer, and which specifically authorizes access to such data. Currently, SPAPs are required to calculate their own URA's, which requires collecting and processing manufacturer pricing data for tens of thousands of NDC's. This results in duplicative processing for manufacturers and States, which is unduly burdensome and inefficient considering CMS is already furnishing the state Medicaid programs with the end result. Manufacturers have supported and advocated to CMS for such data sharing arrangements.

- We request that CMS add clarity to the proposed provision exempting SPAP prices from best price. As proposed, "Any prices paid by an SPAP" are excluded from best price. Because SPAPs are generally third-party payers and do not typically purchase drugs directly, we recommend the provision be modified to specifically

exclude from best price "Any prices under an SPAP including rebates paid to an SPAP".

- We strongly encourage CMS to reconsider including rebates to SPAPs in the AMP calculation, which we find inconsistent with excluding rebates paid under the Medicaid program from the same calculation. Like Medicaid, SPAPs are not typically direct purchasers of drugs. Including manufacturer rebates to SPAPs in the AMP calculation could artificially deflate AMPs and subsequently FULs to a point where they are below pharmacies' acquisition cost, which would be problematic for programs utilizing AMP or FUL for pharmacy reimbursement.

- We support the inclusion of sales for specialty drugs through direct distribution arrangements, where the manufacturer retains ownership of the drug and pays an administration or service fee to a third party for storage, delivery and billing, etc. in AMP calculations. With the advent of genetically engineered biologic drugs direct patient sales distribution systems are becoming more common. Traditionally, these drugs are very expensive because of the complex technology required in the manufacturing processes. Not to include direct patient sales in the AMP calculation most likely will increase prices paid to the distributor. Since genetically engineered biologic drugs are very expensive, overestimating the AMP could result in excess overpayments by third party payers, including state Medicaid programs.

- We are concerned that excluding returned goods from the AMP calculation when returned in good faith without evaluating the effect returns may have on the AMP (i.e. significant increase or decrease in the AMP as a result of a returned good) could lead to inaccuracies in FUL and potential future payment methodologies based on AMP to be used by third party programs.

- We have identified an inconsistency associated with BP, AMP and customary and prompt pay discounts. Customary prompt pay discounts are included in the BP calculations but are excluded in the AMP calculation. We request clarification or a reason for this inconsistency.

- We are concerned with the exemption of payments made by a PDP and MA-PD to manufacturers from BP. With the advent of the Medicaid Part D program, there are substantial sales attributable to PDPs and MA-PDs. If included in BP, we believe these sales arrangements would result in more accurate pricing information and would enhance the Medicaid Drug Rebate program.

- We strongly support the proposal to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand name manufacturer's subsidiary in the calculation of AMP and BP.

- We understand that the upper limit payment for multi-source drugs applies in the aggregate. However, we request CMS clarification on how an aggregate

payment system can be implemented prospectively given the uncertainty of utilization for any of the multi-source drugs subject to the FUL.

- We strongly support the requirement that a FUL must be established for each multi-source drug for which the FDA has rated two or more products as therapeutically equivalent. We also agree with CMS applying the FUL to B-rated drugs in order to discourage substitution of B-rated drugs as a way to avoid the FUL in cases where B-rated drugs would be excluded from the FUL.

- We understand CMS' reason for using the reported nine-digit NDC AMP in establishing the FUL. We also agree with CMS comments that AMP reported at the eleven digit level is advantageous to CMS and the states. We strongly urge that CMS require manufacturers to provide CMS with AMP reported at the eleven digit level and that this information be supplied to the states.

- We support the proposal to determine whether a drug product should have a FUL within 7 days after receiving notification that a therapeutically equivalent product is available. Under the current FUL establishment and notification process, there have been many examples where multi-source products met the definition to be eligible for a FUL but the FUL is not released in a timely manner, resulting in excessive prices to pharmacies over extended periods of time.

- We strongly encourage accurate and timely notification of terminated NDCs associated with the establishment FULs. We request CMS clarify or define the meaning of "terminated". Also, we are concerned that if a FUL is removed without notification, NDCs may continue to be billed by pharmacies and reimbursed by state Medicaid programs. This issue may be compounded when state Medicaid programs continue to reimburse for a product that has been terminated and may reimburse at a rate above the price of the previously posted FUL.

- We strongly support the exception to the 30 percent carve-out policy when the FUL group includes only the innovator single source drug and the first new generic in the market or authorized generic.

- We agree with the conditions relating to physician administer drugs and the necessity of State Medicaid programs to bill manufacturers for rebates. However, physicians currently bill any product within the particular Healthcare Common Procedure Coding System (HCPCS) to the Medicaid program regardless of whether or not the manufacturer participates in the Medicaid Drug Rebate program. We request that CMS define how physicians will be notified of the specific drugs excluded from Medicaid payment under these circumstances.

