

Submitter : Mr. A. gogh

Date: 02/14/2007

Organization : walgreens

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachement, also
Leslie Norwalk, acting administrator.

I cannot stress enough the importance of our entire community expressing our outrage over this ruling. AMP will have a devastating effect on our industry if there are not changes made. Quite simply, business cannot expect to operate at a loss to service medicaid patients.

Give yourself some time to go over this information. The attachment is 7 pages...and is quite a bit to digest. However, we cannot put this aside and forget about it. Come July, when AMP rolls out, you will be kicking yourself for not spending 1 hour to try to improve this ruling.

CMS-2238-P-555-Attach-1.PDF

Submitter : Dr. Akil Ghoghawala

Date: 02/14/2007

Organization : Bienestar Pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

Leslie Norwalk, acting administrator.

I cannot stress enough the importance of our entire community expressing our outrage over this ruling. AMP will have a devastating effect on our industry if there are not changes made. Quite simply, business cannot expect to operate at a loss to service medicaid patients.

GENERAL

GENERAL

see attachment.

CMS-2238-P-556-Attach-1.PDF

Submitter : Ms. dominic palma
Organization : palma , dominic
Category : Pharmacist

Date: 02/14/2007

Issue Areas/Comments

Background

Background

we cannot afford to dispense drugs below our actual costs. the nmubers that you have are false and not what we pay for those drugs. we do not recieve any rebates or incentives for dispensing any drugs.

this will lead to my pharmacy no longer being able to care for many patients that we have cared for for 45 years in business. we will have to send them away and this may lead to the closing of our business and cause further unemployment.

Submitter : Mr. Corey Caillouet
Organization : University of Tennessee College of Pharmacy
Category : Pharmacist

Date: 02/14/2007

Issue Areas/Comments

Background

Background

Pharmacy reimbursement rates set to below actual acquisition costs.

CMS-2238-P-558-Attach-1.DOC

Submitter : Dr. Betsy Miller
Organization : Dr. Betsy Miller
Category : Pharmacist

Date: 02/14/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-559-Attach-1.DOC

Submitter : Mr. David DeCarlo

Date: 02/14/2007

Organization : PharmTri Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

I am a registered pharmacist in the State of New Jersey, practicing for 26 years. I am very concerned that the latest round of cost-cutting by the Bush Administration and CMS is will cause local pharmacies to stop accepting Medicaid. The local pharmacy is the lifeline for many people in our area. We provide many value-added services for free, but will not be able to if the current cuts take effect. Our pharmacy is located close to retirement villages and assisted living facilities. The elderly who live there rely on us daily to provide many services including face to face counseling, free delivery to those who cannot drive, and ever increasing administrative assistance with the myriad of plans, prior authorizations, and other problems that arise due to the new Part-D plans. These people are the frail and old and rely on us daily to help them navigate the new systems, and then properly counsel them on their medications, then get their prescriptions out to the in a timely manner. Our customers rely on us more than ever, yet we do not get paid anything extra to this. The GAO says we will be reimbursed 36% less than our cost, which will force me not to accept Medicaid. I WILL rest this responsibility on CMS and the Bush Administrations' budget cuts, as we have absorbed way too much already, including quadrupling my receivables due to slow payments from the Part-D plans. The senior citizens of our community are due more respect than this, and so are we. Cigna, United Healthcare, and Aetna have all reported record profits this year, but we have had our margin reduced by about 25%, yet our expenses just continue to grow, and administration more onerous for our patients and our organization.

Collection of Information Requirements

Collection of Information Requirements

AMP was never intended to serve as a baseline for reimbursement, and may not have been an effective measure for manufacturer's rebates according to GAO-05-102. If AMP is to serve as the basis for pharmacy's true cost of goods, any and all rebates and price concessions CANNOT be included in the calculation, including rebates paid to the PBM's (eg-Medco, Caremark, etc.). An accurate definition of AMP will lead to increased generic dispensing, and lead to greater rebates to the states, which saves money for the entire system, while encouraging effective patient care.

Drug prices MUST be determined by 11-digit NDC codes, to ensure accuracy in packaging available and commonly used at the retail level, and to eliminate waste.

AMP MUST be reported weekly and accuracy must be guaranteed in the calculation, as our pricing fluctuates rapidly, sometimes on a daily basis. This is only fair, as we must pay bi-weekly or weekly in some cases, and would need this information for daily operation and purchases.

AMP must be kept to the retail class of trade only, as ours is the only one that is transparent and subject to audit. The PBM's are not subject to opening their books, so I feel their information will be at least stacked in their favor to increase their marketshare, and at worst, may show they do not share their rebates promised to their clients, as been seen in recent court cases.

All calculations of AMP MUST BE independently verifiable with full transparency to ensure accurate calculations. Underpayment will have dire consequences for patient care and access.

GENERAL

GENERAL

I hope that CMS will heed the GAO, NCPA, and others in regard to payments under the proposed AMP FUL rules.

The current formula will NOT cover pharmacy acquisition costs for multi-source generic medications.

AMP was never intended to serve as a basis of reimbursement.

To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by the pharmacy, which MUST exclude rebates and price concessions made by manufacturers which are NOT available to pharmacy.

Reporting AMP to an 11-digit NDC only

Excluding all mail-order facilities and PBM pricing form the calculations. These prices are NOT accessible to us.

Remember, we has our hands tied years ago when we were NOT ALLOWED to bargain with the PBM,s there is no other business in healthcare where a wholly-owned subsidiary can refer customers to itself. There is no transparency in the PBM business, which I believe grossly inflates the price of brand-name drugs. Remember how much the branded drugs cost in relation to generics, an incorrect AMP is a recipe for disaster, and is not conducive to generic dispensing.

I cannot and will not allow my business to participate in a program that had many liabilities in the normal course of business, and causes us to lose money. Denying access to vital medications and the delivery system itself will cause major increases in non-compliance resulting in increased emergency room use and hospitalizations.

The increases in prescription spending over the years has improved the quality of life and decreased hospitalizations, which saves money in the long run. Please do not be penny-wise and pound foolish.

I thank you in advanced for taking the time to read my comments, I can be reached at Kadamps@msn.com or Medicinetogo@msn.com

Response to Comments

Response to Comments

AMP must be regulated transparently to ensure correct and timely calculations so as not to place small pharmacies at a disadvantage after they have faithfully served their communities for many years in an ever-shrinking profit structure. I hope that CMS takes these thoughts into account, even if only for respect of our senior population.

Submitter : Richard Boyd
Organization : Ohio Northern University
Category : Individual

Date: 02/14/2007

Issue Areas/Comments

GENERAL

GENERAL

My name is Richard Boyd, and I am a pharmacy student at Ohio Northern University. I am interested in someday owning my own pharmacy. Recently, an issue has come to my attention that would affect my future as a community pharmacist.

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to community pharmacy. It is estimated that the reimbursement will be far below what it actually costs pharmacies to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what pharmacists 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.

A clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs MUST be issued. The definition should be issued as soon as possible, before AMP takes effect.

Please consider all the students and community pharmacists who will no longer be able to operate if this is not resolved.

Sincerely,
Richard Boyd

CMS-2238-P-561-Attach-1.DOC

Submitter : Dr. Jarrett Bauder

Date: 02/14/2007

Organization : Uptown Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Miss. Christie Williamson
Organization : Pennsylvania Pharmacist Association
Category : Pharmacist

Date: 02/15/2007

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 Duquesne University and I also work at The Medicine Shoppe Pharmacy.

