Submitter : Mr. michael tursi **Date:** 02/20/2007

Organization : millys pharmacy

Category : Pharmacist

Issue Areas/Comments

Background

Background

see attachment

CMS-2238-P-1250-Attach-1.DOC

#1250

MILLY'S PHARMACY
2626 FEDERAL STREET
CAMDEN, NEW JERSEY 08105

FEBUARY 20, 2007

VIA ELECTRONIC SUBMISSION

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 manufacters' 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 5[illegible],000 retail pharmacy locations.

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.

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-dight 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.

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

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

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

CMS Must Employ a Complete Definition on Cost to Dispense

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

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

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

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

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

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,
MICHAEL TURSI-OWNER

Submitter :

Date: 02/20/2007

Organization :

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1251-Attach-1.DOC

#1251

DIK DRUG CO.
Family Owned Since 1914

February 20, 2007

VIA ELECTRONIC SUBMISSION

Leslie V. Norwalk, Esq.
Office of the Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Washington, DC 20201

Re: CMS-2238-P ; Proposed Rule: *Medicaid Program; Prescription Drugs* 71 Fed. Reg. 77173 (December 22, 2006)

Dear Ms. Norwalk,

On behalf of our company, Dik Drug Company of Burr Ridge, Illinois, we respectfully submit our comments regarding the proposed rule CMS-2238-P published in the Federal Register on December 22, 2006.

Dik Drug Co. is an independent, regional pharmaceutical wholesale distributor established in 1914.Our primary business is serving independent retail pharmacies in the upper Midwest.

As a distribution link to retail pharmacies we serve a critical role in the delivery of life saving pharmaceutical products through the pharmacies we serve to the end user patient.

Our immediate concern regards the hundreds of pharmacies and in turn the thousands of Medicaid recipients served by our company. Given the considerable amount of time we have spent reviewing the proposed rule and the independent analysis surrounding the rule we fear the very foundation of the program and therefore the delivery of critical service and medication to recipients to be at great risk.

At the core of concern is the intent to establish AMP (Average Manufacturer Price) as the new metric for pharmacy reimbursement on prescriptions dispensed under the Medicaid program. While we will not argue that AMP may not be a useful basis we feel it is imperative that the definition of AMP reflect the actual cost paid by a retail pharmacy. AMP under its current form was never intended to be used as a basis for pharmacy

reimbursement and as such, when used to set federal upper limit, can not possibly cover pharmacy acquisition costs for multi-source generic medications.

In specific, our concerns and comments relating to establishing AMP are:

- Similar to the exclusion of hospital and nursing homes, mail order pharmacies receive special pricing and are not publicly accessible. Sales to these facilities should not be included in AMP.
- Any and all rebates, discounts, and price concessions not available to retail pharmacies must be excluded from AMP. CMS excludes rebates to Medicaid programs, DOD Tricare, and Department of Veterans Affairs but still includes PBM rebates, direct to patient sales, and manufacturer coupons in the AMP calculation. Inclusion of these price concessions, which again are not available to retail pharmacies, will drive the AMP price well below pharmacies' acquisition cost.
- Pricing in multi-source generics is the most volatile in the industry. Under the proposed rule the AMP pricing established will be 60 days behind the market pricing unless reporting is expedited. We believe to achieve any semblance of accuracy AMP data must be reported weekly.

In addition we would comment on the impact of the proposed rule on independent pharmacies.

While a complete and accurate analysis cannot be completed without access to actual AMP prices we would agree with the findings demonstrated in the recently released Government Accountability Office (GAO) report on Medicaid Federal Upper Limits (GAO-07-239R). These findings estimate that AMP-based FUL was 36 percent lower than average retail pharmacy acquisition cost. We would submit no business can withstand a 36% loss on each transaction much less independent pharmacies serving low income areas with very high concentrations of Medicaid beneficiaries. Furthermore, we believe this deficit cannot be overcome by aggressive purchasing practices, rebates, or even potential enhanced dispensing fees.

Thank you for the opportunity to provide our comments on Proposed Rule CMS-2238-P. We hope these comments are constructive in your deliberations in the creation of a final rule that will represent an equitable and reasonable approach to reimbursement for all providers of the critical Medicaid Program.