- Physicians will be responsible with delineating differences in billing Medicare by HCPCS compared to Medicaid by NDC. We expect confusion by physicians and other entities as the actual HCPCS and NDC billing units may differ. To optimize Medicaid coordination of benefits with Medicare Part B fiscal intermediaries and increase the accuracy of invoicing and collection of rebates, we encourage CMS to require that Medicare Part B fiscal intermediaries accept NDC billing of Part B drugs. Otherwise, using HCPCS for Medicare then NDC for Medicaid billing could actually become more burdensome for physicians when trying to coordinate billing for patients eligible for both Medicare and Medicaid. The claim would have to be billed first to Medicare (i.e. primary payer) by use of a HCPCS and then secondarily billed to Medicaid by use of a NDC.

- We have some concerns with the inclusiveness of the list of the 20 multi-source physician administered drugs. The list must be inclusive of all NDCs attributable to a particular HCPCS drug code. We are also requesting an explanation of the process associated with updating and revising the list of the 20 multi-source physician administered drugs.

III. Collection of Information Requirements

- No comments

IV. Response to Comments

- No comments

V. Regulatory Impact Analysis

- We are concerned with the accuracy of pricing data in the monthly AMP file provided to states. A preliminary analysis conducted by the DOH reveals some uncharacteristic relationships between AMP and AWP for certain drugs. We noticed several products with an AMP greater than the current AWP. There were also cases in which the AMP was substantially lower than the AWP for single source drugs. We realize that single source drugs will not be affected by the new FUL methodology. However, it seems unrealistic that AMP for a single source drug is significantly lower than the AWP. Pricing comparison issues may be a result of the unit of measure/payment inconsistencies associated with the published AMP. Since the unit of measure/payment is not provided in the CMS file it is impossible to ascertain or adjust for package size or unit of measure/payment discrepancies. We recommend that the unit of measure/payment information be included in the monthly AMP release/posting.

- We request additional information regarding prices associated with the Retail Price Survey. We are concerned that survey prices will not be of any value in developing payment methodologies or equitable reimbursement

calculations. The proposed rule does not provide any clarification on how these prices will be determined. We request Retail Price Survey methodology details including whether the prices incorporate third party involvement, pharmacy discounts, price concessions or invoice costs. Prices based on usual and customary charges will be of no assistance in developing realistic pharmacy reimbursement rates.

Thank you for considering our comments on the proposed rule.

Sincerely,

Linda J. Jones, R.N., Director
Bureau of Pharmacy Policy and Operations
Office of Health Insurance Programs
New York State Department of Health

Submitter : **Ms. Nanette Meeker** **Date: 02/16/2007**

Organization : **Central City Family Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

This regulation is completely unfair. There is no way that any independant pharmacy can purchase at AMP. Not every town in the US has a large chain pharmacy nor is there any likelihood that there will be. If your intent is to put all independant pharmacies out of business, this is an easy way to do it. Whether CMS likes it or not, businesses do have to make a profit or else they cease to exist.

The first thing you should do is see where the dollars actually go in the pharmacy business. I think you'll find that less than 25% of the money actually goes to the retail side of pharmacy and the 75% that flows to the wholesalers and manufacturers is a much more likely target for reductions.

A cost of dispensing fee based on regional annual independent analysis for cost of dispensing should be included in addition to the FULs for reimbursement determination.

Mail order should not be included in the definition of retail pharmacy as they cannot provide full pharmacy service.

There should be a provision to quickly change the FUL if a provider is requested to provide a product to a patient below cost. (Cost in this case includes the acquisition cost and the cost to dispense.)

CMS-2238-P-720

Submitter : **Date: 02/16/2007**

Organization : **Kraupner Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attached

CMS-2238-P-720-Attach-1.TXT

CMS-2238-P-720-Attach-2.DOC

Sate of New York (PSSNY) proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

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

In conclusion, I support the more extensive comments that are being filed by Pharmacist Society of the Sate of New York (PSSNY) regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Gary Goffner, RPH
Ralph Goffner, RPH
Leonard Colluro, RPH
Anthony Valenti, RPH
Armand Baklajian, RPH
Patricia Johnson, RPH
Saul H. Housman, RPH
Joe La Sala, RPH

cc. Congressman Gary Ackerman
Congressman Timothy Bishop
Congressman Joseph Crowley
Congressman Vito Fossela
Congressman John J. Hall
Congressman Maurice Hinchey
Congressman Pete King
Congresswoman Nita Lowey
Congressman John M. McHugh
Congresswoman Carolyn Maloney
Congressman Jerrold Nadler
Congressman Thomas M. Reynolds
Congresswoman Louise Slaughter
Congresswoman Nydia M. Velazquez
Congressman Anthony D. Weiner
Congressman Michael A. Arcuri
Congresswoman Yvette D. Clarke
Congressman Eliot Engel
Congressman Kirsten E. Gillibrand
Congressman Brian Higgins
Congressman Steve Israel
Congressman John R. Kuhl Jr
Congresswoman Carolyn McCarthy
Congressman Michael R. McNulty
Congressman Gregory W. Meeks
Congressman Charles B. Rangel
Congressman Jose E. Serrano
Congressman Edolphus Towns
Congressman Jim Walsh