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,
Christie Williamson
Student Pharmacist

Submitter : Ms. Malinda Parman
Organization : University of Tennessee College of Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-564-Attach-1.DOC

Submitter : Dr. Walter Guice
Organization : Specialty HelathCare Partners, Inc.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

2-15-07

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

Ms. Norwalk,

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

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

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medication. This does not consider the recently released report from the accounting firm Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies in which it is reported that the median cost of dispensing a prescription for a pharmacy is \$10.51.

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

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

Sincerely,

Walter Guice, Rph., BCNP
Specialty HealthCare Partners, Inc.
Chattanooga, TN. 37421 (423-490-0166)

Submitter : Mr. Terry Griffith
Organization : Tennessee Pharmacists Association
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-566-Attach-1.DOC

Submitter : Mr. Brian Deihl

Date: 02/15/2007

Organization : APhA

Category : Pharmacist

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.

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,

Student Pharmacist

Submitter : Mr. Tim Barrick
Organization : The Clinic Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

The Deficit Reduction Act of 2005 (DRA) that would change the Medicaid program's reimbursement for generic medications to a formula based on 250% of the Average Manufacturers' Price (AMP) will have negative impact on retail pharmacies. Especially independent pharmacies and even more so independent pharmacies in "rural" areas who have a higher than average percentage of their patients who are medicaid eligible. In addition, at this point, no one knows what AMP will be.

If Wholesale Acquisition Cost (WAC) had been designated as the standard, instead of AMP, as was recommended by many pharmacy advocate groups, this issue would be much clearer to everyone. Furthermore, how can group retail pharmacy as a group that includes mail-service pharmacies, hospital out-patient pharmacies, and outpatient clinics when these groups have access to rebate programs and price concessions that true retail pharmacies do not have access to? These price concessions drive the AMP down, therefore more drastically cutting in to profit margins for those pharmacies to do not have access to that type of preferential pricing.

Submitter : Mrs. Patricia Keller

Date: 02/15/2007

Organization : Newbern Discount Drug, LLC

Category : Pharmacist

Issue Areas/Comments

Background

Background

Your current definition of AMP will cause my retail pharmacy to lose money with each Prescription I fill for you.

Why would you ask me to do this ????

We are in a rural area and provide free counselling to many of your patients. These people depend on us to solve their problems.

We have spent in excess of 1000 hours in solving medicare D problems.

We do the same each day with your medicaid / TnCare population.

This is free customer service directly for CMS and does not show as an expense on your budget.

Why kill the organizations who you are getting the largest return for your money.

Note the income statements of the third party benefit managers. Note the increases in their profits from medicaid & medicare. This is where the excesses are in the medical delivery system.

You are after the wrong pot of money.

CMS-2238-P-569-Attach-1.TXT

Submitter : Dr. vicky noling
Organization : north florida pharmacy of mayo, inc
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

I own a small independent pharmacy in a small town. Twenty percent of my prescriptions are paid for through Medicaid, with about 80% of these being prescriptions for children under the age of 18. If we have to discontinue accepting Medicaid due to the new proposed AMP pricing, these clients will have to drive at least 25 miles to the nearest city to have their prescriptions filled. This is a disservice to these underprivileged children, whose parents often can't afford the gas to drive them out of town. A purpose of Medicaid is to help those who need it, and this proposal will negatively affect Medicaid clients, not to mention our local economy, as people will be forced to take their business out of town. Please reconsider this proposal, as I feel I am speaking for MANY small, independent pharmacies, not just myself. This proposal will negatively affect our business, possibly forcing us to close altogether!

Submitter : Mr. Eric Amber
Organization : Medicine Stop Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-571-Attach-1.DOC

Submitter : Dr. Deborah Teague
Organization : IV Solutions Home Infusion Therapy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-572-Attach-1.DOC

CMS-2238-P-572-Attach-2.DOC

Submitter :

Date: 02/15/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

Background

Background

22222

Collection of Information Requirements

Collection of Information Requirements

222222

GENERAL

GENERAL

22222

Regulatory Impact Analysis

Regulatory Impact Analysis

222222

Response to Comments

Response to Comments

22222

Submitter : Thomas Main

Date: 02/15/2007

Organization : Main Drug Inc

Category : Pharmacist

Issue Areas/Comments

Background

Background '

AMP RULING Affecting Medicaid Reimbursement

Collection of Information Requirements

Collection of Information Requirements

AMP is to be the new benchmark for reimbursement for medicaid pharmacy products

GENERAL

GENERAL

On behalf of my employees and their families and myself I would like to oppose the current system for calculating AMP. Under the current system my reimbursement would be significantly less than I am able to purchase the product for. This is due to the fact that my reimbursement rate will be calculated based on what hospitals and other Huge suppliers pay for their medications. I think anyone in the world would agree that we should not be reimbursed based on what a huge hospital pays for their drugs when we can not physically buy the product for a fraction of the cost that these people can buy them for. The AMP should be calculated in a fair manner and it would be just as easily be possible to reimburse different pharmacies based on what their cost are. Thank You and I hope you will consider the lives of the the people this law would cause harm to by loss of access to care and putting pharmacies out of business.

Thomas Main Rph.

Submitter : Mr. WILLIAM PRATHER
Organization : GEORGIA BOARD OF PHARMACY
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

your proposed reimbursement schedules could quite possibly make needed drugs unavailable in rural, medically underserved areas where the Pharmacist may be one of the only sources of not only drugs but other important medical advice. any small business (mine included) cannot afford to fill prescriptions and lose money. mail order pharmacy or large big box stores, not located in many areas simply cannot fill these needs. Please reconsider your cuts and talk to some real small town Pharmacists concerning costs but talk to their patients about the service their Pharmacist provides. If you listen only to the Pharmaceutical Manufacturers and/or PBM industry you are not the whole story.

Thank you,

William Prather R.ph.

Member Georgia Board of Pharmacy

Owner, Blue Ridge Pharmacy

793 east main st

Blue Ridge, Ga.

Submitter : Gary Pettigrew

Date: 02/15/2007

Organization : Gary Pettigrew

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to take this opportunity to express my concerns about the proposed changes in calculating prescription reimbursement that will affect retail pharmacy.

I have owned an independent pharmacy in rural West Tennessee since 1972; therefore I am not a stranger to change.

I am sure you will hear from many qualified individuals in our industry who have greater access to the relevant figures than I do so I will try to focus on other issues.

Reducing reimbursement to a level that is below cost for independent pharmacies will in the long run reduce the level of care many citizens receive. This will occur by either forcing many pharmacies to go out of business or causing them to curtail services. The closing of independent pharmacies will cause the loss of many jobs as well as reduce the support of local activities that many communities depend on. In other words, the destruction of a way of life that is invaluable to the survival of America.

There appears to be many flaws in the proposal. Although I do not claim to be an attorney, I believe I understand the bottom line of these proposals. Please be mindful of the fact that retail pharmacy cannot purchase at the level of mail order. Nor can mail order provide the level of pharmaceutical care community pharmacy does. Therefore, they should not be bundled together in determining drug cost.

Also, even though independent pharmacy has fought for years for transparency from PBM s, that is not the case. Therefore, any inclusion of PBM rebates or discounts should not be considered in the formulas.

Community pharmacy has provided an excellent delivery system for years despite the attacks by government, mail order pharmacies, and insurance companies. This is because independent pharmacist and their support staff want the best for their patients.