Sincerely,

Gary Prester
Vice President of Sales & Marketing
Dik Drug Co.

Submitter : Dr. Leslie Pires **Date:** 02/20/2007

Organization : Women and Infants Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1252-Attach-1.DOC

#1252

February 20, 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 Women & Infants Hospital of Rhode Island, 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. Women & Infants Hospital of Rhode Island is a 137 bed hospital located in Providence, 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. There are several computer systems involved in the recording and dispensing of drugs and the transfer of the appropriate information to the hospital and payer bill processing systems. With considerable effort and constant coordination between pharmacists and business managers, we are able to correctly make this transfer at the J-code level of detail. Adding NDC numbers further complicates this process. A single J-Code can apply to several NDC numbers, and vial sizes and manufacturers are often interchanged depending on the availability of drugs. It is common practice for one dose of chemotherapy drug to be compounded from several different size vials for cost saving purposes. Women & Infants had another payer who required NDC numbers on the bills. After some experience, we found that it is not practical to expect that employees whose training is in billing and who are under considerable pressure to process a large volume of bills each day to consistently determine the correct NDC numbers. Both parties agreed to abandon the NDC number billing in favor of the J-Code methodology.

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. The Rhode Island Medicaid system is based on budgeted cost, so if we lost our 340B discounts, we would seek increased reimbursement from Medicaid in our budget negotiations.

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

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

Sincerely,

Leslie A. Pires, MS, PharmD
Director of Pharmacy

David G. Dillon
Director of Reimbursement

Submitter : Mr. Christopher Dimos **Date:** 02/20/2007

Organization : SUPERVALU Pharmacies

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1253-Attach-1.DOC

#1253

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Jewel-Osco

SCOTT'S

Shaw's Osco

Shop 'n Save

SHOPPERS

February 20, 2007

Via Electronic Mail

Leslie Norwalk, Esq.
Acting Administrator
The Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Subject: Pharmacy Concerns with CMS Proposed Rule on AMP and Release of Data

Dear Administrator Norwalk:

I am writing to ask for your help regarding the impact that a proposed regulation will have on the economic viability of community retail pharmacies and our ability to continue to serve Medicaid beneficiaries. The proposed regulation implements certain Medicaid provisions of the Deficit Reduction Act (DRA) of 2005.

Our company operates over 2,500 supermarkets in the lower 48 states. We have 925 retail pharmacies in those stores serving patients all over America. We are concerned that a proposed December 20, 2006 regulation by the Centers for Medicare and Medicaid Services (CMS) would result in the public release of flawed "average manufacturers' price" (AMP) data; would create a definition of AMP that would not reflect the prices at which retail pharmacies purchase medications; and would cut Medicaid generic payments to pharmacies by $8 billion over the next 5 years, reducing incentives to dispense lower-cost generic drugs.

Delay AMP Data Release: The DRA requires CMS to publicly release AMP data for each brand name and generic drug reimbursed by Medicaid. Also, the DRA directs that AMP data be used to set Federal reimbursement rates for generic drugs. These data were scheduled to be released in July 2006, but CMS appropriately delayed their release because of the widely-documented inconsistencies in how manufacturers calculate AMP data. CMS now says it will release these AMP data this spring.

Redefine AMP To Reflect Retail Pharmacy Prices: It is critical that the AMP data be perceived as a reliable approximation of the prices paid by retail pharmacies for medications. Yet, the proposed regulation significantly falls short in this goal. For example, in the proposed regulation, manufacturers can deduct from their AMP calculation the rebates and discounts that they provide to health plans and pharmacy benefit managers for brand name drugs. These rebates and discounts are paid directly to these entities, not community retail pharmacies. Thus, reducing the AMP value by the amounts of these rebates and discounts could make AMP lower than retail pharmacies' acquisition costs for brand name drugs. This could make AMP unreliable as a retail pharmacy reimbursement benchmark.