Submitter : **Mrs. Jill Mutz** **Date: 02/16/2007**

Organization : **Medical Center Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This proposed regulation would create a definition of average manufacturer s price (AMP), as well as implement the new Medicaid federal upper limit (FUL) program for generic drugs. The proposed regulation, if adopted, would have a significant negative economic impact on my pharmacy, which is located in Bryan. Texas. Medical Center Pharmacy is a major provider of pharmacy services in this community and your consideration of these comments is essential.

It is critical that AMP data be perceived as a reliable approximation of the prices paid by retail community pharmacies for medications. Yet, the proposed regulation falls short in this goal. For example, in the proposed regulation, pharmaceutical manufacturers can deduct from their AMP calculation the rebates and discounts they provide to health plans and PBMs for brand name drugs. These discounts are paid directly to these entities, not to community pharmacies, and in many cases the actual amount of the price concession is not known due to a lack of transparency. Given that retail pharmacies do not benefit from these rebates and discounts received by the health plans and PBMs, the proposed regulatory definition of AMP would not reflect prices at which retail pharmacies purchase medications and, therefore, would be lower than the acquisition cost paid by retail pharmacies for medications. Only manufacturers sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition.

The DRA directs that the federal Medicaid program significantly reduce payments to the pharmacies for generic medications dispensed, yet does not offset these negative losses with an increase in dispensing fees. Without greater direction by CMS to increase the dispensing fees to pharmacies, incentives to dispense lower cost generics may be reduced. A generic prescription costs about $20, while the average brand name prescription costs $120. Recent studies indicate that it costs a pharmacy approximately $10 to dispense a Medicaid prescription, well below the Texas state dispensing fee. An increase in the state dispensing fees can help assure continued dispensing of lower cost generics.

The DRA requires CMS to publicly release AMP data for each brand name and generic drug reimbursed by Medicaid, in addition to directing that AMP data be used to set FULs for generic drugs. CMS initially delayed the original release of data from July 2006, due to widely documented inconsistencies with how pharmaceutical manufacturers calculate AMP data. CMS has indicated it will release this data this spring, yet has not published a final regulatory definition of AMP. Release of this data at this time would be a disservice to the states, to pharmacies and to the market place in general. According to a recent Government Accountability Office report, using AMPs to set FULs for generics would underpay pharmacies by 36 percent. This could significantly discourage generic dispensing with Medicaid. It would be inappropriate to use flawed AWP data to set new Medicaid generic payment rates this spring, as has been proposed by CMS, until a final definition of AMP is obtained.

In summary, this proposed rule could adversely impact the ability of pharmacists to continue to serve Medicaid beneficiaries. Pharmacies are still recovering from the economic impact of major issues experienced under Medicare Part D. Community pharmacists stepped up to make the Medicare Part D program operational, yet they continue to experience poor reimbursement and delays in payment for the products and services provideIt is inconceivable that pharmacies will be asked again to bear the economic impact of inappropriate planning on the part of CMS. In addition, this proposal could adversely impact our ability to continue to serve Medicaid beneficiaries and provide their needed medications.

Submitter : **Miss. Leslie Browner** **Date: 02/16/2007**

Organization : **UT Pharmacy School**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.
I am a student pharmacist at the University of Tennessee College of Pharmacy and am interested in community retail pharmacy practice. I have worked at Walgreens pharmacy, a community retail pharmacy located at 1334 North Highland, Jackson, TN 38301, and I am familiar with the challenges in retail pharmacy practice.

1. Definition of Retail Class of Trade Removal of PBMs and Mail Order Pharmacies

CMS is proposing an overly broad inclusive definition of retail class of trade for use in determining the AMP used in calculating the FULs. The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies can purchase medications. Only manufacturers sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBMs and mail order pharmacies from the AMP determination recognizes that these are not community pharmacies, where the vast majority of Medicaid clients have prescriptions dispensed. Mail order pharmacies do not meet the open to the public distinction, as they require unique contractual relationships for service to be provided to patients. PBMs do not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Both these types of organizations do not dispense to the general public and, therefore, should be excluded from the information used in the calculation of the AMP to be used for determining an FUL. The more extensive comments submitted by the Tennessee Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.
2. Calculation of AMP Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including the elements defined in the proposed regulations is counter to Congressional intent. Rebates and other concessions paid by manufacturers to entities such as mail order pharmacies and PBMs are not shared with community retail pharmacies and, thus, do not reduce the prices pharmacies pay for drugs and are not available to the general public. These rebates and concessions must be excluded from the calculation of the AMP used to determine the FULs.