There have been many studies indicating the cost of filling a prescription (the governments 340B program is a good example). These figures should be considered when making a decision on a change in reimbursement philosophy.

Please be mindful of the information you will receive from people in our industry who are in the know about how inaccurate changes will affect our profession, therefore our nation.

Sincerely,

Gary Pettigrew D. Ph.

Submitter : Mr. HD HIGH
Organization : DELTA PHARMACY
Category : Pharmacist
Issue Areas/Comments

Date: 02/15/2007

GENERAL

GENERAL

AS OWNER OF 2 INDEPENDANT PHARMACIES THIS REIMBURSEMENT
FORMULA WOULD CAUSE US TO LOOSE MONEY- WE HAVE SERVED OUR
COMMUNITY SINCE 1935-WE WOULD HAVE TO DISCONTINUE IN THE
PROGRAM AND CAUSE LOSS OF MANY JOBS-THANKS

Submitter :

Date: 02/15/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

Submitter :

Date: 02/15/2007

Organization : St. Thomas Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

We are unsure that we will have the ability to do this with our current financial system. If we do have this functionality, it would take 3-6 months to update the NDC codes in the Pharmacy System and then take someone at least 4-6 hrs a week to maintain them. This would be about a \$50,000 cost to us to update the NDC and about \$300 a week to maintain them.

Submitter : Dr. Dwight Weaver
Organization : Crain's Pharmacy, Inc.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the proposed AMP Regulation. As the owner of a small-town pharmacy in rural Tennessee I feel that the very existence of my business will be threatened if the CMS adopts the regulation. More than 95% of my income is from the sale of prescriptions and if I must accept reimbursement that results in a loss of 36% or more, as the GAO has determined, my business will not be able to survive.

Submitter : Ms. Karen Hildebrand
Organization : Planned Parenthood of West Texas
Category : Health Care Professional or Association

Date: 02/15/2007

Issue Areas/Comments

Background

Background

GENERAL

GENERAL

I am the CEO of Planned Parenthood of West Texas. We are a small to mid-size family planning agency in rural West Texas. We serve 50 counties and over 14,000 patients. In this area, people have to travel great distances to access basic health care. For our patients, we are, many times, their only healthcare provider. Eighty two percent of our patients live at or below 150% of the federal poverty level; eighty nine percent live at 200% or below. The exclusion of my agency from receiving discounted pricing is devastating. Our patients are poor and it would be difficult for them if we increase what we charge them for their birth control and other pharmaceuticals. But we cannot continue providing pills and not cover the cost. We currently lose money on many of the drugs we provide and we cannot keep our doors open and continue to do this. My agency does not receive Title X funding so we are not eligible for 340b pricing. Although we receive Title XX funding from the state, which reimburses us after we see qualifying patients -those with incomes at or below 185% of the federal poverty level, this does not qualify us for 340b pricing. We are truly a safety net provider and need to be included as part of the approved group.

Submitter : Ms. Susan Melczer
Organization : Metropolitan Chicago Healthcare Council
Category : Health Care Provider/Association

Date: 02/15/2007

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

see attachment

GENERAL

GENERAL

see attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

see attachment

Response to Comments

Response to Comments

see attachment

CMS-2238-P-582-Attach-1.PDF

CMS-2238-P-583

Submitter : Dr. Leslie Stuart
Organization : Tennessee Pharmacists Association
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-583-Attach-1.DOC

Submitter : Mr. James Kelley

Date: 02/15/2007

Organization : Anderson County Discount Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Everything about the new pricing system proposed for pharmacies for Medicaid is absurd. We have been paid by the AWP system with a reimbursement fee. This has been so low, thousands of pharmacies around the country have went bankrupt and even the major chain stores are struggling. It is almost like the airline industry where we are being priced out of business. What is health care going to do when there are only 1-2 drug stores per town and they use 1 pharmacist and 20 techs. The Pharmacy Schools will close or we'll have less of them.

Everyone has to know that this new pricing system is absurd. Every year the reimbursement fees for pharmacies are going way down, especially over the last ten years, yet RX prices are going up. Doesn't everyone know why, because manufacturers are raising costs of drugs by great percentages. One bottle of medicine might cost \$100.00 today, then cost \$150.00 for the exact same bottle four months later. They have no conscience. A manufacturer will call with a new cough syrup that may cost between \$40.00 - \$60.00 for a 4oz. bottle, this is ridiculous! Something for a runny nose or allergies costing that much is ridiculous. Then you take something that cost the pharmacy \$81.00 and you only pay \$84.00 and act like you are going to reduce costs of health care by reducing pharmacy fees from \$2.50 to \$2.25 - Big Deal! Why not reduce the cost of the drug for pharmacies to \$80.00 and save \$3.00 - \$4.00 per prescription. If you really wanted to reduce health care costs, this is the way to go. Also, several years ago, brand manufacturers saw that generics were too cheap. They then bought the generic companies and immediately raised the costs from \$4.00 - \$5.00 per 100 to \$50.00 per 100 and thought that was OK. To save health care costs, what happened again, was reimbursements to pharmacies were cut another 15 cents as if that made any sense. You would think that everyone alive would know where to control health care costs. It is not the drug store and everyone has to know that. Our profit margin is less and less each year but health care costs and RX prices are going up dramatically. Stop the manufacturer from pricing RX's so high and raising them so dramatically and you have accomplished what you are trying to do.

Submitter : Ms. robert logan
Organization : logan's discount drugs, inc.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

Submitter : Mr. Steven Ciullo
Organization : Valley Health System
Category : Hospital

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

As Corporate Director for Pharmacy Services at Valley Health System, I believe that these changes would create an undue hardship on our organization at this time based on the fact that the information requested would have to be provided manually. This would add steps to an already complex medication ordering, dispensing and administration process. Additionally, it may impact patient safety due to changes to hospital workflows, staffing and financial resources. Please note that we will be doing further analysis to estimate the burden and cost to implement this proposal.

Thank you for your consideration of these issues.

Submitter :

Date: 02/15/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 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.

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

Unfortunately, quality health care does come with a cost, and the pharmacy piece is no different. If CMS-2238-P is implemented in its current form, my pharmacy will be reimbursed below the cost of acquisition for the medication. This does not consider the recently released report from the accounting firm Grant Thornton LLP National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies in which it is reported that the median cost of dispensing a prescription for a pharmacy is \$10.51.

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

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

Sincerely,

Lewis Lowe, R.Ph.
Lowe's Pharmacy, Inc.

