

Submitter : Dr. BARRY WALTON
Organization : MAC'S MEDICINE MART, INC
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

February 19, 2007

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

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

Thank you for the opportunity to submit comments on the above mentioned AMP or Average Manufacturer's Price as well as the Medicaid Federal Upper Limit (FUL) program for generic drugs. I am a pharmacist and owner of Mac's Medicine Mart, a community retail pharmacy located at 1425 East Center Street in Kingsport, Tennessee. We are a major provider of pharmacy services in our community, and your consideration of these comments is essential.

I believe CMS is using an exaggerated definition of retail class of trade for determining AMP used in calculating FUL. As it now stands, AMP would have absolutely no relationship to the price I must pay for medications. You should exclude closed shop classes of trade from the calculation such as PBM's (Pharmacy Benefit Managers) and mail order pharmacies. Neither of these types of organizations are community pharmacies, nor do they dispense to the general public; therefore they should be excluded.

AMP should reflect prices paid by retail pharmacies. To do otherwise is contrary to Congressional intent. Rebates or kickbacks paid to PBM's and mail order firms are not shared with community pharmacies. Furthermore, it is currently illegal for my pharmacy to talk to another pharmacy about joining together to negotiate a better price from a mutual supplier. I can assure you that manufacturers and suppliers have little interest in giving a single independent pharmacy a deal anywhere close to what the PBM's and mail order firms pocket each year. Therefore, exclude rebates from the calculation of AMP used to determine FULs.

The Government Accountability Office (GAO) gave Chairman Joe Barton of the House Committee on Energy and Commerce a report dated December 22, 2006 that shows just how detrimental the current plan could be to a small business like my pharmacy. The GAO used AMP-based FULs and compared them with average retail pharmacy acquisition costs for the first quarter of 2006. They used the 50 most frequently used drugs--representing 53% of prescriptions subject to FULs, and the 50 highest expenditure drugs---representing 56% of Medicaid spending on outpatient prescription drugs. The results: the AMP-based FULs were lower for 59 out of the 77 drugs in the sample. Worse, for the entire 77 drug sample, the AMP-based FULs were 36% lower than the average retail pharmacy acquisition costs. Needless to say, a business cannot be sustained if it is forced to continuously sell its products below its actual acquisition costs.

Other issues are obvious&at least for me as a pharmacist. FUL pricing should be based not on AMP but solely on the prices retail pharmacies pay for medications!

Medicaid pricing, heavily regulated by state and federal governments, should be treated consistently with other federal payor programs, and be excluded from AMP!

Manufacturer data reporting, an essential part of price determination, could lag and create the risk of price fluctuations and market manipulation. Recent examples are albuterol inhalers and sertraline (the generic of Zoloft). Albuterol inhalers have quadrupled in price within the past year, yet reimbursement for the inhalers has not kept up. Yet when the bottom fell out of the sertraline market, the reimbursement was often much less than the tablets cost when purchased. This must be addressed!

In closing, I support the more extensive comments 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,

Barry Walton, DPh.
1801 Hermitage Dr.
Kingsport, TN 37664
(423) 914-2600
cc: Senator Lamar Alexander
Senator Bob Corker

Submitter : Taunya Peters
Organization : Scripps Healthcare
Category : Hospital

Date: 02/20/2007

Issue Areas/Comments

GENERAL

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While we realize your goal is allow Medicaid providers to obtain rebates from manufacturers for the dispensing of Pharmaceuticals, hospital systems are not designed to record the manufacturer information or even measurement information. We buy from the manufacturer who can give us the best price for the drug we need at the time, often the purchase is a bulk purchase with an NDC number associated with the package vs. the unit of measure dispensed to patients. As a hospital deal in huge volumes of pharmaceuticals, we are concerned with whether the drug is appropriate for the patient, is the dosage correct, is the patient the right patient, and whether we have an order. We are not concerned the patient got Drug A from Manufacturer A at 8:00a and then got Drug A from Manufacturer B at 10:00a. We would simply report the charges for Drug A 2 units and the associated dollar amount. We would assign an NDC number as best we could but it is more likely to be wrong than right. If you want accurate information from outpatient acute care hospitals we suggest you get the rebate information directly from the pharmaceutical companies as we can not tell Medicaid or any other payer with any accuracy at the patient level the drug manufacturer of the dispensed drug.