While the AMP data is not currently publicly available, so that retail pharmacies can actually determine what the relationship will be between the proposed AMP-based FULs and the prices retail pharmacies pay to acquire the drugs, the GAO has conducted an analysis of this relationship. The GAO used the highest expenditure and the highest use drugs for Medicaid in the analysis. The GAO reported that retail pharmacies will be reimbursed, on average, 36% less than their costs to purchase the drugs included in the analysis. A business can not be sustained if it is forced to continuously sell its products below its actual acquisition costs.

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I worked, where the majority of our business came from prescription drugs. What the other sales in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

Collection of Information Requirements

Collection of Information Requirements

Removal of Medicaid Data

Medicaid pricing is heavily regulated by the state and federal governments. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

4. Manufacturer Data Reporting for Price Determination Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, the Tennessee Pharmacists Association (TPA) proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the TPA comments on the lack of clarity on claw back from manufacturer reporting error.

GENERAL

GENERAL

Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a

particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date before it could be dispensed. It simply would not be feasible or practical to purchase in these quantities. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Submitter : **Christina Bass** **Date: 02/16/2007**

Organization : **University of Tennessee College of Pharmacy**

Category : **Other Health Care Professional**

Issue Areas/Comments

Background

Background

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.
I am a student pharmacist at the University of Tennessee College of Pharmacy and am interested in community retail pharmacy practice. I have worked at Eckerd Pharmacy, a community retail pharmacy located at 1500 W. Main St. Lebanon, TN 37087, and I am familiar with the challenges in retail pharmacy practice.

1. Definition of Retail Class of Trade Removal of PBMs and Mail Order Pharmacies

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Collection of Information Requirements

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GENERAL

GENERAL

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We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date before it could be dispensed. It simply would not be feasible or practical to purchase in these quantities. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Submitter : **Ms. Lori Lamerand** **Date: 02/16/2007**

Organization : **Planned Parenthood Mid-Michigan Alliance**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

Sec Attachment

CMS-2238-P-724-Attach-1.DOC

Lori Lamerand, CEO
Planned Parenthood Mid-Michigan Alliance
3100 Professional Dr., Ann Arbor, MI 48103

Feb. 16, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

As CEO of Planned Parenthood Mid-Michigan Alliance (PPMMA), a non-profit organization that operates health centers in Ann Arbor and East Lansing, I am writing to ask you to designate our organization an important safety net provider in our area.

We provide critical health services to uninsured and underinsured women. Our Ann Arbor and East Lansing health centers serve over 5,000 of patients annually, many of whom could not afford the health services—particularly contraceptives—that we provide.

I am writing on behalf of these thousands of women because they don't have a voice in the critical, life-changing decisions that are made in Washington, D.C.

Furthermore, I am writing because the state of Michigan is currently suffering a severe economic recession which will likely get worse before it gets better. As jobs leave our state and businesses close or go bankrupt, we are seeing more and more people lose their health insurance and their ability to pay for contraception.

For over 70 years in Ann Arbor and over 20 years in Lansing, our health centers have served a segment of the population that cannot normally afford contraception by providing them access to contraception at prices far lower than what is available in the retail market. We have been able to serve this underprivileged community because we could buy contraception from drug manufacturers willing to provide them at nominal prices. Without this ability, we could very soon be out of business in these locations. We dearly need to be able to buy contraception at less than 10% of the average retail price in order to serve poor women who have no other way to get low-cost contraception.

The rule, as put forth by the Centers for Medicare and Medicaid Services ("CMS") on December 22, 2006, gives three kinds of providers ((I) 340B covered entities, (II) intermediate care facilities for the mentally retarded and (III) state owned or operated

nursing homes) the ability to purchase drugs at nominal prices. Some of our health centers are Title X clinics, and therefore are covered as 340B entities. However, Title X funding is being drastically cut, which will have a negative impact on our affiliate and health centers as a whole. . If we also lose the ability to be a safety net provider to our non-Title X health centers, all the poor people we serve throughout our service area could be in jeopardy.

Like other non-340B providers of medical services to the poor, we must rely on section 6001(d) (IV) of the DRA to permit continued access to steeply discounted drugs. The Secretary of the Department of Health and Human Services ("HHS") is authorized to define "other safety net providers" that would be eligible for the nominal pricing exception. We were deeply dismayed when, in the proposed rule, CMS did not define or apply this fourth statutory exception. We very much hope that HHS will exercise the authority granted it by Congress to define "other safety net providers" in the final rule.

The plight of our Ann Arbor and East Lansing health centers, along with other similar non-profit outpatient clinics across the nation, should provide ample evidence to CMS that the other three categories of health services providers are not "sufficiently inclusive" and do not "capture the appropriate safety net providers." Deserving non-profit clinics like our Ann Arbor and East Lansing health centers are not covered by the entities listed in 6001(d), subsections I, II and III. Many of us are slipping through the cracks in this poorly worded clause and taking down our poor clients with us.