Submitter : Ms. Carol Steckel
Organization : Alabama Medicaid Agency
Category : State Government

Date: 02/15/2007

Issue Areas/Comments

Background

Background

See Attachment

Collection of Information Requirements

Collection of Information Requirements

See Attachment

GENERAL

GENERAL

See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attachment

Response to Comments

Response to Comments

See Attachment

CMS-2238-P-588-Attach-1.DOC

Submitter :

Date: 02/15/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-589-Attach-1.DOC

Submitter : Mr. Larry Wilkinson
Organization : Terrace Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-590-Attach-1.RTF

Submitter : Mr. Philip Baier
Organization : Mr. Philip Baier
Category : Individual

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-591-Attach-1.DOC

Submitter : Dr. Gary Louie
Organization : California Pacific Medical Center
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

The regulation requires the pharmacies to submit the NDC code as part of its submission to CMS

GENERAL

GENERAL

This regulation poses undue hardship on the hospital as unless a hospital already has barcoding at the point of patient administration, the hospital information system will be unable to yield a 11-digit unique NDC number to submit to the State Medicaid agency. Majority of hospitals has yet to implement the bar code technology at point of care. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

The impact on workflow, staffing and financial resources of the hospital is quite dramatic, unrealistic and not justifiable given current fiscal and workforce constraints. I would disagree with the proposed rules comments that [W]e believe the cost of adding the NDC to each claim would be minimal. We are not able to estimate the cost to make this change. Just the opposite, we expect that this requirement would require tremendous amount of labor and other resources to implement. I estimate this to be minimally cost in the range of tens of thousands dollar annually. This is a cost that we are unable to absorb.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

This regulation poses undue hardship on the hospital as unless a hospital already has barcoding at the point of patient administration, the hospital information system will be unable to yield a 11-digit unique NDC number to submit to the State Medicaid agency. Majority of hospitals has yet to implement the bar code technology at point of care. The only alternative is to manually submit these claims. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

The impact on workflow, staffing and financial resources of the hospital is quite dramatic, unrealistic and not justifiable given current fiscal and workforce constraints. I would disagree with the proposed rules comments that [W]e believe the cost of adding the NDC to each claim would be minimal. We are not able to estimate the cost to make this change. Just the opposite, we expect that this requirement would require tremendous amount of labor and other resources to implement. I estimate this to be minimally cost in the range of tens of thousands dollar annually. This is a cost that we are unable to absorb.

Submitter : Mark Byrd
Organization : Mark's Family Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-593-Attach-1.RTF

Submitter : Mr. Curtis Riley

Date: 02/15/2007

Organization : Millry Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-594-Attach-1.DOC

Submitter : Mr. Antony Eason
Organization : TAS Drug, Inc.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

I represent TAS Drug, an independent pharmacy serving approximately 1,800 of your entity's beneficiaries in NC's western piedmont. I am writing to request that the finalization of legislation be delayed until more detailed information is made available.

Collection of Information Requirements

Collection of Information Requirements

****Federal Register Vol. 71, No. 246, 12/22/2006 page 77176 Section 447.502

Definitions **** AMP appears to provide reimbursement of acquisition costs only, without consideration of costs of doing business (dispensing costs, labor, packaging, rent, utilities &). TAS Drug, as well as, all other community pharmacies, could not even break even if we were to provide our products at cost. A minimum level of dispensing fee should be included as an alternative to the definition only position.

****Federal Register Vol. 71, No. 246, 12/22/2006 page 77178-77179 Section 447.504 Definition of Retail Pharmacy Class of Trade and Determination of AMP **

Regarding inclusion of mail order pharmacy prices in the definition of retail pharmacy class of trade for purpose of inclusion in the determination of AMP: TAS Drug, as well as, other independent pharmacies does not purchase pharmaceuticals at the same cost as mail order pharmacies and chain pharmacies. This is due in part to our inability to negotiate collectively with manufacturers, and our having to acquire products through wholesaler/distributors (who in turn must impose additional margins for the distribution of the products). The disparity between acquisition costs of mail order/chain pharmacy and independent pharmacy (such as TAS Drug) are very significant. Unfortunately, CMS's inadequate provision of data regarding AMPs to the retail pharmacy industry makes it difficult to respond definitively to this matter, therefore a final rule should be delayed until the CMS can provide more detailed/accurate information to allow a legitimate, valid evaluation of the AMP data.

I do not understand why PBM's rebates, discounts, etc. would be included in AMP calculations. TAS Drug has never received a share of any PBM's rebates. To the contrary, PBM's impose service fees to TAS Drug for the ability to provide service to the patients.

****Federal Register Vol. 71, No. 246, 12/22/2006 page 77187-77188 Section 447.514 Upper Limits for Multiple Source Drugs ***** Regarding the request for comment on 11 digit v. 9 digit NDC calculation of AMP: A number of large bulk size products typically available to direct purchasers at discounted rates are not available for purchase by TAS Drug and other independent pharmacies. The 11 digit NDC should be utilized for FUL calculation to compensate for this disparity. Once again, independent pharmacies should not be asked to provide products and services below their acquisition costs.

GENERAL

GENERAL

In summary: 1. A minimum level of dispensing fee based on national annual independent analysis should be included in addition to the FULs for reimbursement determination. 2. Inadequate provision of hard data by CMS of AMPs to the retail industry hampers our ability to provide definitively accurate commentary on the matter. Therefore, the final rule should be postponed until adequate information is provided to allow for statistically significant evaluation. 3. If mail order is included in the definition of retail pharmacy class of trade, a significant additional increase should be provided to those entities that provide the more desirable mode of delivery of products and services, namely community pharmacies. 4. PBM's rebates, discounts, etc., should not be included in AMP calculations. 5. The 11 digit NDC should be utilized for FUL calculation

In closing, CMS should provide additional information to the industry related to the actual AMP and established FUL prior to implementation of a final rule. This will enable us to make a more educated commentary to help CMS and the legislature meet the intent of the legislation.

Response to Comments

Response to Comments

****Federal Register Vol. 71, No. 246, 12/22/2006 page 77190-77194 Section 447.514 Impact Analysis **** The statement we believe that these legislatively mandated section 6001 savings will potentially have a significant impact on some small, independent pharmacies should be changed to read & will have a catastrophic impact on most independent pharmacies if your entity's proposed changes are ruled on as-is.

Another possible development from the rule changes as-proposed, would be the refusal of pharmacies to accept the reimbursement offered, leaving significant gaps in providers for your entity's beneficiaries.

Submitter : Beverly Guy
Organization : Millry Drugs
Category : Other Technician

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-596-Attach-1.DOC

Submitter :

Date: 02/15/2007

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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 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 and I also work at Rite Aid Pharmacy.

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,

Lindsey Klish

Student Pharmacist

Submitter : Dr. Brent Dunlap
Organization : Plateau DrugCenter
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-598-Attach-1.DOC

Submitter : Dr. Don Dehart
Organization : Mcintosh Drugs
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-599-Attach-1.DOC

CMS-2238-P-599-Attach-2.DOC

Submitter : Deborah Ann Whisenhunt

Date: 02/15/2007

Organization : Mcintosh Drugs

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-600-Attach-1.DOC

Submitter : Mr. DONALD JOHNSTON

Date: 02/15/2007

Organization : HIDEG PHARMACY INC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

IT IS VERY IMPORTANT THAT CMS NOT IMPLEMENT THE PROPOSED CUTS TO THE PRICES PAID TO RETAIL PHARMACISTS FOR THEIR DRUGS AND SERVICES. OUR PATIENTS NEED THE ABILITY TO SEE A NEIGHBORHOOD PHARMACIST FOR ALL THEIR MEICAL NEEDS AND ANY PRICE CUTS WILL HINDER THAT AVAILABILITY.

PLEASE WORK WITH THE NATIONAL PHARMACY GROUPS TO HELP SAVE COSTS IN THE COMPLETE COST OF MEDICAL CARE, QUALITY PHARMACEUTICALS CAN SAVE MORE MONEY IN THE LONG RUN. INCREASED GENERICS WITH A FAIR DISPENSING FEE AND FAIR COST OF GOODS IS NEEDED.THESE DRASTIC CUTS WILL PUT MANEY STORES OUT OF BUSINESS WHICH WILL HUT HEALTHCARE, COST JOBS, CUT TAXES,AND HURT MANY PEOPLE.....

THANK YOU FOR YOUR TIME....

