

Submitter : Mr. Bill Brewster
Organization : Bradford Drug Store
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

I own an independent Pharmacy in a rural area of Georgia and have served this area for 18 years. I am concerned that proposed cuts in Medicaid will adversely affect my business and my ability to remain as a provider for Medicaid recipients in my area. The current proposed basis for determining my cost for generic drugs, average manufacturer's price, would result in a reimbursement far below my acquisition cost and therefore a negative profit on each generic prescription I fill. I ask that this method of evaluating my generic drug cost be redefined in a manner that more closely reflects my true cost of goods. My wholesaler is greatly concerned about the future of retail pharmacy in general, independent and chain pharmacies, if this AMP valuation is used. They know my true cost.

Thank You,

Bill Brewster

Submitter : Mr. Travis Fleming
Organization : University of Tennessee College of Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment.

CMS-2238-P-1001-Attach-1.DOC

Submitter : Mr. Thomas Smith
Organization : Geritom Medical Inc
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

February 19, 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 owner located in Bloomington Minnesota. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

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

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

AMP should reflect prices paid by retail pharmacies. Including these elements is counter to Congressional intent and would result in FULs that are lower than a retail pharmacy's acquisition cost.

3. Removal of Medicaid Data

Including these data elements in the calculation of AMP does not recognize that Medicaid pricing is heavily regulated by the state and federal governments. The inclusion of Medicaid data more likely than not would create a circular loop negating the validity of AMP.

4. Manufacturer Data Reporting for Price Determination Address Market Lag

The risk of price fluctuations 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 Minnesota Pharmacists Association proposes a trigger mechanism whereby severe price fluctuations are promptly addressed by CMS. Furthermore, the Association comments on the lack of clarity on claw back from manufacturer reporting error.

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

We believe that CMS should use the 11-digit AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. 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 submitted by the Minnesota Pharmacists Association regarding this proposed regulation. I appreciate your consideration of these comments and ask that you please contact us with any questions.

Sincerely,

Thomas D Smith

cc. Members of Congress
Senator Klobachar
Senator Coleman
Rep. Ramstead
Rep. Bachman

Submitter : Ms. Eric Hamik
Organization : Registered Pharmacist
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

Background

Background

I have worked in retail pharmacy for over 15 years. My patient include people from all areas of our community. I work in a town of 29,000 people.

GENERAL

GENERAL

I feel that this would be detrimental to pharmacy. The only pharmacies that could operate with this kind of reimbursements would be the Wal-Marts of the country because they could make up for the loses in other areas.

Pharmacy has always made their fees from a margin of cost of goods not a professional fee. This fee has been built into the cost of medication when purchased. This has allowed us to be very accessible to the patients and has worked great. John Doe can call a pharmacy and get unheard of medical advice without ever paying a fee. As a matter of fact the majority of the patients we talk to have not been able to access their doctors or other health care provider and we were their only hope.

If you implement the AMP structure it will take away our only area to collect reimbursement for all of our services. The existing dispensing fees are set to coincide with our purchasing margins NOT TO BE OUR SOLE SOURCE OF INCOME!!!!

I feel that if you go ahead with the current AMP plan without a substantial fee increase that we will see a crisis situation for people trying to get their medications filled. If you remember the medicare fiasco in January of 2006, that would be just the tip of the iceberg compared to this. And by the way, Who was the ones there taking care of all the problems with that??? You guess it the community pharmacists :)

Thank you for listening,
Eric Hamik R.P.

Submitter : Dr. Robin M. Henry
Organization : Walgreens Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mira Signer
Organization : Planned Parenthood Advocates of Virginia
Category : Health Care Provider/Association

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-1005-Attach-1.DOC

Submitter : Mrs. Anna Long
Organization : UT College of Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Mr. Christopher Decker

Date: 02/19/2007

Organization : Pharmacy Society of Wisconsin

Category : Pharmacist

Issue Areas/Comments

Background

Background

comments re CMS 2238-P

GENERAL

GENERAL

comment attached

CMS-2238-P-1007-Attach-1.PDF

Submitter : Mrs. Connie Woodburn
Organization : Cardinal Health
Category : Drug Industry

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-2238-P-1008-Attach-1.DOC

Submitter : Ms. Julie Johnson
Organization : Minnesota Pharmacists Association
Category : Health Care Provider/Association
Issue Areas/Comments

Date: 02/19/2007

GENERAL

GENERAL

See attachment

CMS-2238-P-1009-Attach-1.DOC

Submitter : Mr. J Leon Claywell
Organization : Kentucky Pharmacists Association
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

Submitter : Robert Salmon
Organization : Southern Discount Drugs
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1011-Attach-1.DOC

Submitter : Dr. Katharine Hall
Organization : Regional Medical Center at Memphis
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

Regional Medical Center at Memphis (The MED) is a 335 bed hospital located in Memphis, TN, that qualifies as a disproportionate share hospital (DSH) under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Our electronic billing system is not configured to substitute NDC numbers as identifiers for clinic administered drugs. The manual coding of NDC numbers would come at the expense of staff resources and would disrupt administrative operations. Assuming CMS' estimate of 15 seconds per claim is accurate, when you multiply this by 192,000 doses per year, you are adding 800 hours per year for this administrative activity. But... in my opinion, CMS dramatically underestimates the time required to manually code NDC numbers and the time required would be much greater than this.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. If our hospital were to lose all 340B savings on clinic administered outpatient drugs it would affect us by \$135,000 per year. If clinic administered outpatient drugs include Emergency Department and Ambulatory Surgery medications, our drug expense would increase by \$420,000 per year.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price (AMP), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. To give you some idea of the amount, for the top 10 drugs dispensed by our retail pharmacy, the annual drug expense would increase by \$395,000 if we were unable to use 340B pricing. In regard to nominal contracts, with Nexium? IV alone, we may increase expenditures by \$20,000 per year.

The 340B program has helped safety net hospitals. Even with these savings available, our financial struggles are profound. The proposed regulations would be harmful to the MED.

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

Submitter : Ms. David Ridout

Date: 02/19/2007

Organization : SaintMary's Family Pharmacy-Wege Center

Category : Pharmacist

Issue Areas/Comments

Background

Background

I manage an outpatient pharmacy for Saint Mary's Healthcare which services many specialties as well as indigent programs for the hospital and community, as well as services as a neighborhood pharmacy. We are a major provider of prescriptions for the downtown Grand Rapids MI area which include homeless, HIV and high psychiatric utilizers. We are very concerned about the proposed AMP calculation for the prescription benefit. 95% our our business in third party and of that 95%, 50% is in Medicare and Medicaid programs.

Collection of Information

Requirements

Collection of Information Requirements

Having managed hospital, retail, and closed door pharmacies which include staff model HMO and hospice, I know there is considerable differences in manufacturer pricing. As a matter of fact, the differences are huge. When you factor in mail-order with their rebates from manufacturers based on market share contracts, there is no way we will be able to continue to serve our community if CMS utilizes their cost schedules in it's proposed AMP model. You will put every small pharmacy out of business. Please reconsider what you have proposed to do and ask those organizations which represent the authorities on drug pricing what model is best. You should not be allowed to make these decisions in a vacuum.

GENERAL

GENERAL

My comments are covered in the "Provisions of the Proposed Regulations.

Submitter :

Date: 02/19/2007

Organization :

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

As a practicing pharmacist in a retail independent pharmacy this new potential ruling CMS-2238-P is going to put me and the rest of my employees out of business. How can you expect a small business to dispense these medications at a loss and to continue to stay in business. Maybe the large chains can make up the difference in other store items or combined stores can help out losing stores, but one independent pharmacy can only help out itself and the patients we service.

Please reject this proposal and come up with a fair proposal that we all can live with.

Thank you for this opportunity to speak.