3030 CULLERTON DRIVE, FRANKLIN PARK, IL 60131
(847) 916-4244

Encourage States to Increase Dispensing Fees: The DRA directs that the Federal Medicaid program significantly reduce payments to pharmacies for the generic medications dispensed. Without greater direction by CMS to states to increase their dispensing fees, incentives to dispense lower-cost generics may be reduced. A generic prescription costs about $20, while the average brand prescription costs $120. Recent studies indicate that it costs a pharmacy anywhere from $9 to $11 to dispense a Medicaid prescription, well above the average state dispensing fee of $4.50. Increases in state dispensing fees can help assure continued dispensing of lower-cost generics.

In summary, this proposed rule could adversely impact our ability to continue to serve Medicaid beneficiaries. We appreciate your consideration of our views and thank you in advance for any assistance you may be able to provide.

Sincerely,

SUPERVALU Pharmacies

Christopher T. Dimos/s/

Christopher T. Dimos
President
(847) 916-4244 voice
(847) 916-4310 fax
e-mail: chris.dimos@supervalu.com

cd:vv

Submitter : Mrs. saroj mittal **Date:** 02/20/2007

Organization : seeley pharmacy inc.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

We will go out of business.
Our poor neighborhood will be deprived of Rx services.
PBM are ripping our viability.
Poor patients wont be able to get face to face RPh consulation.
- the formula for AMP based FULs in the proposed rule will not cover pharmacy acquisition costs for mulple source generics medications.
- AMP was never intended to serve as a basis for reimbursements.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cos paid by retail pharmacy. This will be accomplished by
- *excluding all rebates & price concessions made by mfg which are not available to retail pharmacy.
- *excluding all mail order facilities & PBM pricing from AMP calculation. Mail order facilities & PBMs are extended special prices from MFG & they are not publicly accessible in the way that our brick mortar Rxs are publickly accessible.
- Reporting AMP at the 11 digit NDC level to ensure accuracy

Submitter : Mrs. Caroline York **Date:** 02/20/2007

Organization : MedImmune

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1255-Attach-1.DOC

CMS-2238-P-1255-Attach-2.DOC

#1255

MedImmune

February 20, 2007

Leslie V. Norwalk, Esquire, 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:

MedImmune would like to thank you for the opportunity to comment on the Medicaid Program; Prescription Drugs proposed rule (the Proposed Rule).[1] MedImmune recognizes the significant effort involved in proposing such a comprehensive regulation and hopes that the following comments will help build on the process CMS has started.

MedImmune, a company focused on the treatment of infectious diseases, cancer and inflammatory diseases, is dedicated to advancing science and medicine to help people live better lives. The Proposed Rule will have a substantial impact on how individuals access the prescription drugs they depend on to help them live better lives. It is therefore important to MedImmune that the Final Rule promulgated by CMS be as clear and complete as possible. It is with this in mind that MedImmune offers the following comments for CMS' consideration.

1. **CMS Should Clarify That Manufacturers May Continue to Exclude Sales to Hospitals from AMP When the Manufacturer Cannot Determine Whether a Sale is for Inpatient or Outpatient Usage.**

[1] 71 Fed. Reg. 77,174 (Dec. 22, 2007).

Under current CMS guidance, all sales to hospitals are excluded from the AMP calculation.[2] The Proposed Rule purports to exclude from AMP only those sales to hospitals that are for inpatient use.[3] Sales to hospitals where the drug is used in the outpatient pharmacy would be included in the AMP calculation.[4] MedImmune currently is unable to identify whether hospital sales are for inpatient or outpatient usage, and believes that other manufacturers are in the same position. For this reason, MedImmune asks CMS to clarify that manufacturers may continue to exclude all sales to hospitals from AMP when the manufacturer cannot determine whether a sale is for inpatient or outpatient use.

2. CMS Should Clarify that Home Healthcare Pharmacies are Part of the Retail Pharmacy Class of Trade.

The Proposed Rule includes a definition of the retail pharmacy class of trade to facilitate the uniform calculation of AMP, which the Medicaid statute defines as the average price received by manufacturers from wholesalers for drugs distributed to the retail pharmacy class of trade. The proposed definition is "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[5] In addition to providing this general definition, CMS also has provided specific guidance on the retail or non-retail status of a number of entities in the Proposed Rule. The Proposed Rule is silent, however, as to the retail status of home healthcare pharmacies. Home healthcare pharmacies purchase drugs and provide them to patients who are being treated in their homes. These patients are part of the general public. As the proposed definition includes such entities in the retail class of trade, MedImmune urges CMS to clarify that home healthcare pharmacies are part of the retail pharmacy class of trade in the Final Rule.