On top of that, we have been told by several manufacturers who have historically sold to us at nominal prices that we will have to pay full wholesale prices for all contraception going forward. The belief on the part of CMS that inclusion of non-340B safety net providers in the nominal pricing exception will have an adverse effect on best price is misplaced. Eliminating hundreds of Planned Parenthood health centers from the nominal price exception will not affect best price at all—the only consequence of this policy will be to preclude manufacturers from charitably helping safety net providers like us to serve our patients.

In conclusion, Planned Parenthood Mid-Michigan Alliance is a non-profit outpatient health care facility that serves a critical function in the health and well being of over 5,000 uninsured and underinsured women in Ann Arbor and East Lansing. We are able to provide these services and deeply discounted contraception to these women only because we can purchase contraceptives from drug manufacturers at nominal prices, as we have been doing for over [number] years. Carving safety net providers like Planned Parenthood Mid-Michigan Alliance health centers out of the nominal pricing exception would be devastating to our mission and to our operations—without nominally priced drugs we will likely have to close our doors. Planned Parenthood Mid-Michigan Alliance urges CMS very strongly to reconsider its position and apply the safety net provider exception as provided in the DRA.

Sincerely,

Lori Lamerand
CEO and President
Planned Parenthood Mid-Michigan Alliance

Submitter : **Ms. Stacy James** **Date: 02/16/2007**

Organization : **Planned Parenthood of Montana**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-725-Attach-1.DOC

Planned Parenthood®
of Montana

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February 15, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the CEO of the only Planned Parenthood affiliate in the state of Montana. As such, we cover a vast amount of territory with a small population. Our patient load is largely uninsured and live below the poverty level. Although we receive Title X funding at four of our clinic sites, 10 of our sites receive no federal funding. In most cases we provide the only health services that these women and men access and are able to afford. Most of our patients seek reproductive health care services including oral contraceptives. As they are not insured and live below the poverty level, they cannot afford to purchase contraceptives anywhere else.

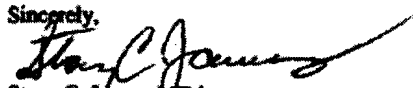
Our affiliate started as one clinic in 1969 with a commitment to the people of Montana to provide quality affordable health care and low cost contraceptives. As we saw a great need for low cost contraceptives and compassionate, confidential services in the most rural parts of our state, we developed small clinic sites across the state that allowed greater access to individuals much closer to home. At many of our locations, the closest family planning clinic may be over 100 miles away. The poor cannot afford to drive that far to receive care, nor are they able to afford the cost of oral contraceptives from the pharmacy. They are in an untenable position with few job opportunities and little local health care. Approximately 60% of our patients are below 100% of poverty and only 26% of our patients have any insurance. We do not wish to abandon those patients who are most in need.

For 38 years Planned Parenthood of Montana has been very proud to provide low-cost high-quality reproductive health care and contraceptives. We have been able to do this because we have been able purchase contraceptives from manufacturers who were willing to partner with us by providing nominal pricing for those most in need. Of the 18,000 patients we serve, some 2700 do not have the benefit of 340B priced contraceptives which are provided to the client on a sliding fee scale. Those 2700 patients are just as important to us and have the same critical need for subsidized care as our "Title X" patients. We do not wish to abandon them, but we cannot afford to buy and they cannot afford to purchase oral contraceptives at retail market prices.

Currently the only entities that are eligible for nominal pricing are 340B eligible entities, intermediate care facilities for the mentally retarded and state owned and operated nursing homes. Ten of our sites do not qualify under any of these eligibilities. We are not able to add these clinics to our Title X contracts. Therefore these clinic sites cannot receive nominal pricing and these patients will be unable to access care and contraceptives except with your help.

As a "safety net provider" for these poor and uninsured people, Planned Parenthood of Montana depends on our ability to purchase contraceptives at nominal prices. Should we be unable to do that, there will no longer be a "safety net" for these patients. We are asking you, as the Centers for Medicare and Medicaid Services, to use your authority to name not-for-profit, outpatient clinics such as ours as safety net providers so that we may continue our 38 years of service to greatest number of people possible.