Submitter : Keith Boyett
Organization : Mt. Vernon Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-602-Attach-1.DOC

Submitter : Dr. Brent Dunlap
Organization : Scott County Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-603-Attach-1.DOC

Submitter : Joyce Walker
Organization : Mt. Vernon Pharmacy
Category : Other Health Care Provider

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-604-Attach-1.DOC

Submitter : Dr. Bill Dunlap
Organization : Plateau DrugCenter
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-605-Attach-1.DOC

Submitter : Dr. Caye Renager
Organization : Mcconaghy Drugs
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-606-Attach-1.DOC

Submitter : Mr. Trevor Williams
Organization : Smith Drug Co.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

Ms. Norwalk,

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

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

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

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

My pharmacy and others have already been hit hard by many factors including poor(pathetic) reimbursements from PBM's who administer the Medicare Part D plan. These companies such as Humana,Caremark,Express Scripts, Medco and many others are ripping off Medicare, the American people, as well as the community pharmacy.

These same companies are FORCING millions of employees of companies to obtain their prescriptions through mail order. This takes business away from my store on a weekly basis. These many factors along with AMP pricing may very well drive me out of business. MY DRUGSTORE HAS BEEN SERVING OUR COMMUNITY FOR ALMOST 100 YEARS!!!!

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

Sincerely,

Trevor Williams, RPh

Submitter : Mr. ERNIE RIDDLE
Organization : RIDDLE EXPRESS PHARMACY
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT

Submitter :

Date: 02/15/2007

Organization : Mark's Family Pharmacy

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-609-Attach-1.RTF

Submitter : Mr. Stephen Griffin
Organization : Griffin Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

I,m Steve Griffin, RPh. owner of Griffin Pharmacy with 2 locations in the Birmingham, Al. area and our original location in the small town of Sipsey, Al. We have 36 full time employees and have been in business 26 years.

GENERAL

GENERAL

I want to express my concern with the proposed rule (CMS-2238-P) regarding the pharmacy providers based on the AMP model as set forth in the Deficit Reduction Act of 2005. If the pharmacy reimbursements utilizing AMP as outlined in this rule are implamented I will be forced to discontinue service to medicad patients due to the fact that my reimbursement would be below my aquisition cost for the drugs.

Even a report by the GAO states that community pahrmacies such as mine would lose an average of 36% on each generic prescription filled for a Medicaid beneficiary.

A recently relased report from the accounting firm Grant Thornton LLP indicated the median cost for dispensing a prescription is \$10.51.

Pharmacist were here when CMS instituted the Medicare Part D Prescription Drug and they took care of the patients by allowing them to have their medications while trying to work through all the new reimbursement mechanisms. During that time due to all the confusion my pharmacy's payments were delayed for over 90 days. this is only one example when pharmany came through. Please consider the importance of community pharmacies when debating the AMP pricing model.

Sincerely,

Stephen H. Griffin, R.Ph.

Submitter : sally slusher
Organization : NC Association of Pharmacists
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

February 18, 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.

1. Remove PBM and Mail Order from 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 the North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Sally J. Slusher
NC Association of Pharmacists

GENERAL

GENERAL

February 18, 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

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 - (i) Creates consistency in the Regulation
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- (i) Represents the most common package size dispensed by retail pharmacies

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

Sincerely,

Sally J. Slusher
NC Association of Pharmacists

Submitter : Wilbur Price
Organization : McConaghy Drugs
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-612-Attach-1.DOC

Submitter : Dan McConaghy

Date: 02/15/2007

Organization : McIntosh drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-613-Attach-1.DOC

Submitter : Ms. Stephanie Capron
Organization : Ritzman Pharmacies, Inc.
Category : Drug Industry

Date: 02/15/2007

Issue Areas/Comments

Background

Background

**Collection of Information
Requirements**

Collection of Information Requirements

**Provisions of the Proposed
Regulations**

Provisions of the Proposed Regulations

Regulatory Impact Analysis

Regulatory Impact Analysis

Response to Comments

Response to Comments

CMS-2238-P-614-Attach-1.TXT

Submitter : Dr. John Kessler

Date: 02/15/2007

Organization : Dr. John Kessler

Category : Pharmacist

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

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 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

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 The North Carolina Association of Pharmacists 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, the North Carolina Association of Pharmacists 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 North Carolina Association of Pharmacists regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

John M Kessler, Pharm. D. BCPS
President and Chief Clinical Officer
SecondStory Health, LLC
919.621.8973
jkessler@secondstoryhealth.com

CMS-2238-P-616

Submitter : Aubrey Bryan Higdon

Date: 02/15/2007

Organization : Mt. Vernon Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-616-Attach-1.DOC

Submitter : Brightman B. Coker

Date: 02/15/2007

Organization : McConaghy Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-617-Attach-1.DOC

Submitter :**Date: 02/15/2007****Organization :****Category : Pharmacist****Issue Areas/Comments****GENERAL****GENERAL**

Hello I am an independant pharmacist trying to make a living just like everyone else. I understand the proposed changes to pharmacies reimbursement is about to change. The proposed changes are very flawed and if implemented as they stand will force many individuals such as myself out of business and greatly reduce our patients access to care.

The AMP calculation you are attempting to use has many flaws:

1)including mail-order pharmacies in the calculation.

Mail-order pharmacies have special prices not available to retail pharmacies.

2)Rebates to PBM's.

This has nothing to do with retail pharmacy. It is out of our control. And we do not see any of this money. If CMS wants it go after the PBM.

3)Pricing updates happen daily in this trade. This means I can buy a drug today for more than CMS is willing to reimburse. CMS will update 30 days after the month end. That means we will be reimbursed much less than our cost for 60 days. This in my mind is just stealing from pharmacies to help CMS budget. The standard in this industry is that PBM's update their data DAILY!!!!

4)NDC is going to be 9 digits not 11. The standard is 11. Why change? Again to steal rightful money owed to pharmacies to put back into CMS budget. This is not right. The last 2 digits are necessary to insure correct pricing. Different package sizes cost different amounts. If CMS reimbursement is based on a bottle of 5000 Which would be the cheapest, And I by a bottle of 100 my cost is a whole lot higher per tablet than the price that was based on 5000 units.)

5)GAO finds AMP will be 36% below invoice price. How will stay in business. The answer we will not. Decreasing patients access and quality of care. So if that is your goal to save monet here to spend more later, I assure you will accomplish that.

6)CMS does not account that we are professionals. Requireing 6 years of professional education. We are the most accessable base of knowledge. Patients walk in the store all the time with questions or problems that we fix at no charge. How is this accounted for? When you go to the doctors you need an appointment which is billed for their time. CMS definition must account for pharmacists time dispensing, counseling, time on the telephone, fax, email with Medicaid agencies, PBMs, billing information, real costs like rent, utilities, mortgages etc. CMS is treating us like retailers. We do not just resale goods. We provide an irreplaceable service, which is being jepordized.

Thank You for your time.

Brian Bryk

Submitter : Norman John McConaghy

Date: 02/15/2007

Organization : McConaghy Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-619-Attach-1.DOC

Submitter : Mrs. June Adams

Date: 02/15/2007

Organization : Adams Pharmacy and Home Care Inc

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am a small business owner that services over 250+ medicaid patients. I do not have access to the pricing this AMP is based on. My cost to dispense to patients is \$10.50+ since many of the patients require special packaging. This is so very unfair to put my business out of business. I cannot operate my business with these unfair practices. What other business in the country operates with the margins pharmacies are forced with?? I know of none that have not gone out business. These patients will lose access to their medications and the pharmacist that takes the time to explain it to them. Sincerely, June Adams

CMS-2238-P-620-Attach-1.WPD

CMS-2238-P-620-Attach-2.WPD

Submitter : Ms. Laura Lanman

Date: 02/15/2007

Organization : APhA-ASP

Category : Health Care Professional or Association

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.