3. CMS Should Clarify That Physicians Are Part of the Retail Pharmacy Class of Trade.

CMS provided a general definition of retail pharmacy class of trade in the Proposed Rule and specific guidance regarding the retail or non-retail status of a number of distinct entities. CMS did not, however, provide guidance regarding the retail status of the physician class of trade. For the reasons described below,

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[2] 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991) (Medicaid Rebate Agreement at I(a)); 71 Fed. Reg. at 77,179 ("We propose to incorporate the explicitly listed exclusions in section 1927 of the [Social Security] Act and in the national rebate agreement, which are direct sales to hospitals . . . .");Medicaid Drug Rebate Program Release #29 for Participating Drug Manufacturers (June 17, 1997).

[3] 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. pt. 447.504(h)(4)).

[4] Id. (proposed 42 C.F.R. pt. 447.504(g)(3)).

[5] Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).

MedImmune asks CMS to clarify that physicians are part of the retail pharmacy class of trade in the Final Rule.

MedImmune believes that physicians fit within the definition of wholesaler, and wholesalers are included in the retail pharmacy class of trade. The Proposed Rule defines a wholesaler as "any entity . . . to which the manufacturer sells, or arranges for the sale of, the covered outpatient drug, but that does not relabel or repackage the covered outpatient drug.[6] When a manufacturer directly or indirectly sells product to a physician, the physician is a wholesaler.

Physicians also satisfy the definition of retail pharmacy class of trade itself. CMS defined retail pharmacy class of trade as an "outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[7] Physicians purchase drugs from a manufacturer or wholesaler and dispense those drugs to their patients, who are members of the general public.[8] Physicians are not excluded from the retail pharmacy class of trade by any statute or regulation and as they satisfy both the definitions of retail pharmacy and wholesaler, CMS should clarify that physicians are part of the retail pharmacy class of trade.

4. CMS Should Clarify that Service Fees Paid to Group Purchasing Organizations Are Excluded from AMP and Best Price.

The Proposed Rule includes a definition for bona fide service fee and directs the inclusion in the calculation of AMP and BP of all administrative and service fees that do not meet this definition, regardless of whether the entity receiving the fee takes title to the drug.[9] This is a change from CMS' prior guidance, which has been that administrative and service fees are included in AMP and Best Price only to the extent that they are paid to an entity included in the AMP and Best Price calculations.[10]

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[6] Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(f)).

[7] Id. (proposed 42 C.F.R. pt. 447.504(e)).

[8] In this way, physician are like outpatient clinics, an entity included in the retail pharmacy class of trade, because anybody can make an appointment and be treated. See id. at 77,197 (proposed 42 C.F.R. pt. 447.504(g)(8)).

[9] 71 Fed. Reg. at 77,195, 77,197-98 (proposed 42 C.F.R. pts. 447.502, .504(i), .505(e)(1)). CMS adopted this same provision in the 2007 Physician Fee Schedule (PFS) Final Rule. See 71 Fed. Reg. 69,624, 69,666 (Dec. 1, 2006). In that context, CMS stated that it was "premature" to adopt specific guidance regarding the treatment of fees paid to pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) and indicated that it intended to study the matter further. Id. at 69,669.

[10] Medicaid Drug Rebate Program Release #14 for Participating Drug Manufacturers (Dec. 20, 1994).

The preamble to the Proposed Rule explains that this change is motivated by CMS' concern that administrative and service fees may affect the price at which the manufacturer makes a product available.[11] MedImmune recognizes this concern where the fee is paid to a purchasing entity, but urges CMS to clarify that fees paid to non-purchasers, and in particular group purchasing organizations (GPOs), remain exempt from the AMP and Best Price calculations, and need not be evaluated under the bona fide service fee definition. Fees that are paid to a non-purchaser by definition cannot affect the price at which a manufacturers sells its products and should be excluded from the calculations for that reason.