Submitter : Dr. Ray Marcrom
Organization : Marcrom's Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1015-Attach-1.DOC

Submitter : Nicky Otts
Organization : ReCept Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-2238-P-1016-Attach-1.DOC

Submitter : Mr. RICKY GUIDRY, RPH
Organization : LOUISIANA INDEPENDENT PHARMACIES ASSOCIATION
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

Background

Background

I own and operate a small independent pharmacy in a rural area in Louisiana and am very concerned about my existence with the AMP definition.

Collection of Information Requirements

Collection of Information Requirements

If the proposed regulations stand as they are presented, my pharmacy will probably go out of business.

GENERAL

GENERAL

If I am forced to be reimbursed at below the cost of a drug on one side of the equation, it would only be fair that I receive an adequate dispensing fee which would include a reasonable profit. I know that pharmacy is a complicated business and does not follow any other business known to man. In my store 90% of revenue is from prescription drugs and 10% is from gifts or over-the-counter medications. Of the 90% of revenue from prescription drugs, 85% is reimbursed by 3rd parties including Medicare Part D and Medicaid. Currently, we have no negotiating rights with any 3rd party payor. The contracts that we receive are take it or leave it contracts! This is why we are asking Congress to give us the power to come together as one to negotiate these reimbursement contracts. My biggest concern is when 50% of rural pharmacies are forced to close because of the inability to make reasonable profit, Medicare and Medicaid people, usually on fixed incomes will be forced to travel 30 to 60 miles round trip to get their prescriptions filled. With the cost of gasoline at about \$2.15 a gallon, this will be a hardship and the poorest of the poor in this country. If the federal government can live with this, one could ask the question if they have a heart or a soul.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

I find it very unfair to target cuts on the backs of pharmacies when drug manufacturers and pharmacy benefit managers (PBM's) have not been mentioned on being cut like we will if the current rule stays the way it is!

Regulatory Impact Analysis

Regulatory Impact Analysis

It seems that everyone involved in this law and regulation are treating life saving chemical (medications) like it is some kind of commodity! This is not the case. These prescription drugs are not like corn or cotton. My point being that everyone who requires prescription drugs should pay the same price regardless if they buy it from a local pharmacy or a mail order pharmacy. We need to even the playing field when it comes to the cost of a drug. Quantity discounts in the different classes of pharmacy trade should not exist.

Response to Comments

Response to Comments

It seems to me that any regulatory agency dealing with health care in this country should look at the bottom purpose which is to deliver medications to the people who need them and to make sure that they understand side effects, interactions, missing doses and allergic reactions. This is the job that pharmacists do daily.

Submitter : Mrs. Christina Riddle

Date: 02/19/2007

Organization : Marcrom's Pharmacy

Category : Other Technician

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1018-Attach-1.DOC

Submitter : Mr. Michael Keogh
Organization : Independent Pharmaceutical Consultant
Category : Individual

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1019-Attach-1.DOC

Submitter : Dr. Tom Marcrom
Organization : Marcrom's Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1020-Attach-1.DOC

Submitter : Mrs. Sheila Jones
Organization : Marcrom's Pharmacy
Category : Other Technician

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1021-Attach-1.DOC

Submitter : Dr. Kim Roberts
Organization : Marcrom's Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1022-Attach-1.DOC

Submitter : Dr. Richard Randolph
Organization : Marcrom's Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1023-Attach-1.DOC

CMS-2238-P-1024

Submitter : Mrs. Susan Helms
Organization : Marcrom's Pharmacy
Category : Other Technician

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1024-Attach-1.DOC

February 19, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacy technician at Marcrom's Pharmacy, located at 1277 McArthur St., Manchester, TN 37355. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I work, where the majority of our business comes from prescription drugs. What the "other sales" in the pharmacy are should

not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Susan Helms

4457 Murfreesboro Highway
Manchester, TN 37355

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Lincoln Davis

Submitter : Mr. Jack Hutson
Organization : Rhode Island Pharmacists Association
Category : Association

Date: 02/19/2007

Issue Areas/Comments

Background

Background

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

Summary

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

CMS-2238-P-1025-Attach-1.DOC



Rhode Island Pharmacists Association

1643 Warwick Avenue, PMB 113, Warwick, RI 02889
737-2600 Fax: 737-0959

March 3, 2007

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

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

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

Summary

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

§447.504 Determination of AMP

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

Defining Retail Pharmacy Class of Trade

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

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

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

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

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

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

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

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

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

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

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers - the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health

plans and not the pharmacies.”¹ Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that “AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs.”² The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

Market Manipulation

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

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

¹ Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.

² GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

³ §447.510(d)(2)

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

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

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

Record Keeping

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

Additional Comments

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

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

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

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

Sincerely,



Jack Hutson
Executive Director

cc. Members of Congress in Rhode Island

CMS-2238-P-1026

Submitter : Dr. Melissa Stanley
Organization : Marcrom's Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1026-Attach-1.DOC

February 19, 2007

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

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

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist of Marcrom's Pharmacy, a community retail pharmacy located at 1277 McArthur St, Manchester, TN 37355. We are a major provider of pharmacy services in the community, and your consideration of these comments is essential.

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

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

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

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

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

The CMS claims that almost all stores sell goods other than prescription drugs, and that overall sales average more than twice as much as prescription drug sales. This is not the case in the pharmacy in which I work, where the majority of our business comes from prescription drugs. What the "other sales" in the pharmacy are should

not be used in any decision regarding determination of the FULs. FUL pricing should be based solely on the prices retail pharmacies pay for drugs.

3. Removal of Medicaid Data

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

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

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

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

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

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

Sincerely,

Melissa Stanley
232 Dorsey Ave.
McMinnville, TN 37110

cc: Senator Lamar Alexander
Senator Bob Corker
Representative Lincoln Davis

CMS-2238-P-1027

Submitter : Dr. Christy Saunders

Date: 02/19/2007

Organization : Thomas Drug Store

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1027-Attach-1.TXT

#1027

February 19, 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. Thomas Drug Store is located in Wilson, NC. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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,

Christy P. Saunders, Thomas Drug Store

CMS-2238-P-1028

Submitter : Mrs. Karen Rose
Organization : Thomas Drug Store & HME
Category : Nurse
Issue Areas/Comments

Date: 02/19/2007

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1028-Attach-1.TXT

February 19, 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-A020

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. Thomas Drug Store is located in Wilson, NC. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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 - (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,

Karen Rose, RN, Thomas Drug Store & HME

Submitter : Mr. Patricio Gonzales

Date: 02/19/2007

Organization : Planned Parenthood Assoc.Hidalgo Co. Tx Inc.

Category : Health Care Provider/Association

Issue Areas/Comments

Background

Background

Planned Parenthood Association of Hidalgo County is a 501 c (3) health care provider for the 43 years. We are situated on the Texas Mexico border and serve two of the most poorest counties in the country Hidalgo and Starr Counties. Our poverty rates range from 41% to over 50% in Hidalgo and Starr Counties respectively as compared the national average of 13.3%. The total population between both counties is approximately 720,000 residents. We serve approximately 17,000 poor uninsured women and men annually in all of our 10 medical centers. The average income for these individuals is less than \$14,000. They depend on the preventive care and birth control we provide them so that they can work and provide for their families. Our population is so dependent on the care and discounted pricing offered through the 340B program for the past 43 years. We are their only safety net provider, medical home base and source of referrals for primary care and medications.

Collection of Information Requirements

Collection of Information Requirements

The proposed rules issued at the end of December 2006 through the Deficit Reduction Act(DRA) does not extend the best price exception to all of our centers. Our clinics and clients depend on this discounted pricing for their birth control and other medications. These proposed changes will dramatically impair our sites to offer preventive health care. Without these discounted prices our centers would not be able to continue operations as a safety net provider for poor and uninsured individuals. My agency requests that these changes not be implemented without a correction to the DRA that will allow medical centers that provide preventive care to poor women and men. This technical change to the DRA will not cost the government any additional charges or funding.