Sincerely,



Stacy C. James, MBA
Chief Executive Officer
Planned Parenthood of Montana
Billings, MT

Submitter : **Edwin Rowe** **Date: 02/16/2007**

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

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-726-Attach-1.DOC

February 15, 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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Rowe's Pharmacy, a community retail pharmacy, located at 2416 Memorial Boulevard, Kingsport, TN 37664. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

1. Definition of "Retail Class of Trade" – Removal of PBMs and Mail Order Pharmacies

CMS is proposing an overly broad inclusive definition of "retail class of trade" for use in determining the AMP used in calculating the FULs. The proposed regulatory definition of AMP would not reflect the prices at which retail pharmacies can purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional retail pharmacies should be included in the AMP definition. Excluding PBMs and mail order pharmacies from the AMP determination recognizes that these are not community pharmacies, where the vast majority of Medicaid clients have prescriptions dispensed. Mail order pharmacies do not meet the "open to the public" distinction, as they require unique contractual relationships for service to be provided to patients. PBMs do not purchase prescription drugs from a manufacturer or wholesaler or dispense drugs to the general public. Both these types of organizations do not dispense to the "general public" and, therefore, should be excluded from the information used in the calculation of the AMP to be used for determining an FUL. The more extensive comments submitted by the Tennessee Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP – Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including the elements defined in the proposed regulations is counter to Congressional intent. Rebates and other concessions paid by manufacturers to entities such as mail order pharmacies and PBMs are not shared with community retail pharmacies and, thus, do not reduce the prices pharmacies pay for drugs and are not available to the "general public." These rebates and concessions must be excluded from the calculation of the AMP used to determine the FULs.

While the AMP data is not currently publicly available, so that retail pharmacies can actually determine what the relationship will be between the proposed AMP-based FULs and the prices retail pharmacies pay to acquire the drugs, the GAO has conducted an analysis of this relationship. The GAO used the highest expenditure and the highest use drugs for Medicaid in the analysis. The GAO reported that retail pharmacies will be reimbursed, on average, 36% less than their costs to purchase the drugs included in the analysis. A business can not be sustained if it is forced to continuously sell its products below its actual acquisition costs.

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in my pharmacy where 99.2% of our business comes from prescription drugs. What the "other sales" in the pharmacy are should not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

Medicaid pricing is heavily regulated by the state and federal governments. Medicaid should be treated consistently with other federal payor programs, and also be excluded from AMP in the proposed regulation.

4. Manufacturer Data Reporting for Price Determination – Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. In order to address these concerns, the Tennessee Pharmacists Association (TPA) proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the TPA comments on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date before it could be dispensed. It simply would not be feasible or practical to purchase in these quantities. The prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used.

In conclusion, I support the more extensive comments that are being filed by the Tennessee Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact me with any questions.

Sincerely,

C. Edwin Rowe, D.Ph.
434 Center Street
Gray, TN 37615

cc: Senator Lamar Alexander
Senator Bob Corker
Representative David Davis

Submitter : **Miss. Lisa Mull** **Date: 02/16/2007**

Organization : **Expert-Med, Inc.**

Category : **Individual**

Issue Areas/Comments

Background

Background

I am a sales executive at Expert-Med, Inc. and have been selling generic pharmaceuticals over the past 5 1/2 years to Independently-owned pharmacies across the country.

Collection of Information Requirements

Collection of Information Requirements

Please reconsider the reimbursement limits that will be set on independently-owned pharmacies. One of the biggest complaints I have from independent pharmacies,right now, is that they are losing money on medicaid prescriptions. Some times they get reimbursed right above costs of their acquistion cost. And, at times, these reimbursements from Medicaid are close to our cost (the distributor).

I have found over these past 5 years that independent pharmacies all have different acquisition costs. Acquisition cost vary tremendously between independent pharmacies that are small to ones that are in big cities with closed-door, geriatric or hospice contracts. In other words, when it comes to standardizing reimbursement rates they can not be put on the same level. This could drive small pharmacies out of business, and these are the pharmacies that are providing services to customers who are homebound and rely on the pharmacy's delivery service to get their meds. Chain store pharmacies are not providing these services. Independent pharmacies are. Wal-Mart makes money of f of bikes, food, clothing,etc. Their $4 prescriptions draw customers in and while they wait for their medication to be dispensed, they shop around for other things. Stores like these can absorb lower reimburesement rates. However, independently-owned pharmacies make their living off of the medication and service they provide to their customers. And from the feedback I get from my customers on a daily basis medicaid and 3rd party reimburesements hurt already. Please reconsider this strategy. Look at the impact that this could have to indepents. They are an invaluable asset to communities across America. Let's not destroy their efforts.

Suzanne Lamon
Reeves Drug Store, Inc,
125 North First Street
Pulaski, Tennessee 38478

February 16, 2007

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

To Whom It May Concern:

Thank you for the time to review this comment concerning the Deficit Reduction Act of 2005.

I am a pharmacist and the daughter of a mother and father who are both pharmacists. I was raised in our family-owned drugstore which was previously owned by my great-uncle. For YEARS our store has provided not only the service of dispensing drugs to our customers/patients, but also dispensed knowledge and assistance in their health care needs. Pharmacists are considered to be one of the most trusted professions of a community and the most accessible health care provider in a community. Additionally, we also assist our patients in making sure that they can get their medications by offering delivery within city limits and even mailing prescriptions to those who live outside of our little town's city limits for those that cannot get to town for lack of transportation, illness, etc. Therefore, I believe that you should sincerely consider the impact you are about to make in the lives of our patients, our store, and our community when you choose to pick on the retail end of prescription drugs to lower cost without looking at the entire pharmaceutical industry or without looking at how it will affect many pharmacy businesses.