GPOs are organizations that negotiate contracts with manufacturers on behalf of their members, which are hospitals, clinics, and other healthcare providers. GPOs generally do not purchase drugs and therefore any fees paid to them are not price concessions and should not be included in AMP and Best Price. MedImmune recognizes that GPOs may choose to pass on to their member purchasers some portion of the fees received from a manufacturer, but where that passing on is not part of the GPO's arrangement with the manufacturer, it is inappropriate to conclude that the shared fees represent price concessions of the manufacturer. For these reasons, MedImmune urges CMS to clarify that service fees paid to GPOs are excluded from AMP and Best Price.

5. MedImmune Supports the Exclusion of Returned Goods from AMP.

In the Proposed Rule, CMS has included a provision excluding "[r]eturned goods when returned in good faith" from AMP.[12] As CMS explained in the preamble to the Proposed Rule, crediting returned goods back to the manufacturer in the quarter of sales or receipt caused difficulty when the effect of the return was to substantially reduce, or make negative, a drug's AMP.[13] Excluding returned goods from the AMP calculation will resolve this problem. It will also help ease the administrative burden of including such transactions. Therefore, MedImmune supports the exclusion of returned goods from AMP and asks CMS to retain this provision in the Final Rule.

6. MedImmune Supports CMS' Definition of Customary Prompt Pay Discounts and Asks CMS to Also Exclude Customary Prompt Pay Discounts from the Calculation of Average Sales Price.

One of the major changes imposed by the Deficit Reduction Act of 2005 (DRA) is that AMP now is to be used to calculate federal upper payment limits (FULs).[14] In consideration of the fact that AMP will be used to determine not only rebate

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[11] Id. at 77,180, 77,183

[12] Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(h)(13)).

[13] Id. at 77,181.

[14] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(a).

liability but also reimbursement rates, the DRA amended the Medicaid statute to exclude customary prompt payment discounts provided to wholesalers from the AMP calculation.[15] The rationale for doing so is that wholesalers generally do not pass on these discounts on to the retail pharmacy class of trade and thus these discounts should not affect the price used to determine the reimbursement rates for such entities.

As CMS is aware, average sales price (ASP) is used to calculate reimbursement rates in the Medicare context.[16] However, under the Medicare statute, prompt pay discounts are *included* in the calculation of ASP.[17] MedImmune contends that because ASP also is used as a reimbursement metric, customary prompt pay discounts provided to wholesalers should be excluded from the ASP calculation as well. Such an exclusion is consistent with the purpose of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to match reimbursement rates to the average price available to physicians. Therefore, MedImmune urges CMS to seek a legislative change to exclude customary prompt pay discounts from ASP.

The Proposed Rule includes a definition of customary prompt pay discounts to implement the statutory exclusion of such discounts from the AMP calculation. The definition is "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date."[18] MedImmune supports the use of the definition as it is currently worded and urges CMS to retain it in the Final Rule.

7. CMS Should Provide Additional Guidance Regarding the Treatment of Tricare Utilization in the Calculation of AMP.

The Department of Defense (DoD) changed its pharmacy benefit plan in 2004, creating the Tricare Retail Pharmacy Initiative (TRRx). In a letter issued by the Department of Veterans Affairs (VA), DoD claimed that sales through retail pharmacies pursuant to TRRx were depot sales and qualified for federal ceiling prices (FCP).[19] This allowed DoD to obtain rebates on TRRx utilization in an amount that ensured DoD's cost did not exceed the relevant FCP.[20] CMS previously has required manufacturers to exclude sales and rebates related to TRRx utilization from AMP and Best Price.[21]

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[15] See Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c)(1).
[16] Social Security Act § 1847A, 42 U.S.C. § 1395w-3a.
[17] Social Security Act § 1847A(c)(3), 42 U.S.C. § 1395w-3a(c)(3).
[18] 71 Fed. Reg. at 77,179, 77,196 (proposed 42 C.F.R. pt. 447.504(e)).
[19] See The Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs, 464 F.3d 1306, 1311 (Fed. Cir. 2006).
[20] Medicaid Rebate Program Release #69 for Participating Drug Manufacturers (May 13, 2005).
[21] Id.