Submitter : Ms. Jonna Gardner
Organization : Thomas Drug Store & HME
Category : Other Technician

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1030-Attach-1.TXT

#1030

February 19, 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-A020

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. Thomas Drug Store is located in Wilson, NC. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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 - (i) Creates consistency in the Regulation
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 - (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,

Jonna Gardner, Thomas Drug Store & HME

CMS-2238-P-1031

Submitter : Mrs. Stacey Boone
Organization : Thomas Drug Store
Category : Other Technician

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1031-Attach-1.TXT

February 19, 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. Thomas Drug Store is located in Wilson, NC. We are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

Stacy Boone, Thomas Drug Store & HME

CMS-2238-P-1032

Submitter : Mr. R. David Yost
Organization : AmerisourceBergen Corporation
Category : Health Care Industry

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1032-Attach-1.DOC

the involved parties. Furthermore, administrative fees – a term typically used to describe fees manufacturers pay to GPOs and PBMs to support the contracting functions those entities perform on behalf of numerous buyers or health plans – meet the definition of a *bona fide* service fee under a variety of circumstances consistent with CMS' preamble guidance published with the 2007 Physician Fee Schedule Rule. Therefore, we recommend that CMS clarify, either in § 447.504(i)(1) itself or by adding a new paragraph to the subsection, that all fees that manufacturers pay to customers or third parties meeting the definition of a *bona fide* service fee are to be excluded from the calculation of AMP.

Customary Prompt Pay Discounts

AmerisourceBergen applauds CMS' decision to include language in the Proposed Rule expressly instructing manufacturers to exclude Customary Prompt Pay Discounts ("CPPDs") given to wholesalers when determining AMP. We also support the definition CMS provided for the term "customary prompt pay discount" in an effort to clarify the types of price concessions that should not be included in the AMP calculation. We are particularly pleased that the agency did not incorporate any specific payment amounts or time terms in the definition. Although we anticipate that some manufacturers may ask CMS to further define the various aspects of CPPDs, we encourage CMS to maintain the proposed definition in the Final Rule because this approach allows manufacturers and wholesalers the necessary flexibility to negotiate payment terms, including CPPDs, based on their particular situations and the commercial conditions at the time of the particular transaction. We believe that this flexibility also will promote competition in the healthcare distribution business, which ultimately will lower distribution costs.

Also, in order to avoid potential confusion, AmerisourceBergen requests that CMS clarify that its requirement that cash discounts be deducted from the calculation of AMP and Best Price *does not* include CPPDs.

Retail Pharmacy Class of Trade

AmerisourceBergen agrees with CMS that in order to qualify as a member of the retail pharmacy class of trade, an entity must provide public access. For that reason, we disagree with including certain entities listed in 42 CFR § 447.504(e) as part of the retail pharmacy class of trade. Specifically, mail-order pharmacies, PBMs, and hospital pharmacies should be excluded from the definition of retail class of trade. In addition to these entities, AmerisourceBergen also believes that CMS should clarify that sales of drugs to physicians for administration in their offices should not be included in the retail pharmacy class of trade for the purpose of calculating AMP.

We object to the inclusion of PBMs in the retail pharmacy class of trade because PBMs contract with retail pharmacies to offer pharmacy services at prearranged prices to enrollees in the health plans the PBMs represent. They negotiate insurance payment terms, which is significantly different from arranging for the purchases of drugs that pharmacies make from their manufacturer and wholesaler vendors. PBMs do not affect the net prices manufacturers are paid by wholesalers and retail pharmacies for drugs dispensed to the general public. Therefore, under the controlling statutory definition of AMP, the contract terms between manufacturers and PBMs, and any related rebate payments provided to PBMs, should not be factored into the determination of AMP.

AmerisourceBergen supports CMS' decision to exclude sales to Long-Term Care facilities ("LTC") and urges CMS to exclude sales to other entities that do not satisfy the threshold public access criterion from manufacturers' AMP calculation, including sales to mail-order pharmacies. The reason CMS gave for excluding sales to LTC pharmacies from the calculation of AMP was that those pharmacies are closed operations that serve only the residents of specific LTC facilities, not pharmacies that are open to the general public. The same is true for mail-order pharmacies, the vast majority of which are affiliated with PBMs or with health plans that administer pharmacy benefits internally. These mail-order pharmacies are not open to the general public and the services provided are more limited than those provided by community pharmacies. Access to any particular mail-order pharmacy is limited to individuals enrolled in a health plan with a mail-order option that is sponsored by the organization that operates the pharmacy or that contracts with the PBM that operates the pharmacy. In other words, mail-order pharmacies are closed operations in the same way that LTC pharmacies are closed operations.

PBM Rebates

AmerisourceBergen objects to CMS' proposal for deducting PBM rebates from the AMP calculation. CMS' proposal for deducting PBM rebates when AMP is calculated is contrary to the statutory definition of AMP at Social Security Act § 1927(k)(1) (as amended by the DRA) and to the definition of AMP in the Rebate Agreement. Both definitions say AMP is "the average price *paid to* the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade (emphasis added)." Rebates *paid by* the manufacturer to a PBM that does not buy or take possession of drugs simply do not qualify. They are not part of the price paid to the manufacturer by the pharmacies in the PBM's retail pharmacy network because those pharmacies do not share in the PBM rebates. CMS does not have the statutory authority to reinterpret the definition of AMP to focus on the net revenues realized by manufacturers instead of the net costs incurred by retail pharmacies for the drugs they dispense.

Additionally, although PBMs only collect rebates on single source drugs,² CMS' position on the handling of these rebates will have a negative impact on State Medicaid budgets. The OIG found that some manufacturers do not currently view transactions with PBMs as sales and, therefore, do not net PBM rebates out when they calculate AMP.³ It also observed that other manufacturers only include a portion of their PBM rebates in AMP.⁴ As a result, the Proposed Rule's treatment of PBM rebates will lead to lower AMPs and lower rebate payments on some single-source products. We do not have access to the data needed to estimate the total revenue reduction, but we are confident the losses will be significant since the CBO recently reported State Medicaid programs received rebates in 2003 on single source drugs that averaged 31.4% of AMP.⁵ Further, the CBO observed that the percentage of State Medicaid revenues tied to rebates on single source drugs has been trending upward.

² *Prescription Drug Pricing in the Private Sector* at p 12; *Pharmacy Benefit Managers* at 50-55.

³ *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005*, OIG (A-06-06-00063) (May 30, 2006).

⁴ *Id.*

⁵ *Payment for Prescription Drugs under Medicaid* at Table 2.

Dispensing Fee

AmerisourceBergen applauds CMS' decision to recommend that State Medicaid programs "reexamine and reevaluate the reasonableness of the dispensing fees paid as part of a pharmacy claim"⁶ if they elect to adopt AMP-driven pharmacy reimbursement formulas. We urge CMS to consider the results of a recently completed national survey of dispensing costs when it reviews proposed State Plan Amendments revising Medicaid pharmacy reimbursement formulas. Grant Thornton LLP obtained cost data from nearly half the retail pharmacy outlets in the United States for the 6-month period from March through August 2006 and determined that the mean cost of dispensing per prescription was \$10.50 and the mean cost of dispensing per pharmacy was \$12.10.⁷ For the 65 million Medicaid prescriptions included in the sample, the mean cost per prescription was \$10.51 and the mean cost per pharmacy was \$12.81. Given these cost data, it will no longer be acceptable for States to skimp on payments for dispensing services to Medicaid recipients once they take steps to trim the margins on ingredient costs that have been subsidizing Medicaid dispensing for years.