Response to Comments

Response to Comments

Our hospital has concerns regarding the collection of information requirements of the proposed rule which requires providers of out-patient Medicaid patients including hospitals to submit NDC numbers for drugs. Section 447.520 suggestions that it would only take provider 15 seconds per claim to assign NDC numbers which equates to under 9 cents per claim. While we appreciate this estimate, we disagree with the expected cost. Based on having appended NDC number and the volume of pharmaceuticals dispensed in an outpatient acute care hospital setting, we estimate the time to be approx. 30 seconds per line item of pharmaceutical reported on the claim at a rate of \$.18 cents per line item. Based on Quarter 1 volumes for our five facilities this could cost our facilities an additional \$306,000. The unfortunate part is that the expected reimbursement from Medicaid on these charges is less than \$87,000. We feel this rule is onerous such that providers may forfeit being paid by Medicaid for pharmaceuticals in order to avoid the cumbersome burden of appending NDC numbers to drugs.

Submitter : Christine Charbonneau

Date: 02/20/2007

Organization : Planned Parenthood of Western Washington

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

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"See attachment"

Regulatory Impact Analysis

Regulatory Impact Analysis

"See attachment"

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

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

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

Submitter : Steve Simenson
Organization : Goodrich Pharmacy
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

GENERAL

GENERAL

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 Anoka, 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,
Steven T. Simenson, BPharm
Managing Partner
Goodrich Pharmacy
100 Monroe Street
Anoka, Minnesota 55303

cc. Senator Amy Klobuchar
Senator Norm Coleman
Representative Michelle Bachman

Submitter :

Date: 02/20/2007

Organization :

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1442-Attach-1.DOC

DATE: FEBRUARY 19, 2007

SUBJECT: CMS-2238-P

FROM: BORGESS MEDICAL CENTER PHARMACY DEPARTMENT

TO WHOM IT MAY CONCERN:

The current costs to implement the changes required to meet the objective of this proposal can only be estimated due to the complexity involved. Borgess Medical Center does not currently conduct bedside drug barcoding at the point of medication administration. **To assure 100% accuracy between medications dispensed and the NDC number submitted, manual entry will be necessary.**

Our billing process is currently designed such that an overhaul of three computer systems would be required to pass the NDC code from the point of order entry to **final bill submission for our** outpatient medications. Additionally, BMC's billing system, Medipac, would need to be upgraded to print the NDC on the appropriate UB form for submission to CMS required. This will necessitate considerable monetary and time expenditures. Finally, the billing system (Mpac) will need to be reprogrammed to identify the outpatient visits and to flag those related meds for NDC submission.

This issue is further complicated by the necessity for regularly scheduled NDC maintenance. Please note that this 11-digit code changes with the strength, dosage form, and package size ordered. NDC maintenance is a task not easily completed due to the daily variability in purchasing medications; i.e., the product we purchase depends upon cost and availability of product. The Inpatient Pharmacy also utilizes automated unit dose dispensing for which we have contracted personnel for the purpose of repackaging medications. These personnel perform their ordering separately of the Inpatient Pharmacy which would require the creation of a secondary listing and NDC submission system. Finally the issue of simple maintenance of the NDC numbers and systems support would require a **\$50,000** expenditure in salaries for new FTE support positions within the pharmacy department and an additional **\$30,000** in salary for increased IT support. Another **\$60,000** will need to be added for manual billing if IT reprogramming is unsuccessful. Ultimately, this proposal will only serve to divert critical pharmacy financial resources and staff time from patient safety to billing compliance. Direct patient care will suffer as a result of this proposal's implementation.