It is my understanding that the implementation of using the AMP calculation would result in a loss for our pharmacies just to fill the prescription. This may not hold true for some mail-order houses of large PBM's that can purchase large quantities and sometimes quantities that are not even available to our buying groups. You must look at the entire picture before you consider the AMP not just how one entity can purchase that drug. The playing field is not equal for all involved in purchasing pharmaceuticals. And you have not even included the manufacturers of the name brand drugs that raise the cost of drugs dramatically. I understand that these companies have to recoup their cost of research that goes into creating a life saving drug. However, you also consider that they are able to produce and pay for an ad on national TV to inform you of that. They also seem to be making enough profit to create and produce ads to inform patients

about their particular drug as to increase the sales of their product. Should this not be the decision of the well-trained and educated physician, not the drug manufacturer to ask the consumer to ask their doctor? While we are discussing large amounts of profit we can also discuss the large PBM's and the salaries and benefits of their CEO's and what they are paying their stockholders. It seems to me that all of this profit is money that is being taken away from the consumers, businesses providing insurance to their employees, and government.

By focusing on the smaller pharmacy businesses in the cost of the deficit for the government and creating an absurd reimbursement for dispensed medications and care for the patient, you will be in effect closing the doors on access to medication and medical information to one of the neediest populations in our country. WE ARE A BUSINESS. We have to make a profit to survive to pay our employees, to pay our light bill, to keep the store up and running. We are not asking to make millions, but to make a fair wage for the cost of the drug and the time that we spend taking care of the Medicaid patients in our state. Ask some Medicaid patients who they go to for help with their medication? Who do they depend on for assistance? How many of those people do and are able to obtain their drugs from mail-order facilities for which you have based some of your prices? I feel confident that you will find that most Medicaid patients depend on their community pharmacist for help and support of the medications in addition to their questions and concerns about other health problems. We, the community pharmacist, are an asset to you. We are the people that are on the front lines caring for this population. All we are asking is that you reimburse us for the services that we provide you and your patients. Do not take away from us and leave the larger entities with the biggest profits untouched.

If you decide that the new AMP calculation is the best course of action for your deficit, then you will most likely be faced with the crisis of where and how Medicaid patients will receive their medications. However, if you choose to give a fair reimbursement to community pharmacies, Medicaid patients will be able to obtain the same service from the group of individuals that they have been receiving it from for years.

Again, I appreciate your time in the is matter.

Sincerely,

Suzanne Lamon, PharmD

Submitter : **Mr. Lawrence Sage** **Date: 02/16/2007**

Organization : **Indiana Pharmacists Alliance**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-732-Attach-1.DOC

March 12, 2007

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

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

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

Summary

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

§447.504 Determination of AMP

This section of the proposed regulation addresses the methodology CMS will employ to determine AMP when the final regulation goes into effect. The methodology employed to set forth the above tasks creates three areas of concern: (i) the proposed definition of the retail pharmacy class of trade; (ii) the inclusion of Medicaid sales price data and its potential for

artificial market impact; and (iii) the treatment of discounts rebates and price concessions. The following comments address these three areas of concern.

Defining Retail Pharmacy Class of Trade

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

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

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

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

this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

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

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

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

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

While CMS recognizes the inherent lack of transparency to data in mail order and PBM pricing and contractual relationships, it advises that "removal [of mail order pharmacies] would not be consistent with past policy, as specified in Manufacturer Releases 28 and 29." Unfortunately, the past policies relied upon in this statement reflect an understanding of the pharmaceutical supply chain that is nearly a decade old, Manufacturer Releases 28 and 29 date to

1997. The level of vertical integration between PBMs and manufacturers, complexity of the rebate and price concession processes, and evolution of the marketplace require CMS to re-examine this policy. Furthermore, the calculation of AMP in Manufacturer Release 29 includes nursing home pharmacy pricing, while such pricing data is excluded in the currently proposed version of AMP. CMS is correct in changing policy with regard to nursing home pharmacies, and, as noted previously, the rationale for exclusion of nursing home pharmacies, as well as mail orders and PBMs, with regard to dispensing to the general public, is sound.

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive.

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

§447.510 Requirements for Manufacturers.