We also recommend including a few additional elements in the list of services detailed in proposed 42 CFR § 447.502 that must be considered when a dispensing fee representative of fully loaded costs is developed. We are hesitant to rely on the "[p]harmacy costs include, but are not limited to" language currently used to preface the list because of the inadequacy of dispensing fees paid by State Medicaid programs over the years. The revised definition also needs to include the time pharmacists spend entering billing information into their computer systems and communicating by telephone, fax and email with State Medicaid agencies and PBMs about coverage and billing questions. As with other third party drug programs, the Medicaid program creates an additional cost due to accounts receivables, which can have a substantial impact on a community pharmacy. More importantly, the Proposed Rule must include as an element of pharmacy costs the important health, safety and counseling services community pharmacists routinely provide – typically based on an individualized understanding of the customers' medical needs and personal preferences – to ensure that each physician's prescription leads to the best drug regimen for the patient.

Innovator Multiple Source, Multiple Source, and Single Source Drugs

The Proposed Rule also does not define "covered outpatient drug" but rather lets stand without elaboration the definition of covered outpatient drug in the Medicaid Drug Rebate Statute at Social Security Act § 1927(k)(2). That statutory definition reaches beyond drugs approved by the FDA under NDAs, BLAs, antibiotic approvals or ANDAs to over-the-counter (OTC) products that have been prescribed by a physician. To capture the full breadth of the Medicaid drug benefit, we recommend including a definition of covered outpatient drug in the Final Rule that addresses both OTC and prescription drug products. The statutory definition of covered outpatient drug also incorporates grandfathered products and drugs still undergoing the DESI review process. The Proposed Rule's definitions of single source, innovator multiple source and multiple source drugs do not, however, reach all of the products that came to market

⁶ Medicaid Drug Rebate Program Release for State Medicaid Directors No. 144 (December 2006).

⁷ *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, prepared for The Coalition for Community Pharmacy Action by Grant Thornton, LLP (January 2007), available at http://www.rxaction.org/publications/COD_Study.cfm. The cost of dispensing per pharmacy treats every pharmacy equally, regardless of prescription volume. It is higher than the cost of dispensing per prescription because high-volume, lower-cost stores are weighted more heavily in this statistic.

before 1962 and remain commercially available today. To avoid any ambiguities, AmerisourceBergen suggests CMS revise the definitions of multiple source, innovator multiple source and single source drugs to address these gaps.

Lagged Methodology

AmerisourceBergen also is concerned that the Proposed Rule does not set forth a methodology for dealing with lagged unit data or lagged discounts when monthly or quarterly AMPs are calculated. This lack of guidance is problematic because the Proposed Rule requires manufacturers to consider sales and associated price concessions extended to State Children's Health Insurance Programs ("SCHIPs") and State Pharmaceutical Assistance Programs ("SPAPs") when they determine AMP. This requirement is virtually impossible to achieve because manufacturers have no way of knowing how many units of drug were dispensed to enrollees in these programs or what their program rebate liabilities will be until they receive quarterly rebate invoices from the States. Unfortunately, our experience shows that these invoices rarely arrive prior to the stipulated deadline for filing quarterly AMP reports under the Proposed Rule. Depending on the plan, Part D rebate demands and PBM rebate demands also may arrive too late to be properly included in quarterly calculations.

Therefore, we believe that the best approach to address the inevitable delays in the receipt of data critical to AMP calculations is to include instructions for processing lagged data into the Final Rule. We strongly recommend using a 12-month rolling percentage methodology similar to that required in the ASP rule.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time also can distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, AmerisourceBergen encourages CMS to build a well-defined smoothing methodology for handling all price concessions – not just lagged concessions – and for handling lagged unit data that must be considered when AMP is determined. We believe that the methodology would operate much like the 12-month rolling percentage methodology specified for quantifying lagged discounts under the ASP rule. However, for AMP purposes, we suggest instructing manufacturers to look to the four (4) full calendar quarters before the reporting period to calculate the rolling 12-month percentage. That percentage could then be used to determine all three monthly AMPs and the quarterly AMP.

If CMS is not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates because chargebacks often relate back to sales from previous quarters. Because of the complexities involved, we request that CMS provide examples showing how the methodology should be applied in both the monthly and the quarterly context. Those examples also should take into account the proper treatment of the various types of bundled sales.

AMPs and FULs Set at 11-Digit NDC Level

AmerisourceBergen strongly disagrees with the Proposed Rule's instruction to calculate and set Federal Upper Limit ("FUL") reimbursement at the 9-digit NDC level for purposes of calculating AMP. We are concerned with the utilization of the 9-digit AMPs because this methodology would exclude tying FULs to the package sizes most frequently purchased by pharmacies.

In order to address this concern, and to ensure that the most accurate FUL reimbursement and AMP are calculated for a given product, we urge CMS to modify the Rule to require manufacturers to calculate and report AMPs at the 11-digit NDC level. The utilization of 11-digit level NDCs would permit FULs to be established based on the most commonly purchased package sizes, and this approach would be consistent with past FUL calculation practices.

AMPs and Outlier Methodology

We applaud CMS's recognition of the need to eliminate outlier AMPs from the determination of FUL. Eliminating the sale of product that is extremely short-dated or otherwise distressed avoids setting an artificially low FUL based upon prices that do not reflect true market conditions (comparable to CMS' decision to disregard AMPs for NDCs that have been terminated). To ensure that reimbursement is adequate to permit retail pharmacies to buy from reputable suppliers with sufficient supply to meet retail pharmacy demands, we would prefer to see FULs calculated using the weighted average AMP of the therapeutically equivalent products available in the market. However, if CMS decides it will not take that approach, we propose that the outlier test should incorporate market-share as a fundamental criteria in defining outliers. To that end, we support requiring manufacturers to report, along with monthly AMPs, data at the 11-digit level (as discussed above) on the volume of product sold during the period. CMS could then classify monthly AMPs associated with low market share as outliers that do not represent available prices.

Specifically, we recommend examining AMPs on a cumulative market share basis starting with the lowest reported AMP, then the next highest and so on, rejecting AMPs until a cumulative market share of 50% is reached. This approach will allow CMS to focus directly on whether a low-priced NDC is only available on a "limited basis"⁸ (rather than the indirect price-based test CMS proposed). Doing so should "ensure that a drug is nationally available at the FUL price"⁹ because it will disregard AMPs that, despite low price, were only able to capture less than half the market. If product, from one or more sources, is not available to at least 50 percent of the market, its price is not indicative of true market conditions and, being available in only limited quantity, it's not available for sale nationally. For example, if manufacturers reported monthly AMPs for five NDCs of a given drug/strength/dosage form of a multiple-source product of \$0.30, \$1.50, \$4.50, \$5, and \$5.50 with corresponding sales volumes of 100 units, 400 units, 6000 units, 3500 units, and 500 units, the first two would be classified as outliers as they represent less than a 5% market share. The FUL would be set based on the \$4.50 price because the 6,000 units added to the previous 500 units (100 + 400) would cross the 50% market share threshold. In other words, \$4.50 is the lowest price for a product that is available

⁸ 71 FR at 77188 (Dec. 22, 2006); see also proposed rule §447.514(c).

⁹ *Id.*

for sale nationally. This contrasts with an FUL of \$3.75 (250% x \$1.50) under the price-based outlier methodology described in the proposed Rule – an FUL that would not be representative of prices for half the market (and would likely result in a local pharmacy losing money on most Medicaid sales).

Definition of Wholesaler

AmerisourceBergen is concerned that the Proposed Rule defines “wholesaler” in an overly expansive fashion, including within the reach of the definition not only traditional full-service wholesalers and specialty distributors but also pharmacy chains, pharmacies, and PBMs. See 42 C.F.R. § 447.504(f). We request that this definition be revised so that it is consistent with the provisions of the Food Drug and Cosmetic Act incorporating the Prescription Drug Marketing Act (PDMA)¹⁰ and with the definitions of “wholesale distributor,”¹¹ “wholesale distribution,”¹² and “distribute”¹³ in the FDA regulations that govern prescription drug marketing. Although we believe these definitions are quite broad, they adequately and appropriately limit wholesalers to entities engaged in selling, offering to sell, delivering, or offering to deliver drugs to persons other than a consumer or patient.