Thank you,
Borges Medical Center

Submitter : Christine Charbonneau

Date: 02/20/2007

Organization : Planned Parenthood of Western Washington

Category : Health Care Provider/Association

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

"See Attachment"

CMS-2238-P-1443-Attach-1.DOC

February 20, 2007

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

RE: File Code CMS-2238-P

Dear Administrator Norwalk:

I am the CEO of Planned Parenthood of Western Washington. We serve over 152,000 women each year for family planning services. These are low income women who rely on us for not only their contraceptive care, but the care we provide to them is the only healthcare that 80% of the women we serve, receive.

We have been fortunate to be able to subsidize the care to these women through access to a charitable contribution from pharmaceutical companies through Nominal pricing. This has been a boon to the women we serve, who get their contraceptives at low or no cost. It also helped my agency, which has been able to provide the services which are our mission for free or low cost. It has allowed the pharmaceutical firms a chance to make charitable gifts, and they have been rightly able to point to their corporate citizenship as a result. Lastly but significantly, the Federal Government, which has been able to offer a family planning program to more and more poor people, for very little cost and flat ongoing investment.

The very existence and fiscal viability of Planned Parenthood of Western Washington turns on its ability to purchase oral contraceptives at less than 10% of the average wholesale price. Without these steeply discounted drugs, we will no longer be able to provide the low-cost outlet for poor women that they so desperately need, and that we very much want to continue to provide.

As you know, the proposed rule, published by the Centers for Medicare and Medicaid Services ("CMS") on December 22, 2006, to implement section 6001(d) of the Deficit Reduction Act of 2005 ("DRA") -- preserves the ability of three kinds of providers ((I) 340B covered entities, (II) intermediate care facilities for the mentally retarded and (III) state owned or operated nursing homes) to purchase drugs at best price ineligible nominal prices. Some Planned Parenthood affiliates have Title X clinics, and therefore qualify for 340B in those sites. However, since Title X has not been funded beyond the level the program had reached in 1977, clinics which have been developed since then, most of which have been part of a deliberate expansion to serve rural women and women from

the Southern US States, have not shared in the Title X funding which was already allocated, and therefore did not qualify for the 340b program. If Planned Parenthood of Western Washington has to pay \$30 per cycle of oral contraceptives in our rural sites, we will most assuredly not be able to give them away to women in need. The economics of that could never pencil out.

Non-340B providers of medical services to the poor must rely on section 6001(d)(IV) of the DRA to permit its continued access to steeply discounted drugs. As you know, that section authorized the Secretary of the Department of Health and Human Services (“HHS”) to define “other safety net providers” that would be eligible for the nominal pricing exception. We are requesting that you add family planning providers to the “safety net” category in the final rule.

Clearly, if the sole providers of care to rural women well within the Federal Poverty Levels contemplated by your family planning waivers to the States do not qualify as safety net providers, you have not, in fact, adequately captured the list of such providers that Congress intended you to identify.

We know that if we do not have access to Nominal pricing, and we are excluded from 340b due to the dearth of Title X funds, we will have to pay open market prices for our supplies. If we are no longer here to prescribe for these women, or if women cannot afford to help pay for their pills, you, the Federal and State governments, will pay market prices for their deliveries and the care of the children they were not prepared to have.

As Nominal Pricing predated best price and Medicaid rebates, and the two systems have existed symbiotically together for all of the years of the rebate program, the idea that adding family planners back into this cohort somehow would suddenly have an adverse effect on the rebate program simply doesn't make sense. Eliminating our exception just relieves pharmaceutical companies of any responsibility to offer charitable pricing while gaining no advantage whatsoever for the Federal Government.

In conclusion Planned Parenthood of Western Washington is a non-profit outpatient health care facility that serves a critical function in the health and well being of over 152,000 uninsured and underinsured women in Washington State. We are able to provide these services and deeply discounted oral contraceptive medications to these women only because we can purchase oral contraceptives from drug manufacturers at nominal prices, as we have been doing since the 1970s. Carving safety net providers like us out of the nominal pricing exception would be devastating to our mission and to our operations, and would prevent CMS from meeting its own stated goals. I urge CMS very strongly to reconsider its position and apply the safety net provider exception as provided in the DRA.

With Regard,

Christine Charbonneau
President/CEO

Submitter : Ms. Rebecca Snead

Date: 02/20/2007

Organization : National Alliance of State Pharmacy Associations

Category : Pharmacist

Issue Areas/Comments

Background

Background

The National Alliance of State Pharmacy Associations, representing all state pharmacy associations, 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.