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

Market Manipulation

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

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

rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

[3] §447.510(d)(2)

would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

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

Record Keeping

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

Additional Comments

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

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form

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

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

Sincerely,

Lawrence J. Sage
Executive Vice President
Indiana Pharmacists Alliance

Cc Senator Evan Bayh
Richard Lugar
Representative Julia Carson

Submitter : **Mrs. Melissa Maeker** **Date: 02/16/2007**

Organization : **The University of Texas Health Center at Tyler**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-733-Attach-1.DOC

February 5, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

To Whom It May Concern:

On behalf of The University of Texas Health Center at Tyler, 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 University of Texas Health Center at Tyler is a 115 bed hospital located in Tyler, Texas, 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. Hospital billing systems are not created to pull this data to a bill. To accommodate, our facility would be required to pay for custom programming from our software vendors. In addition, this would require an additional FTE in the pharmacy department to facilitate continuously updated NDC files in the Pharmacy software. It is not feasible to ask that hospitals attempt to manually add these NDC numbers to a bill. As contracts change quarterly, hundreds of drug NDC #s would need to be modified to ensure integrity in reported data. An estimate of financial ramification to our facility would be over $60,000 per year not including custom programming cost estimated over $30,000. This doesn't even take into consideration a facility having more than one brand of generic being used at the same time in different areas of the facility due to inventory changes.

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. It has long been understood in the hospital community that hospital clinic administered drugs are exempt from rebate requirements under the Medicaid stature. Yet the express purpose

of the NDC collection rule for "physician administered drugs" is to facilitate rebate collections by the States. The new rule proposed by CMS to implement Section 6002 of the DRA should take this pre-existing statutory exemption from rebates into account, and similarly except hospital outpatient clinic drugs from the new NDC collection rule. It makes no sense to require the states to collect NDC information so that they can more easily collect rebates on drugs that are exempt from rebates in the first place. Many of these medications are extremely expensive. If all cost savings are passed through to the Medicaid program, it leaves hospitals moving very expensive medications for small fees. This in addition to increased administrative burden and costs bring up a strong debate within our hospital on whether it is worth participating in the 340B program.

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. CMS should clarify that the new formula for AMP computation is not applicable in calculating 340B ceiling prices, because the 340B statute expressly provides for continuing to utilize the statutory definition of AMP that existed prior to enactment of the DRA. Driving up 340B costs will have a negative ramification across our facility.

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,

Melissa Maeker R.Ph.
Director of Pharmacy
The University of Texas Health Center at Tyler
Tyler, Texas

Submitter : **Mr. Michael Porter** **Date: 02/16/2007**

Organization : **Medicine mart**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This proposed regulation will be absolutely devastating to theRetail pharmacy sector, especially independent pharmacies. Our service and advice to our customers is certainly worth more 1.50 or 2.00. I don't think you are aware of what kind of inventory we have to keep in stock to supply meds to the customers. There is a cost on keeping that inventory on our shelves which may sell quickly or not. If it doesn't sell quickly then we are stuck with it. We are a very trusted profession whcich deserves to be compensated for our services. Right now you are merely paying us to stick a label on the bottle. The costs of running a pharmacy are very high and pharmacist salaries are high as well due to the shortage. We can't stand any more cuts in our reimbursement. We should be paid 10.00 per prescription.We deserve more than what you are trying to pay us. Pharmacists are the ones who save insurance companies millions of dollars per year because of our advice of choosing products that do have generics, and some people ask us if we recommend the generic over the brand. They trust us! Please do not pass this reform. There are other ways to cut costs. Pharmacy has already been cut to the bone. May independents will go out of business and their customers will suffer.

Submitter : **Dr. Nancy Horn** **Date: 02/16/2007**

Organization : **Dr. Nancy Horn**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-735-Attach-1.TXT

March 12, 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

I am pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs. My pharmacy, Corner Drug Winchester, is located at 26 E Broadway, Winchester, KY We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

1. Definition of "Retail Class of Trade" – Removal of PBMs and Mail Order Pharmacies

Excluding PBMs and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed. These organizations do not dispense to the "general public." The more extensive comments submitted by Kentucky Pharmacists Association have addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

2. Calculation of AMP – Removal of Rebates, Concessions to PBMs and Mail Order Pharmacies

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent.

3. Removal of Medicaid Data

Including these data elements is "bootstrapping" the AMP calculation and does not recognize that Medicaid pricing is heavily regulated by the state and federal governments.

4. Manufacturer Data Reporting for Price Determination – Address Market Lag and Potential for Manipulation

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified

under the proposed structure. In order to address these concerns, Kentucky Pharmacists Association proposes a "trigger mechanism" whereby severe price fluctuations are promptly addressed by CMS. Furthermore, we comment on the lack of clarity on "claw back" from manufacturer reporting error.

5. Use of 11-Digit NDC versus 9-Digit NDC

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

In conclusion, I support the more extensive comments that are being filed by Kentucky Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Nancy S. Horn, Pharm.D., R.Ph.

cc. Congressman Ben Chandler
Senator Mitch McConnell
Senator Jim Bunning
American Pharmacy Services Corporation