We do, however, agree that warehousing pharmacy chains and warehousing mass merchant and supermarket pharmacy operations should be treated as wholesalers for purposes of calculating AMP and Best Price. They function virtually identical to traditional wholesalers and specialty distributors: they buy drugs directly from manufacturers and/or other wholesalers; consolidate orders for products from a variety of sources; and distribute the drugs to pharmacies within their chain, which resell the drugs at retail to consumers who present a prescription. Also, warehousing chains, warehousing mass merchants and supermarkets are licensed as wholesalers under State laws implementing the requirements of the PDMA.

Although we agree that the above entities should be treated as wholesalers under the Rule, we object to identifying other entities including mail-order pharmacies operated by PBMs, as wholesalers. These entities are quite different from wholesalers because they have a limited product inventory, routinely sell drugs to consumers and patients and they rarely function as or are licensed as wholesalers under applicable State laws.

We are particularly troubled by the inclusion of PBMs in the definition of wholesaler. Although many PBMs operate mail-order pharmacies, they typically function merely as an ancillary to the PBM’s primary business operation. As discussed above, we do not believe these types of entities should be classified as wholesalers.

As discussed above, we urge CMS to align that definition with the definitions of wholesale distributor, wholesale distribution, and distribute in the FDA regulations implementing the PDMA. We also suggest including a statement in the preamble to the Final Rule saying CMS has adopted those FDA definitions which are well-recognized throughout the industry.

¹⁰ P.L. 100-293.

¹¹ 21 CFR § 203.2(dd).

¹² 21 CFR § 203.2(cc).

¹³ 21 CFR § 203.2(h).

Postponing the Posting of AMPs

AmerisourceBergen urges CMS to consider delaying postings of AMPs because there are valid reasons for delay and in consideration that the delay likely will be for a reasonably short period of time. We believe a delay is appropriate in this instance because many critical issues related to ensuring the accurate calculation of AMP remain unresolved and are unlikely to be completely resolved and understood throughout the industry prior to the scheduled posting of AMPs. In the past, CMS wisely has delayed implementing programs because too many problems remained unresolved, and the agency took additional time to resolve those outstanding issues related to the program. We believe that approach may be useful in regard to the public posting of AMPs, and that the posting should be delayed until all the regulatory changes have been finalized and manufacturers have been given sufficient time to update their systems to satisfy the final reporting requirements.

Therefore, we urge CMS to delay website postings until the new AMP rule becomes effective, or at a minimum to preface any web-postings of AMP values with an introductory discussion explaining the current shortcomings of AMP as a measure of retail prices and pharmacy acquisition costs and highlighting the potential for changes in the calculation methodology underlying AMP over the next year.

Retail Survey Price

We had hoped CMS would address implementation issues related to DRA § 6001(e) in the Proposed Rule. We were looking forward to the opportunity to comment on how and from what sources data underlying RSP should be collected and how the data should be used to determine “a nationwide average of consumer purchase prices, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available)”¹⁴ since the DRA defines RSP but provides little other substantive guidance on RSP-related issues. For example, because RSP is supposed to be representative of “consumer purchase prices” at retail, we wanted to talk about how CMS and its vendor would ensure only pharmacies within the retail class of trade are surveyed. We wanted to speak to how CMS would ensure valid results by structuring surveys to include an appropriate sample size and geographic distribution. We also wanted to discuss other steps that could be taken to ensure that RSP data is true to the statutory requirement to capture the out-the-door prices pharmacies charge consumers.

We note Medicaid Drug Rebate Program Release No. 144 for State Medicaid Directors dated December 15, 2006 – a week before the Proposed Rule was published in the *Federal Register* – advises States that CMS will begin disseminating a monthly national survey of retail prices beginning in January 2007. We take that promise to mean CMS is moving forward with plans to implement DRA § 6001(e). That said, we strongly urge CMS to engage stakeholders, as soon as possible and in a meaningful way, in the development of the procedures the RSP contractor will be tasked with using when it collects, aggregates, and disseminates RSP data. Including stakeholders in the regulatory processes relating to the implementation of DRA § 6001(e) likely will allow the development of RSP policies and procedures that anticipate issues associated with data availability and adequacy, reflect a more nuanced approach to data collection and analysis, and, in the end, result in the dissemination of RSP data that is – as the

¹⁴ DRA § 6001(e) adding Social Security Act § 1927(f)(1)(A).

DRA mandates – representative of consumer purchase prices at retail for outpatient prescription drugs.

In closing AmerisourceBergen appreciates the opportunity to provide you its comments on this important Proposed Rule. We are available at your convenience to address any concerns related to these Comments, the proposed Rule, or the pharmaceutical supply chain.

Sincerely,

A handwritten signature in black ink that reads "R. David Yost". The signature is written in a cursive style with a large, stylized "Y" and "O".

R. David Yost

CMS-2238-P-1033

Submitter : Mr. Dennis Roberts

Date: 02/19/2007

Organization : The Regional Medical Center at Memphis

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1033-Attach-1.TXT

2/19/07

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

To Whom It May Concern:

On behalf of the Regional Medical Center at Memphis (The MED), I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. The Med is a 335 bed hospital located in Memphis, TN, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. In general, hospitals' electronic billing systems are not configured to substitute NDC numbers as identifiers for clinic administered drugs. The manual coding of NDC numbers comes at the expense of staff resources and disruption of administrative operations. CMS underestimates the time required to manually code these NDC numbers into the billing system.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. If our hospital were to lose all 340B savings on clinic administered outpatient drugs it would affect us by \$135,000 per year. If clinic administered outpatient drugs include Emergency Department and Ambulatory Surgery medications, our hospital would be affected by \$420,000 per year.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. For example, with Nexium® IV alone, we may increase expenditures by \$20,000 per year.

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

Sincerely,
Dennis Roberts
Pharmacist
The Regional Medical Center at Memphis

Submitter : Mr. jignesh patel
Organization : columbia pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

Background

Background

I am a pharmacist and have been working in various community pharmacies for the past 12 years.

GENERAL

GENERAL

I believe that the idea of reimbursing pharmacies based on AMP is not realistic as this doesnot reflect the actual cost to the pharmacies. This is going to be so very true for generic drugs. Also to go along with the cost of drugs there is no specifications on the reimbursement of dispensing fee which at the present is no were close to the actual cost of dispensing a prescription. The average gross profits for pharmacy after the Medicare Part D have gone down & if the AMP reimbursement is implemented I think that the community/independent pharmacies will really have a tough time being in business & the others will be paying their pharmacy overheads selling front end. I think controlling the cost of drugs could be much effective if the government controls the pricing of drugs from manufacturers, Since every year the cost of brand Drugs goes up by 15-30% on average. It would be interesting to see manufacturers cross examined for how they come up with pricing of brand drugs & how they justify the price increases then after, each year at the rate of 10-30%. I hope its not about how much influence each sector has against the survival of an entire sector. I am a 37year old pharmacist, I started an independent pharmacy in NYC 6 years back & I think with all the changes that have been implemented in the name of cost cuts, have ultimately affected the quality of service that we render & for the time to come I think the law makers want us to run pharmacy business like a factory where the primary goal will be quantity rather then quality. I hope my comments are read & thought about. Thank you for the time.

Submitter : Mr. Krishnayya Bikkina
Organization : K&C Pharmacy D/B/A Nicks Drugs
Category : Pharmacist

Date: 02/19/2007

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-1035-Attach-1.PDF

1035



K&C PHARMACY T/A NICK'S DRUGS

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VIA ELECTRONIC SUBMISSION

February 19, 2007

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

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

As an owner of an independent pharmacy store in New Jersey serve a diverse Medicaid patient population for pharmacy care needs, I am very troubled by the CMS proposed regulation referenced above that seeks to define and establish an average manufacturers' price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that my independent pharmacy can afford to continue provide Medicaid generic pharmacy prescription services to my Medicaid prescription patients without incurring unsustainable financial losses.