A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only HALF the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy acquisition costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : john mcconaghy
Organization : john mcconaghy
Category : Individual

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-622-Attach-1.DOC

Submitter : Ms. Nancy Kachel
Organization : Planned Parenthood of Arkansas and Eastern Oklahom
Category : Health Care Provider/Association

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-623-Attach-1.DOC

Submitter : Mr. Jeffrey McCloud
Organization : McCloud Family Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

I am a pharmacist and co-owner of McCloud Family Pharmacy in Huntington, WV. I have been a pharmacist for 12 years and opened my own establishment in 2005.

Collection of Information Requirements

Collection of Information Requirements

The government will reimburse using the AMP schedule for generic drugs beginning in July 2007. The effect of this will be for 36% of Medicaid rx's we fill, we will take a loss, thus making it impossible to be profitable as a business taking Medicaid recipients.

GENERAL

GENERAL

See attachment.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

We calculated our cost to dispense a prescription to break even to be \$10.50 in addition to cost of the drug.

Regulatory Impact Analysis

Regulatory Impact Analysis

We are against the induction of AMP due to its adverse effect on our business as a whole.

Response to Comments

Response to Comments

The impact of this bill could lead to our dissolution.

CMS-2238-P-624-Attach-1.DOC

CMS-2238-P-624-Attach-2.DOC

CMS-2238-P-624-Attach-3.TXT

CMS-2238-P-624-Attach-4.DOC

Submitter : Mr. Lynn Connelly
Organization : Medicine Mart
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

The government cannot expect ANY business to sell prescription drugs below cost and stay in business. Each class of trade should be separated. For instance, retail, mail order, and long term care pharmacies all purchase at different cost levels and the same AMP figures should not be used for every class of trade.

We are only asking the government to be reasonable and fair.

Submitter : Mr. Don Waldron, Jr.

Date: 02/15/2007

Organization : Mr. Discount Drugs

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

February 15, 2007

Centers for Medicare and Medicaid Services
Attention: CMS 2238-P Mail Shop C4-26-05
7500 Security Blvd.
Baltimore, MA 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's 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(s) is located _____. We are a major provider of pharmacy service 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 PEMs 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 the Mississippi Independent Pharmacies Association has addressed differentiation, consistency with federal policy, and the benefits of excluding these data elements.

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

AMP should reflect prices paid by the 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 the 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 the Mississippi Independent Pharmacies Association proposed 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 of 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 Mississippi Independent Pharmacies Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,
Don Waldron, Jr.
Mr. Discount Drugs
4832 Poplar Springs Drive
Meridian, MS 39305

Submitter : Mr. Joel Amundson
Organization : Allina Hospitals & Clinics
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

I am a practicing pharmacist since 1972, and plan to continue to practice for another 8-10 years. I read in the Feb issue of Drug Topics that reimbursements for generics under Medicaid would be less than acquisition by an average of 36%. How can a pharmacy, or any business, continue when we can't cover our costs? Over 85% of our activity is dispensing RX medication and counseling patients, which is free. If we do not get sufficiently get reimbursed, most pharmacies will not even be around when payors decide to provide Medication Therapy Management (MTM) reimbursement to pharmacist providers. Pilot projects are years away in getting data and agreement that pharmacist's provide valuable services for patients and help assure their medications will be safe, effective, and cost effective. In both hospital and retail settings, pharmacists have significant value to patients and other health care providers. If the current reimbursement strategy continues, the only pharmacies left will be the big box retailers and mail order. Patient access to pharmacists will be much more limited, and patients will have a much less effective outcome following their medication use. It is important to remember that medications are not a commodity like groceries. Medications are powerful and can do a lot of good, or they can do a lot of bad. Pharmacists are a key resource to the public and to other health care professionals in assuring the appropriate use of medications for the patient. We can easily show annual savings in health care costs for patients that exceeds every pharmacist's annual salary. Physicians and nurses rely on pharmacists every day to assure the right thing happens regarding medication. So until pharmacy reimbursement, either through dispensing, or through patient counseling (MTM) when it is in place, you cannot expect good results if you beat up on pharmacies until they are forced to close. Please come up with a better plan. Note that the primary reason drug prices are high are due to pharmaceutical companies and the lack of an effective negotiation to achieve better pricing of pharmaceuticals. Targeting the local pharmacy is missing the mark completely. Pharmacists regularly do what they can to help patients find ways to save money on their medications. Most people who visit their local pharmacy already know that. Like many pharmacists, I have enjoyed my role in serving patients and helping them use medications appropriately for better health. We are there because we enjoy helping people. The reimbursement needed to keep the pharmacy doors open is our only key issue. Please make the changes needed by targeting the drug companies and insurance companies....those that are only business-focused. Right now there is too much focus on decreasing reimbursement to health care providers! You are very welcome to contact me if you wish. Joel Amundson 763/559-0974

Submitter : Mr. Kevin Hartman
Organization : Nashville Pharmacy Services, LLC
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-628-Attach-1.RTF

Submitter : Mr. Mark Lowry
Organization : Lineville Clinic Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

I have owned my own pharmacy for 7 years, my wife & I invested several thousand \$ to do this and ever since we bought this pharmacy we have seen our business gross increase greatly but due to 3rd party insurance and fed and state medicaid and medicare we have literally almost gone broke. We cannot take any cuts in reimbursement at all. Please do not lower our reimbursements.

GENERAL

GENERAL

Please do not lower the retail pharmacy's reimbursements by lowering the cost factor of the reimbursement. My profit is shrinking daily and if you pass this lowering of the amp then most all retail pharmacies will be forced to close. I have over \$300 thousand dollars invested and can't hardly pay the bills. Do not ruin this business as small business is what made this country great.

Submitter : Mr. Michael Smathers
Organization : SCPA, and Return Solutions, Inc
Category : Drug Industry

Date: 02/15/2007

Issue Areas/Comments

Background

Background

Servicing pharmacies in the Southeast since 1979 in the service sector.

GENERAL

GENERAL

I have been working with pharmacies in the Southeast, in particular South Carolina, since 1979. Over the past 7 to 8 years, I have unfortunately seen many community pharmacies either being bought out or closed because of the continued lack of reimbursement for their time, effort, education, investment in the community, and having to compete in an unlevel field of business. These men and women daily tell me they don't know how long they can hold on because of lack of profits and continued cuts in reimbursements.

It's a sad day when I tell these professional pharmacists that "it can't get any worse", and then it does. Why is it that each time there is a program to supposedly save the consumer on the price of their prescriptions, it is always the independant pharmacists who have to pay for it? Where is the free enterprise?

Submitter : Mr. Lemuel Boyett
Organization : Family Health Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

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

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

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

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

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

Submitter : Mr. Fred Calcaterra

Date: 02/15/2007

Organization : Family Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I operate an independent pharmacy in Southern Illinois and struggle to care for Medicaid and Medicare patients. The pricing that we are subjected to is not sufficient to give quality prescription service. Many patients need delivery, which is a huge expense for use. Our electric utility is Ameren CIPS and they have recently been allowed to increase rates up to 100%. How are we to receive lower rates and stay profitable? Also in Illinois we have had a minimum wage law that increased wages to \$7.50 an hour. I cannot continue to have expenses increase and not be able to increase my prices. How do you suppose I can continue or do you not want individuals who are small business owners to continue to have employees and be the "Backbone of America!" Please do not allow the Deficit Reduction Act pertaining to the Medicaid program to happen.