The TRRx program was invalidated by the Federal Circuit in September 2006.[22] As a result, manufacturers are no longer paying rebates on TRRx utilization and DoD is refunding to manufacturers the rebates it received during the program's existence. Nonetheless, the Proposed Rule specifically defines Tricare as a depot sale and directs its exclusion from the calculation of AMP and Best Price.[23] As the DoD currently is not requiring the payment of rebates in relation to Tricare utilization, MedImmune asks CMS to clarify whether CMS continues to consider Tricare utilization to be a depot sale, and excluded from AMP and Best Price, even when no rebates are paid.[24]

If CMS directs the treatment of Tricare utilization as a depot sale even in the absence of rebate payments, MedImmune also asks CMS to provide additional guidance regarding the treatment of such utilization where manufacturers are unable to separately identify it. As noted above, manufacturers currently are not required to pay rebates on TRRx utilization and therefore DoD is not providing manufacturers with data that would enable manufacturers to identify and separately quantify that utilization. Accordingly, if CMS continues to consider Tricare utilization to constitute a depot sale even in the absence of rebate payments, MedImmune asks CMS to clarify that Tricare utilization does not have to be excluded from AMP and Best Price when the manufacturer is unable to identify it as such.

8. CMS Should Adopt the ASP Methodology for Smoothing Lagged Price Concessions to Calculate Monthly AMP and Adopt the Same Methodology, or a Weighted Average of the Monthly AMPs, for Calculating Quarterly AMP.

Section 6001(b) of the DRA requires monthly reporting of AMP.[25] This requirement is in addition to the mandatory quarterly reporting previously in place.[26] In 2004, after much consideration and effort, CMS adopted a methodology for calculating lagged price concession in ASP quarterly reports.[27] This methodology has been subject to formal review through notice and comment rulemaking and currently is used by manufacturers of drugs covered by Medicare Part B. Allowing manufacturers to use the same methodology for smoothing lagged eligible price concessions in the monthly AMP calculation will reduce the administrative burdens, risk of error, and complexity of such calculations. For these reasons, and the reasons outlined below, MedImmune urges CMS to adopt the ASP methodology for smoothing lagged eligible price concessions for the

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[22] The Coalition for Common Sense in Government Procurement, 464 F.3d at 1318.
[23] 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. pts. 447.504(h)(3), .505(d)(4)).
[24] MedImmune notes that there should be no need to recalculate prior quarter AMP to include Tricare utilization as treatment in prior quarters conformed to CMS' guidance at the time.
[25] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(b).
[26] See 71 Fed. Reg. at 77,185.
[27] 69 Fed. Reg. 55,763 (Sept. 16, 2004) (codified at 42 C.F.R. pt. 414.804(a)(3)).

monthly calculation of AMP, and also to permit the use of this same methodology, or a weighted average of the monthly AMPs, for calculating quarterly AMP.[28]

Monthly Reporting

The ASP smoothing methodology for lagged eligible price concessions, as adapted for use in the monthly calculation of AMP, would begin by deriving the 12-month rolling average ratio of AMP-eligible price concessions to the AMP-eligible sales. This ratio then would be applied to the AMP-eligible sales in the reporting month to derive the estimate of the lagged eligible price concessions for that same period. CMS already has approved the use of this methodology in the context of another price that is used to determine reimbursement rates, ASP, and therefore MedImmune believes it is appropriate to use this methodology for AMP as well, given its new use as a reimbursement metric.

Should CMS permit the use of the ASP smoothing methodology, MedImmune urges CMS to permit manufacturers to update the smoothing ratio on a quarterly rather than monthly basis, such that the ratio for the most recent 12-month period that precedes the first month in a quarter would be applied in the monthly AMP calculation for each month in that quarter. For example, a manufacturer would derive a ratio based on the period January through December 2006 and apply that ratio to each of the monthly AMP calculations for January, February, and March 2007. For the three months in the second quarter of 2007, the manufacturer would update that ratio to reflect the data for the period April 2006 through March 2007.