Below are my specific comments on and recommended changes to the proposed rule:

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

Public Access Defines Retail Pharmacy Class of Trade

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

"Retail pharmacy class of trade" definition should only include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies - a definition that currently encompasses some 55,000 retail pharmacy locations.



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

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

Treatment of Manufacturer coupons with regard to Best Price.

Inclusion of Direct-to-Patient Sales with regard to AMP.

AMP Must Differ From Best Price

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

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

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.

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

PBM price concessions reporting to CMS.

PBM Transparency Necessary to Assess Manufacturer Rebates

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



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

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

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

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

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

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

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

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

Impact on small pharmacies demonstrated by (General Accountability Office (GAO) findings

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



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

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

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

CMS Must Employ a Complete Definition on Cost to Dispense

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

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

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

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

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



K&C PHARMACY T/A NICK'S DRUGS

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In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by
 1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
 2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*
- Reporting AMP at the 11-digit NDC level to ensure accuracy.

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,

A handwritten signature in black ink, appearing to read "Krishnayya Bikkina".

Krishnayya Bikkina

CMS-2238-P-1036

Submitter : James Dunaway
Organization : Dunaway's Imperial Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1036-Attach-1.DOC

February 19, 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,

James E. Dunaway, R.Ph.

CMS-2238-P-1037

Submitter : ROBERT WHEATLEY
Organization : ONTARIO PHARMACY, INC.
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

SUBJECT: MEDICAID PROGRAM: PRESCRIPTION DRUGS;AMP REGULATION
CMS 2238-P RIN 0938-AO20

THE ONTARIO PHARMACY CORPORATION IS WRITING TO PROVIDE OUR VIEWS ON CMS' DEFINITION OF AMP AS WELL AS IMPLEMENT THE NEW MEDICAID FEDERAL UPPER LIMIT PROGRAM FOR GENERIC DRUGS.

OUR CORPORATION OPERATES FIVE PHARMACIES IN 2 STATES, OREGON AND IDAHO. WE ARE A MAJOR PROVIDER OF PHARMACY SERVICES IN THE COMMUNITIES IN WHICH OUR STORES ARE LOCATED.

THE PROPOSED REGULATION, IF ADOPTED, WOULD HAVE A SIGNIFICANT NEGATIVE ECONOMIC IMPACT ON MY PHARMACIES. IT COULD JEOPARDIZE MY ABILITY TO PROVIDE PHARMACY SERVICES TO MEDICAID BENEFICIARIES AND THE GENERAL PUBLIC. THIS REGULATION SHOULD NOT MOVE FORWARD UNLESS SUBSTANTIAL REVISIONS ARE MADE. INCENTIVES NEED TO BE RETAINED FOR PHARMACIES TO DISPENSE LOW-COST GENERIC MEDICATIONS.

I SUPPORT THE MORE EXTENSIVE COMMENTS THAT ARE BEING FILED BY THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES REGARDING THIS PROPOSED REGULATION. WE APPRECIATE YOUR CONSIDERATION OF THESE COMMENTS AND ASK THAT YOU PLEASE CONTACT US WITH ANY QUESTIONS. THANK YOU.

SINCERELY,

ROBERT WHEATLEY, RPH
ONTARIO PHARMACY, INC.
925 SW 3 AV
ONTARIO, OREGON 97914
541-889-8087

CMS-2238-P-1038

Submitter : Mr. James Martin
Organization : Texas Pharmacy Association
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

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

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

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

CMS-2238-P-1039

Submitter : Mr. Wesley Wheeler
Organization : Valeant Pharmaceuticals International
Category : Drug Industry

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1039-Attach-1.PDF

February 19, 2007

BY ELECTRONIC DELIVERY

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

Re: CMS-2238-P (Medicaid Program; Prescription Drugs)

Dear Administrator Norwalk:

Valeant Pharmaceuticals International (“Valeant”) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services’ (“CMS”) Proposed Rule regarding Medicaid price reporting (the “Proposed Rule”).¹ Valeant is a global, science-based specialty pharmaceutical company that develops, manufactures and markets pharmaceutical products, primarily in the areas of neurology, infectious disease and dermatology.

Valeant is pleased that CMS has chosen to further clarify the rules surrounding the average manufacturer price (“AMP”) and best price calculations, and we agree with many of CMS’ proposals. We are disappointed, however, that CMS has not taken this opportunity to include in the Proposed Rule the statutory time limit on a State’s ability to revise utilization amounts for which Medicaid rebates are claimed, and we are commenting to urge CMS to include such a provision in the Final Rule. We also are responding to CMS’ request for comments regarding the feasibility of including rebates paid to Pharmaceutical Benefit Managers and other similar entities in the calculation of AMP. Valeant believes that such a requirement would present a significant operational burden and urges CMS to eliminate this requirement from the Final Rule. Last, Valeant requests that CMS provide additional clarity regarding the Customary Prompt Discount quarterly reporting requirement.

¹ 71 Fed. Reg. 77,173 (Dec. 22, 2006).

I. **CMS Should Include in the Final Rule a Provision Limiting the Time Period In Which a State May Submit Utilization for a Rebate Payment.**

The Medicaid rebate statute requires States to report to each manufacturer not later than 60 days after the end of each rebate period information on the covered outpatient drugs dispensed and paid during the period.² This is an explicit statutory deadline with no exceptions. In the 1995 Proposed Rule, which was never finalized, CMS took the position that this language does not relieve manufacturers from their obligation of paying rebates in situations in which the States fail to meet this deadline.³ Under current CMS policy, therefore, there appears to be no limit on how long after a rebate period ends a State may submit revised utilization amounts and claim a rebate. CMS has never provided any rationale or statutory language as a basis for this interpretation of the Medicaid statute, and has never issued this policy through notice-and-comment rule-making such that it could be subject to stakeholder review and comment.

Valeant believes that this CMS policy is unsupportable given the explicit statutory language and lack of formal rule-making, and also bad policy, as it subjects manufacturers to potentially indefinite rebate liability for late claims submitted by State agencies. Valeant asks that CMS include in the Final Rule a provision that would limit manufacturer liability for Medicaid rebate payments to claims submitted by State agencies within 60 days of the end of the rebate period, in order to comply with the language of the Medicaid statute. In the alternative, Valeant urges CMS to at least implement the one year limitations period included in the 1995 Proposed Rule. Such a provision is equitable, would meet the needs of both the States and manufacturers, and comports with general business principles.

CMS itself recognized the need for a time limit on State submissions of rebate claims in the 1995 Medicaid price reporting proposed rule (the "1995 Proposed Rule").⁴ The 1995 Proposed Rule included a deadline of one year from the end of a rebate period for States to bill manufacturers.⁵ Although the 1995

² Social Security Act ("SSA") § 1927(b)(2)(A).

³ Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers; Proposed Rule, 60 Fed. Reg. 48,422, 48,460 (Sept. 19, 1995).

⁴ *Id.*

⁵ The 1995 Proposed Rule included the following proposed section 447.530(c)(3):

- (3) If a State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ends—
- (i) a manufacturer is not required to pay a rebate on those drugs; and
 - (ii) a State may be considered out of compliance with section 1927 of the Act for failure to collect rebates.

Proposed Rule was never finalized, the need for this provision remains. As CMS explained at the time, imposing a deadline of one year from the time a State pays a claim is equitable “because it parallels the . . . timeframe for providers’ and States’ responsibilities”⁶ under Medicaid, which permit pharmacies up to one year to submit claims to the States for drugs dispensed to Medicaid beneficiaries and up to one year for States to pay such claims.⁷

A one-year time limitation is fair to the States as well as the manufacturers. States would not have to forfeit rebates on Medicaid utilization where circumstances are such that they are unable to submit the utilization information to meet the 60-day deadline set forth in the Medicaid drug rebate statute, and Manufacturers would not have indefinite Medicaid rebate liability when a State fails to report its utilization data within the 60-day timeframe.