Sincerely,
Fred Calcaterra

Submitter : Mr. Dave Campana
Organization : Alaska Department of Health and Social Service
Category : State Government

Date: 02/15/2007

Issue Areas/Comments

Background

Background

Comments on the CMS-2238-P.

GENERAL

GENERAL

See Attachment

CMS-2238-P-633-Attach-1.DOC

Submitter : Dr. Blake Dunlap
Organization : Plateau DrugCenter
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-634-Attach-1.DOC

Submitter : Dr. Derek Quinn
Organization : Westlake Drug, Inc.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

The proposed reimbursement system associated with this regulation is one of many options to control the cost the Medicaid program. Two concerns, however, present themselves readily with this regulation. First, regardless of the basis for reimbursement, pharmacists must be fully reimbursed for the cost of the drug to their pharmacy as well as for the overhead and professional service associated with dispensing the prescription. This regulation does not have a provision to ensure that pharmacists are at least reimbursed for the acquisition cost of the drug and for the professional service provided. Second, generic reimbursement has always included an incentive to use generic drugs by giving a higher percentage margin than brand name reimbursement. This incentive contributes to an overall lower healthcare cost through the use of low cost generic drugs. Without this incentive and with reimbursements being potentially less than acquisition cost, the number of providers choosing not to accept Medicaid reimbursement will begin to skyrocket and leave patients without access to their prescription drugs.

First, please consider the addition of a minimum reimbursement mandate that guarantees coverage of both the acquisition cost as well as the professional service being provided. Second, require the use of therapeutic alternatives when an alternate product in the same class has a generic available and in this way control the use of expensive brand-name medications.

Respectfully submitted,

Derek J. Quinn, Pharm.D., R.Ph.
Pharmacist

Westlake Drug, Inc.
8822 Portage Road
Portage, MI 49002
269.327.3049
www.westlakedrug.com

Submitter : Dr. Blake Dunlap
Organization : Scott County Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-636-Attach-1.DOC

Submitter : Dr. Mike Baker
Organization : Scott County Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-637-Attach-1.DOC

Submitter : David Hueter
Organization : David Hueter
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-638-Attach-1.PDF

Submitter : Mrs. Wanda Dunlap
Organization : Scott County Pharmacy
Category : Individual

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-639-Attach-1.DOC

Submitter : William Arrington
Organization : University of Tennessee Memphis
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-640-Attach-1.DOC

Submitter : Mr. William Holt

Date: 02/15/2007

Organization : Jones Drug

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

You will drive the smaller independent pharmacies out of business. This is a small store in a small elderly town. There is not a larger store for 25 miles in any direction. The nations elderly will suffer from this!!!

Submitter : Ms. Paula Gianino
Organization : Planned Parenthood of the St. Louis Region
Category : Health Care Provider/Association

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

Regarding File Code CMS-2238

Dear CMS Administrator,

I am the CEO of Planned Parenthood of the St. Louis Region (PPSLR) and Reproductive Health Services (RHS) of PPSLR in St. Louis Missouri. We are a 75 year old non profit health care organization that provides gynecologic and reproductive medical services to over 34,000 women, men and teens each year.

Two thirds or more of our patients are poor, with no insurance, living at or below 200% of the federal poverty level. We operate six family planning centers and one fully licensed ambulatory surgical center; in all of our locations we provide various medications, the majority medications dispensed are oral contraceptives. All of our locations sell and/or dispense for free medications at far below local retail pharmacy rates; retail pricing is beyond the reach for the super majority of our patients.

All of our centers operate on a sliding fee scale in order to serve those in need; we participate in Medicaid and other sources of funding to subsidize the comprehensive care we provide. These sources of funding do not fully cover the costs for all patients.

In some of the counties where our facilities are located, we are the only provider of services on a sliding fee schedule, or without other restrictions that cause barriers for our clients. We provide approximately \$150,000 a year in charity care at RHS, our surgical center.

Our ability to serve our clients, especially at our centers which do not receive 318 or 340b status, is totally dependant upon our ability to continue to purchase pharmaceuticals at nominal pricing, from willing companies. Without nominal pricing, we will no longer be able to purchase and provide low cost contraception to our patients. This will have a dramatic impact on their ability to access contraception, which will lead to further unintended pregnancies, increased numbers of children, increased abortions, increased human, financial and social costs to the patient, our community and society.

We know that we save taxpayers close to \$4.00 for every dollar we allocate for family planning services--multi billions of dollars are saved. And nominally priced pharmaceuticals are the foundation of the success of family planning providers in non Title X or 340b or 318 entities.

We have just learned as of 2/14/07 that two of our four 340b registered health centers may lose this status within the next two months when our Title X contracts are renewed. This is devastating news; we have not even completed an impact analysis, while we await clarification and final decision. This is a real and perfect example of why nominal pricing is so critical and of why public health entities such as ours--those dedicated to serving impoverished and underserved populations--are in such tenuous/vulnerable states given this dynamic regulatory environment.

We are in desperate need for stability in these regulatory areas so that we can plan, serve, and even expand services to more individuals in need. We are the safety net providers for our community and for the country, all of us are needed because the numbers of individuals grow each year.

I urge CMS to use its authority to authorize "safety net providers" for eligibility for nominal pricing. We are the front line providers, the non profit entities, such as PPSLR and RHS, whose mission it is to serve low income and uninsured women, men and teens, and who provide services on a sliding scale.

The future of four of our current family planning centers, and our surgical center may be dependent upon nominal priced pharmaceuticals; this will have an impact on over 26,000 patients in our region.

Respectfully submitted,

Paula M. Gianino
President and CEO
Planned Parenthood of the St. Louis Region and
St. Louis, MO
RHS of PPSLR

Submitter : Dr. Frank Fariello

Date: 02/15/2007

Organization : Dr. Frank Fariello

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

a few major issues with the AMP (average manufacturer price) rule.

1. pharmacy acquisition costs for multiple source generic medications are not covered in the formula for AMP based Federal Upper Limits.
2. Average Manufacturer Price was never intended to serve as a basis for reimbursement, in order for AMP to be used it must be redefined to reflect the ACTUAL COST PAID BY RETAIL PHARMACY (not PBMS!!!!)

to redefine (AMP) 3 things must happen

1. all rebates and price concessions made by manufactures which are not available to retail pharmacy MUST BE EXCLUDED!!!!!!
2. exclude all mail order facilities and PBM pricing from AMP calculations (mail order facilities and PBMs are extended special prices from manufacturers and they ARE NOT PUBLICLY ACCESSIBLE IN THE SAME WAY THAT RETAIL PHARMACIES ARE PUBLICLY ACCESSIBLE
3. the reporting of AMP at the NDC number level to ensure accuracy

Submitter : Mr. Bob Dufour
Organization : Wal-Mart Stores, Inc.
Category : Private Industry

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mrs. Kim Custer
Organization : Planned Parenthood of North East PA
Category : Other Health Care Provider

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

While we, Planned Parenthood of North East Pennsylvania, are not an affected provider, we serve the same patients. We are a safety net provider, serving 37,000 patients annually with low-to-no cost birth control and reproductive exams. The low-income, uninsured and underinsured women we serve would have no other access to birth control, if they were not able to receive them from an agency such as this at little to no cost. Although we currently receive the funding that allows us to provide contraception at a low cost, there is no guarantee that we will not be affected in the future. Therefore we ask you to create a designation that protects all safety net providers so we may ensure all women are treated and served with dignity.