Collection of Information

Requirements

Collection of Information Requirements

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

GENERAL

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See Attachment

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

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.

Regulatory Impact Analysis

Regulatory Impact Analysis

CMS-2238-P-1444-Attach-1.PDF

NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS

5501 PATTERSON AVE., SUITE. 202, RICHMOND, VA 23226
PHONE: (804) 285-4431 FAX: (804) 285-4227 WWW.NASPA.US

February 13, 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 National Alliance of State Pharmacy Associations (NASPA), representing all state pharmacy associations, is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

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

§447.504 Determination of AMP

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

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

Defining Retail Pharmacy Class of Trade

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

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

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO’s own definition of retail pharmacy in its December 22, 2006 report entitled: *“Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,”* the GAO defines retail pharmacies as “licensed non-wholesale pharmacies that are open to the public.” The “open to the public” distinction is not 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.

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

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

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

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

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

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

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

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

§447.510 Requirements for Manufacturers.

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

Market Manipulation

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

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)

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

Pricing Lag

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

Severe Price Shifts

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



Rebecca P. Snead



Submitter : Mr. Mark Shabashov

Date: 02/20/2007

Organization : Inland Empire Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

Background

Background

Proposal for reimbursement is well below our cost to dispense prescription. Recent studies have shown the cost to process a prescription is approximately \$10.50. This \$10.50 does not include the cost of the medication. If this legislature goes through our pharmacy will be forced to cancel our medicaid contract and I am sure many other if not all pharmacies will. Access to care will be limited if not stifling to the medicaid population. This legislation also is forcing pharmacies to dispense brand name drugs for better payment which will result in increased cost to the state.

Submitter : Sandra Eck
Organization : Eck Drug Co., Inc.
Category : Pharmacist

Date: 02/20/2007

Issue Areas/Comments

Background

Background

Medicaid Program: Prescription Drugs; AMP Regulation CMS 2239-P RIN 0938-AO20

GENERAL

GENERAL

As the owner of a rural community pharmacy, I am gravely concerned about this legislation's impact on my ability to continue to provide pharmaceutical services to the Medicaid patients in my area, Western Carter County. Since I am in the "Independent Retail Class of Trade", I must pay the highest drug prices of all groups. This legislation reimburses me BELOW my generic drug acquisition cost. Please read the extensive comments of the Oklahoma Pharmacists Association which I support. January 1, 2007, I stopped providing Medicare Part B drugs, DME equipment, and supplies due to inadequate ASP (average sales price) reimbursement and the new expensive accreditation requirements. Do you want to deny all healthcare access to our nation's rural citizens? You are regulating me out of business.
Thank you for my chance to comment.

Submitter :

Date: 02/20/2007

Organization : TTUHSC-SOP PDC Beta Rho Chapter

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

It is imperative that the pharmacist dispensing fee is raised as costs continue to increase. Also the increase in Medicaid beneficiary s at the current rate of \$4 is not feasible when technology and administration costs are also increasing. Maybe the dispensing fee could be calculated by the ratio of Medicaid to non-Medicaid recipients

In the determination of the AMP, it seems like it will make it harder for community pharmacies to compete with the retail giants as their prescription volume is much lower and will be harder to recover the expenses. The discounts the larger retail pharmacies get when purchasing generics far outweighs the community pharmacies buying power.

In regards to the determination of the best price, all factors should be considered, as most pharmacies are involved in all aspects of prescription discounts and rebates.

When thinking about the FUL with A-rated and B-rated drugs as a current student we have learned that sometimes it is the B-rated drug that is needed for various reasons in the treatment of patients, and although not proven to be therapeutically equivalent may be justified.

Submitter :

Date: 02/20/2007

Organization : **Midwestern University APhA-ASP Chapter**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The proposed rule does not address APhA's concerns for adequate reimbursement under an Average Manufacturer's Price (AMP) based reimbursement formula or our concerns regarding payment for pharmacist services (dispensing fee):

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

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