This limitation is also consistent with general business principles. As CMS explained in the preamble to the 1995 Proposed Rule, a rebate submission time period that is longer than one year translates into the manufacturer being responsible for rebates more than three years after the drug is dispensed. Specifically, providers are given one year to submit a claim, the State is given one year to pay the claim, and under this proposed provision, the State would have one year to claim the rebate. As CMS noted in the 1995 Proposed Rule, the Internal Revenue Service generally requires that records be maintained for only three years, subject to exceptions, and thus this proposed timeframe is consistent with general business principles.⁸ Significantly, manufacturers may not be able to validate rebate claims for more than three years after a drug is dispensed. Although CMS finalized regulations in 2004 requiring manufacturers to maintain records relating to their rebate calculation for ten years,⁹ manufacturers remain liable for late utilization claims for an indefinite period (including prior to the finalization of this 10-year record retention requirement), and it is conceivable that disputes involving utilization claims for which manufacturers have not maintained records may arise. As CMS stated in the preamble to the 1995 Proposed Rule, “[a]dding more disputes to the resolution process for data where no records may exist is not . . . a cost effective or efficient manner of operating the drug rebate program.”¹⁰

See 1995 Proposed Rule, 60 Fed. Reg. at 48,486.

⁶ 1995 Proposed Rule, 60 Fed. Reg. at 48,460.

⁷ 42 C.F.R. § 447.45(d).

⁸ 60 Fed. Reg. at 48,460.

⁹ 69 Fed. Reg. 68,815 (Nov. 26, 2004).

¹⁰ 60 Fed. Reg. at 48,460.

Finally, we note that a one year timeframe for the submission of Medicaid utilization data will encourage States to pursue potential lost revenue in a timely manner in the event it discovers that its initial utilization data submission is understated, thus ultimately benefiting the States and the federal government. Moreover, this one year time period is a sufficient amount of time to permit the States to properly determine their utilization data, and it serves the significant business interest of manufacturers by enabling them to close their financial books within a reasonable timeframe.

II. Inclusion of PBM and Similar Rebates In the Calculation of AMP Presents a Significant Burden to Manufacturers.

The Proposed Rule requests comments on the operational feasibility of incorporating rebates from Pharmacy Benefit Managers, as well as similar entities such as Medicare Part D Plans and State Pharmacy Assistance Programs, in the calculation of AMP.¹¹ Valeant believes that this obligation would present very real operational difficulties. Sales and chargeback data typically are stored in the same, or at least linked, information technology systems, and can be more readily imported into a manufacturer's government pricing calculations. Rebate data, by contrast, typically are housed in a separate system, such as an accounts payable system or stand-alone electronic spreadsheets, and therefore may not be systemically tied or linked to sales data. As a result, manual intervention usually is necessary to include rebate data in government pricing calculations. Such manual steps not only pose significant operational burden, but also increase the likelihood of error. For all of these reasons, Valeant urges CMS to eliminate this requirement from the AMP calculation.

III. CMS Should Clarify the Customary Prompt Payment Discount Data To Be Reported on a Quarterly Basis.

The Proposed Rule directs that manufacturers report each quarter the Customary Prompt Payment ("CPP") discounts "paid to all purchasers in the rebate period."¹² CPP discounts typically are not affirmatively "paid" by a manufacturer, as may be the case with discounts that take the form of rebates. Rather, entities that have been offered a CPP discount typically realize that discount by reducing the payment of the invoice at issue by the amount of CPP discount earned. For this reason, Valeant requests that CMS clarify that the CPP discounts to be reported as those taken or realized by purchasers, rather than those paid by the manufacturer.

¹¹ 71 Fed. Reg. at 77,179 .

¹² *Id.* at 77,198 (proposed 42 C.F.R § 447.510(a)(3)).

The Proposed Rule also does not specify whether the CPP discounts to be reported are those offered by the manufacturer on sales that are invoiced in the reporting quarter or those taken or realized by the purchaser on invoices paid in the quarter. There is a time lag between the date that an invoice is issued and the date by which it must be paid in order for the CPP discount to be available, and therefore using one or the other data set will affect the CPP data reported for the quarter. As AMP is designed to measure the sales price in a quarter, inclusive of arrangements that subsequently adjust the price realized, Valeant believes the appropriate data to report are the CPP discounts offered on sales in the quarter, and requests that CMS adopt this approach in the Final Rule.

Finally, the Proposed Rule does not provide any guidance on the proper format for reporting customary prompt pay discount data. There are a number of different ways that such data may be submitted. Therefore, in addition to clarifying the issues discussed above, Valeant requests that CMS provide guidance regarding the format manufacturers should use to report customary prompt pay discount data to the agency.

Valeant appreciates the opportunity to comment on the Proposed Rule, and we look forward to working with CMS on these critical issues. Please do not hesitate to contact me if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Wesley P. Wheeler
President – North American Region
Valeant Pharmaceuticals International

Submitter : Mr. Don Wall
Organization : Professional Pharmacy of Greer, Inc.
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

Dear sirs,

As owner or co-owner of 5 independent pharmacies, I am very concerned about the Rx reimbursement being changed to AMP. It is calculated that this will result in reimbursement below cost for independent pharmacies. If this is the case, we will have no option other than to refuse to fill any Rx on which we lose money. While being concerned about the state of our deficit budget, I fell it is the fault of grandstanding politicians and resent being asked to lose money while performing my job.

Submitter : Miss. Brooke Crawford
Organization : East Tenn. State University College of Pharmacy
Category : Health Care Professional or Association

Date: 02/19/2007

Issue Areas/Comments

Background

Background

I am pleased to have the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS December 20, 2006, proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a student pharmacist at the East Tennessee State University College of Pharmacy and am interested in community retail pharmacy practice. I have worked at Ingles Pharmacy, a community grocery retail pharmacy located at 1200 W. Jackson Blvd., Jonesborough, TN, and I am familiar with the challenges in retail pharmacy practice.

Collection of Information Requirements

Collection of Information Requirements

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

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

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

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

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

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

I believe that CMS should use the 11-digit NDC AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug. Some drug products are sold in extremely large drums or package sizes (e.g., 5,000, 10,000, 25,000 or even 40,000 tablets or capsules) that are not practical for a typical retail pharmacy to purchase due to the excess amount of product and carrying cost that would result from holding this large quantity in inventory for a much longer than usual time. In some community retail pharmacies, the product would go out of date.

GENERAL

GENERAL

See Attachment

Regulatory Impact Analysis

Regulatory Impact Analysis

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

Sincerely,

CMS-2238-P-1041

**Brooke Crawford
1840 Presswood Rd. #17
Johnson City, TN 37604**

CMS-2238-P-1042

Submitter :

Date: 02/19/2007

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1042-Attach-1.DOC



CEDARS-SINAI MEDICAL CENTER.

**Department of Pharmacy Services
8700 Beverly Blvd., Room A-845
Los Angeles, CA 90048
Phone: (310) 423-5611
Fax: (310) 423-0412**

February 19, 2007

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

To Whom It May Concern:

On behalf of Cedars-Sinai Medical Center, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Cedars-Sinai is a 950 bed hospital located in Los Angeles, California, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program.