Submitter : Mrs. keisha brown
Organization : Bergen Point Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

WE, AS AN INDEPENDENT PHARMACY, ARE OPPOSED TO THIS PROPOSED RULING BECAUSE THERE ARE MANY THINGS THAT DOESNT MAKE SENSE FOR BUSINESS, MUCH LESS PATIENT CARE. FIRST, THE FORMULA FOR AMP(AVERAGE MANUFACTURER PRICE) BASED FULS(FEDERAL UPPER LIMITS)IN THE PROPOSED RULE WILL NOT COVER ACQUISITION COSTS FOR MULTIPLE SOURCE GENERIC MEDS.(IF OUR COSTS CAN'T BE COVERED WE CANNOT SERVE PATIENT AND WITHOUT SUFFICIENT REIMBURSEMENT WE CANNOT PAY OUR EMPLOYEES MUCH LESS LIVE!!!) SECONDLY, AMP WAS NEVER INTENDED TO SERVE AS A BASIS FOR REIMBURSEMENT. THIRDLY, AMP MUST REFLECT ACTUAL COST PAID BY RETAIL PHARMACY TO BE AN APPROPRIATE BENCHMARK. THIS ACCOMPLISH THIS ONE MUST EXCLUDE ALL REBATES AND PRICE CONCESSIONS MADE BY MANUFACTURERS WHICH ARE NOT AVAILABALE TO RETAIL PHARMACY. ONE MUST EXCLUDE ALL MAIL ORDER FACILITIES AND PBM PRICING FROM AMP CALCUATION. (MAIL ORDER FACILITIES AND PBMS ARE EXTENEDED SPECIAL PRICES FROM MANUFACTURERS AND THEY ARE NOT PUBICLY ACCESSIBLE IN THE WAY THAT BRICK AND MORTAR PHARMACIES ARE PUBLICALLY ACCESSIBLE.) ONE MUST ALSO REPORT AMP AT THE 11 DIGIT NDC LEVEL TO ENSURE ACCURACY.

BOTTOM LINE USING AMP IS NOT REALISTIC FOR RETAIL PHARMACIES BECAUSE WE DONT BUY AT AMP. WE DONT BUY DIRECTLY FROM THE MANUFACTURERS SO WE DONT SEE REBATES AND PRICE CONCESSIONS. THE WHOLESALERS, MAIL ORDER HOUSES, AND PBMS SEE THESE BREAKS IN PRICE. WE ONLY SEE WHAT THE WHOLESALERS WANT TO CHARGE US AFTER THEY HAVE MARKED UP THERE LOW COST. SO IT WOULD BE AN INJUSTICE TO RETAIL PHARMACIES TO IMPOSE SUCH A RULE AND ESSENTIALLY PENALIZE US FOR DOING BUSINESS AS USUAL. WE WILL NOT BE ABLE TO PAY OUR BILLS WITH PAYMENTS FROM MEDICAID, OR ANYONE FOR THAT MATTER, GIVING US BELOW COST WITH A EXTREMELY LOW REIMBURSEMENT. THEREFORE NOT BEING ABLE TO SERVE OUR MUTUAL PATIENTS.

Submitter :

Date: 02/15/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Center for Medicare and Medicaid Services

Attn: CMS 2238-P Mail Stop C4-26-05

7500 Security Blvd

Baltimore, MD 21244-1850

Subject: Medicaid Program: Prescription Drugs: AMP regulation

CMS 2238-P RIN 0938-AO20

I am pleased to submit the following comments to the Centers for Medicaid and Medicare 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.

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 most Medicaid patients have their prescriptions filled. PBMs and mail order pharmacies do not dispense prescriptions to the general public.

2. AMP should reflect prices paid by retail pharmacies, without including rebates , concessions to PBMs and mail order pharmacies.

3. Including Medicaid data in AMP calculation does not recognize that Medicaid pricing is heavily regulated by state and federal governments.

4. By allowing Manufacturer to report date used for the calculation of the AMP will create a template for market manipulation and fraud, due to the increased risk involved in both price fluctuations and market manipulation due to timing of manufacturer reporting and the extended ability to revise reported data under this proposed structure.

There ought to be a trigger mechanism to address severe price fluctuations by CMS.

5. We believe that CMS should use the 11 digit AMP value for the most commonly dispensed package size by retail pharmacies to calculate 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 regulation 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 appreciate your consideration of the above comments and ask that you please contact us with any questions.

Sincerely,

Kafi Agboola

cc: Rep Albert Wynn

CMS-2238-P-648

Submitter : William Brown
Organization : W.R.B. Enterprises, Inc.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : William Brown
Organization : S.S. Brown Enterprises, LLC
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-649-Attach-1.DOC

Submitter : William Brown
Organization : W.R.B. Enterprises, Inc.
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-650-Attach-1.DOC

Submitter : Rose Baran
Organization : Rose Baran
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-651-Attach-1.DOC

Submitter : Mr. Joseph Roney
Organization : New Jersey Pharmacists Association
Category : Health Care Provider/Association

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-652-Attach-1.DOC

Submitter : Mr. Matthew Leonard

Date: 02/15/2007

Organization : CVS/pharmacy Inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-653-Attach-1.PDF

Submitter : Mr. GLENN KOSIROG
Organization : KOSIROG REXALL PHARMACY
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

Background

Background

INDEPENDENT PHARMACY

Collection of Information Requirements

Collection of Information Requirements

CMS-2238-P: IMPLEMENTING THE MEDICAL DRUG REBATE PROGRAM PROVISIONS OF THE DEFICIT REDUCTION ACT OF 2005

GENERAL

GENERAL

I am clearly against the proposed regulation of the Deficit Reduction Act, as it will have a devastating impact on our business. No independent pharmacy can stay in operation while experiencing a 36% loss on each transaction. Especially our business which is located in a low income area and is mostly dependent on income from Medicaid.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

CMS.HHS.GOV WEBSITE

Response to Comments

Response to Comments

devastating

Submitter : Mr. NICK HOLLAND
Organization : JONES DRUG STORE
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

WE ARE LOCATED IN A RURAL AREA SOME 20 TO 25 MILES FROM ANY MAJOR TOWN.MANY PATIENTS ARE POOR..MANY LACK TRANSPORTATION TO OTHER TOWNS FOR PHARMACY SERVICES.IF THE PROPOSED RULE (CMS-2238-P)REGARDING REIMBURSEMENT TO PHARMACIES IS APPROVED THE NEEDY WILL SUFFER BECAUSE WE'LL BE UNABLE TO FILL MEDICAID PRESCRIPTIONS OR WILL CEASE TO EXIST.

Submitter : Mr. Bradford Sturgis
Organization : College City Drug
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-656-Attach-1.TXT

Submitter : Mr. Anthony Warford
Organization : Corner Drug Store of Sturgis
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mr. Tom Frazer
Organization : Sturgis Pharmacy
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-658-Attach-1.DOC

Submitter : Mr. Tony Warford
Organization : Corner Drug Store of Sturgis, LLC
Category : Pharmacist

Date: 02/15/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-659-Attach-1.DOC