This approach decreases the complexity of the monthly calculation, because the ratios will not need to be updated on a monthly basis. This is a significant concern to MedImmune, as the advent of the new monthly reporting requirement significantly increases the operational burden and complexity of these calculations, such that any approach that limits such complexity without decreasing accuracy is one that should be adopted. To that end, MedImmune believes this approach increases accuracy because it permits manufacturers to use quarterly rather than monthly data to derive the ratios, and as quarterly data typically are subject to greater validation than monthly data, this approach also is likely to yield a more accurate result. Finally, this approach is advisable given the use of AMPs to set reimbursement rates, as the use of a single ratio for each month in a quarter will limit the likelihood of significant fluctuations in those figures. For all of these reasons, MedImmune urges CMS to permit use of the ASP smoothing methodology for lagged eligible price concessions in the monthly calculation of AMP and to

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[28] In the 2007 Physician Fee Service (PFS) Final Rule, CSM specifically declined to adopt a smoothing methodology for lagged ineligible sales. To the extent that CMS approves use of the ASP methodology for calculating lagged eligible price concessions for monthly and quarterly AMP, MedImmune asks CMS to clarify that manufacturers may use whatever methodology they currently use in the ASP context to determine lagged ineligible sales in the AMP context as well.

permit manufacturers to update the ratio used in that methodology on a quarterly rather than a monthly basis..

Quarterly Reporting

MedImmune also urges CMS to permit manufacturers to apply the ASP smoothing methodology in the calculation of quarterly AMPs, or in the alternative, to permit manufacturers to derive quarterly AMPs from a weighted average of monthly AMPs. In either case, manufacturers would be under no obligation to update quarterly AMP figures to reflect late-arriving data because such data would be accounted for through the use of the ASP smoothing methodology. This approach again would decrease the complexity of these calculations, as manufacturers would be able to account for lagged data in the same way for both their monthly and quarterly calculations, and also result in significant administrative savings to manufacturers as well as CMS and the States, all of which would benefit from a sharp decline in the amount of prior period adjustments needed. Manufacturers still would be obligated to correct quarterly AMPs in the cases of errors, as well as to restate Best Price for late-arriving data, but the amount of prior period adjustments still would decline significantly. MedImmune therefore urges CMS to allow manufacturers to adopt one of these approaches in their calculation of quarterly AMP.

9. CMS Should Clarify a Number of Issues Related to Recalculating Base Date AMP.

CMS recognized in the Proposed Rule that the prospective changes to the definition of AMP mandated by the DRA and included in the Proposed Rule could affect the additional rebate component of the unit rebate amount, which is calculated by comparing a "base date" AMP with the current quarter's AMP.[29] To prevent additional rebate amounts from increasing artificially due solely to these definitional changes, CMS has proposed to allow manufacturers to recalculate base date AMP so that it conforms with this new definition.[30] MedImmune supports this decision but asks CMS to clarify a number of issues related to recalculating base data AMP.

CMS has stated that it is giving manufacturers the "option" to recalculate base date AMP because CMS is "aware that some manufacturers may not have the data needed to recalculate base date AMP or may find the administrative burden to be more costly than the savings gained."[31] In accordance with this statement, CMS should clarify that manufacturers retain complete discretion to determine whether or not to recalculate base date AMP and may choose not to do so even if they have

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[29] 71 Fed. Reg. at 77,185.
[30] Id.
[31] Id.

the necessary data available. The availability of data and the balance of costs and benefits from recalculation likely will vary among a manufacturer's products, and so CMS also should clarify that the decision to recalculate may be made as to each product individually. Finally, as manufacturers may have changed their AMP calculation methodology since a given product's base date AMP quarter, and will need to change that methodology further to comply with the Final Rule, MedImmune also requests CMS to clarify that manufacturers that do choose to recalculate are to use their current AMP methodology when doing so, inclusive of the Final Rule requirements.

The Proposed Rule states that recalculated base date AMPs are to be submitted with the submission for the first full quarter after the publication of the Final Rule.[32] That submission necessarily will occur after the January 2007 effective date for statutory changes to the calculation of AMP.[33] For the intervening quarters, there is strong likelihood that additional rebates will increase due to the statutory changes to AMP. MedImmune therefore asks CMS to clarify that it will apply any revised base date AMPs to those intervening quarters and recalculate rebate liability beginning with the first quarter of 2007.