We recognize the need for a consistent approach to Medicaid rebate policies and for establishing a standard formula for pricing of pharmaceuticals, however, we are concerned that the regulations, as written, have unintended consequences that would inadvertently shift costs to hospitals. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create a significant burden for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. Currently, our billing system is not setup to include the NDC numbers in the Chargemaster and be added onto the UB92. To obtain this capacity, our hospital will have to make significant changes to our billing system, at considerable expense in terms of staff resources and disruption of operations. Until the billing system can be modified, a manual process would have to be put in place if the NDC number is required. If the NDC number is only required for billing the Medicaid patients, it means that Finance would have to inform the pharmacy billing staff which claim and which drugs need to have the NDC numbers added. The pharmacy staff will then have to manually look up the NDC information and provided that to Finance to be added onto the UB92. This manual process can take up to 10

to 15 min of staff time per drug per Medicaid claim which is significantly greater than the 15 seconds estimated by CMS.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. If this were to occur, our hospital would lose these savings. The impact that it would have on our hospital would be approximately \$2.2 million based the cost savings achieved on 340b drugs during this fiscal year. Due to the administrative and financial burden mentioned above in order to provide the NDC number, it may no longer be feasible for us to participate in the 340B program which in turn will prevent us from providing medication services to meet all patient needs.

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing. We are extremely concerned with the increase in outpatient drug prices that would result if higher AMP figures were to be used for calculating 340B prices since our hospital is currently a disproportionate share hospital. We are also concerned with the additional financial burden that our hospital will incur due to the loss of nominal pricing contracts in the non-340B participating areas, i.e., the inpatient patient populations. It is possible that manufacturers will interpret the DRA act to eliminate nominal pricing to the entire health system. This act will essentially lead to the undue and improper increases in the costs of drugs to our healthcare facility and ultimately our patients. Due to the seriousness of this potential misinterpretation by the manufacturers, the Office of Affairs sent out a letter on January 30, 2007 to all the manufacturers to clarify the issue of AMP calculation and should not include the prompt pay discount.

We recognize the need to have a cohesive approach to the management of prescription drugs under the Medicaid program, however, we hope that you will give serious consideration to the issues addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Rita Shane, Pharm.D., FASHP
Director, Pharmacy Services
Cedars-Sinai Medical Center

CMS-2238-P-1043

Submitter : Mr. James Martin
Organization : Texas Pharmacy Association
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1043-Attach-1.DOC

March 3, 2007

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

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

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

Summary

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

§447.504 Determination of AMP

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

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

Defining Retail Pharmacy Class of Trade

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

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

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

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

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

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

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

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

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

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

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

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

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

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

§447.510 Requirements for Manufacturers.

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

Market Manipulation

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

¹ Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.

² GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

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

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

‘Claw-back’

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

Pricing Lag

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

Severe Price Shifts

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

³ §447.510(d)(2)

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

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

Record Keeping

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

Additional Comments

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

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

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

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

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

Sincerely,



Jim Martin, R.Ph.

cc. The Honorable John Cornyn
The Honorable Kay Bailey Hutchison
The Honorable Joe Barton
The Honorable Kevin Brady
The Honorable Michael C. Burgess
The Honorable John R. Carter
The Honorable Mike Conaway
The Honorable Henry Cuellar
The Honorable John Abney Culberson
The Honorable Lloyd Doggett
The Honorable Chet Edwards
The Honorable Louie Gohmert
The Honorable Charles A. Gonzalez
The Honorable Kay Granger
The Honorable Al Green
The Honorable Gene Green
The Honorable Ralph Hall
The Honorable Jeb Hensarling
The Honorable Ruben Hinojosa
The Honorable Sheila Jackson Lee
The Honorable Eddie Bernice Johnson
The Honorable Sam Johnson
The Honorable Nicholas Lampson
The Honorable Kenny Marchant
The Honorable Mike McCaul
The Honorable Randy Neugebauer
The Honorable Solomon Ortiz
The Honorable Ron Paul
The Honorable Ted Poe
The Honorable Silvestre Reyes

The Honorable **Ciro D. Rodriguez**
The Honorable **Pete Sessions**
The Honorable **Lamar S. Smith**
The Honorable **William M. "Mac" Thornberry**

Submitter : Mr. Francis Rodriguez

Date: 02/19/2007

Organization : self

Category : Other Technician

Issue Areas/Comments

**Collection of Information
Requirements**

Collection of Information Requirements

1) With respect to manner in which Average Manufacturers Prices are determined: I suggest that the definition of retail pharmacy be such that entities that would have access to unique rebate or price reductions that would not be available to retail, community pharmacies, not be included in any survey for establishing average manufacturers prices (AMP); or, in the alternative, that such unique rebates or price reductions not be considered in the calculation of AMP. 2) With respect to Dispensing Fee: I suggest that it is appropriate for CMS to specify those costs that must be taken into account by each state in determining its dispensing fee. A recent study sponsored by the Coalition for Community Pharmacy of data gathered from 23,000 community pharmacies located nationwide indicates that, depending on the state, the dispensing cost range from \$8.50 to \$13.08 per prescription. That cost range is far above the dispensing fee schedule of the State of New Jersey, where I live. I suggest that a federally-funded cost-to-dispense study is in the public interest. If the totality of changes proposed by these regulations result in reduced, timely access of the patient population to community, retail pharmacies because there are fewer of those pharmacies, the health-cost savings envisioned by these changes would be of only short-term value; long-term, costs would rise as those patients are forced towards costlier health-provider alternatives.

Submitter : Mr. Michael Murphy
Organization : Mississippi Discount Drugs
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

Background

Background

I have been an independent pharmacy operator for over 25 years. We fill over 8,000 prescriptions per year. We service a small town in central Mississippi, where over 50% of the residents are either on Medicaid or have Medicare Part D. I feel my business is typical of other independent operations.

Collection of Information Requirements

Collection of Information Requirements

The proposed regulations of AMP. Average Manufactures Price is not based on my ability to purchase generics. It takes in to account the Medicaid contracts and PBM contracts. Most of these type entities get some type of rebate. It is my understanding you will apply the rebates to find AMP. I do not get rebates. I am afraid if you use the pricing these entities net, it will be below my cost. Your intentions are to help control cost. I understand the task. But your cost control method is unfair to independents like me. All of our cost are increasing and with AMP our retail price will decrease. Forcing many business out of business. Who will service these patients?

GENERAL

GENERAL

I am only asking for fair pay for a fair product. This new pricing will eliminate any possibility of that. The rates of reimbursement now are below the value of the service now. We can help control cost, by controlling the drug therapy and many other services that will produce a healthy population.

Regulatory Impact Analysis

Regulatory Impact Analysis

I ask that you take hospitals, government agencies and government programs out of your calculation. ONLY use retail operations to find what the drugs cost the true service providers of the public.

Response to Comments

Response to Comments

The use of AMP will certainly limit my ability to continue to provide the service level I have provided in the past. Since AMP is truly unknown, only a projected AMP is available, It is my worst nightmare that even with the high volume and past success I will be unable to make a profit. We are almost there now. AMP will be the demise of pharmacy in the retail market.

Submitter : Mr. Curtis Eirew

Date: 02/19/2007

Organization : Sail Drug Pharmacy

Category : Health Care Professional or Association

Issue Areas/Comments

Background

Background

The formula used on the "AMP"-based FULs will not cover the acquisition costs paid by retail pharmacies and will jeopardize the care of millions of patients by retail pharmacies who will no longer be able to offer their personal services like delivery etc. The community retail pharmacies are struggling now and with the proposed AMP - This will not only hurt the retail pharmacy, but most of all the patients who depend on them.

Submitter : Dr. Mary Mundell
Organization : Susitna Professional Pharmacy
Category : Pharmacist

Date: 02/19/2007

Issue Areas/Comments

GENERAL

GENERAL

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. Susitna Professional Pharmacy is my pharmacy and is located in rural Wasilla, Alaska. Nearly 70% of our services are for medicaid/medicare patients, thus we are a major provider of pharmacy services in the community and your consideration of these comments is essential.

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

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

Sincerely,

Mary D. Mundell, RPh-owner
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