10. CMS Should Confirm That Data Reported on a Quarterly Basis Will Remain Confidential.

The Medicaid rebate statute provides that information submitted by manufacturers pursuant to reporting requirements must be kept confidential.[34] Section 6001(b)(2)(C) of the DRA amends the confidentially requirements of the rebate statute by requiring that the Secretary make AMPs publicly available on a monthly basis.[35] This provision does not affect the confidentiality of Best Price, customary prompt pay discounts, and nominal price data, which are reported to CMS on a quarterly basis, or of unit rebate amounts. MedImmune urges CMS to make clear in the Final Rule that this data will remain confidential.

MedImmune understands that monthly AMP is being made available to States so that States may refer to that information in setting reimbursement rates but urges CMS to refrain from making quarterly AMPs publicly available. In the Proposed Rule, CMS stated that it intends to make quarterly AMP available because the DRA "does not specify that the [confidentiality] exception only applies to monthly AMP."[36] MedImmune contends that only monthly AMP should be made available as the DRA provides that "the Secretary shall provide *on a monthly basis*

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[32] 71 Fed. Reg. at 77,185.
[33] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001.
[34] Social Security Act § 1927(b)(3)(D), 42 U.S.C. §1396r-8(b)(3)(D).
[35] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(b)(2)(C).
[36] 71 Fed. Reg. at 77,186.

to States . . . the most recently reported average manufacturer prices."[37] Unlike monthly AMP, which may be used to set reimbursement rates, there is no need for the public to have access to quarterly data, and, as CMS noted, "quarterly AMP would not necessarily be identical to the monthly AMP due to the potential differences in AMP from one timeframe to the next."[38] Because there is no need to publish quarterly AMP and because doing so may cause confusion, MedImmune asks CMS to revise its position and keep quarterly AMP confidential.

If CMS retains the provision in the Proposed Rule making quarterly AMP publicly available, MedImmune asks CMS to adopt the same smoothing methodology for the calculation of monthly and quarterly AMP to ensure that there is consistency between the two figures.

11. CMS Should Calculate Federal Upper Limits Using the 11-digit National Drug Code.

As previously noted, the DRA amended to the Medicaid drug statute to provided for the calculation of FULs using AMP.[39] Currently, AMP is reported by the nine-digit National Drug Code (NDC). In the Proposed Rule CMS stated that it intends to continue to use AMP reported at the nine-digit NDC level to calculate FULs but asked for comments on the alternative approach of using an 11-digit NDC instead.[40] MedImmune supports calculating FUL at the 11-digit NDC for the reasons described below.

The rationale for calculating AMP at the NDC-9 level for rebate purposes is based in the fact that rebates are paid at the dispensed unit level and such units all share the same NDC-9. When used for reimbursement however, MedImmune is concerned that an AMP calculated at the NDC-9 level could result in reimbursement rates that do not account for significant purchase price disparities between different package presentations. The Proposed Rule itself also describes a number of benefits from calculating FULs at an 11-digit, rather than nine-digit, NDC level:[41] Reimbursement rates would be set by the most common package size without causing significant computational difficulties while at the same time providing valuable information about AMP for different package sizes; AMP would correlate with State Medicaid drug payments, which are computed at the 11-digit level; and using the 11-digit NDC for AMP calculation would increase transparency. For all of these reasons, MedImmune urges CMS to calculate FULs using the 11-digit NDC.

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[37] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(b)(2)(C).
[38] 71 Fed. Reg. at 77,186.
[39] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(a)(2).
[40] 71 Fed. Reg. at 77,187.
[41] See Id.

12. MedImmune Writes in Support of a Number of Positions Taken by the Biotechnology Industry Organization

As a manufacturer of biological products, MedImmune is a member of the Biotechnology Industry Organization (BIO) and fully supports those comments that BIO itself submits regarding the Proposed Rule. MedImmune, however, also wishes to note its particular support of BIO's comments regarding patient coupons – that such transactions should be excluded from AMP and Best Price because they do not affect the price of a drug; certification – that the certification requirement for AMP and Best Price should take into consideration the "knowledge" element of the Medicaid civil money penalty provision; proportionality of Medicaid rebates – that manufacturer rebate liability should be proportional to State Medicaid expenditures when Medicaid is a secondary payor; and time limits on State rebate claims – that CMS should implement the statutory time limit on State submission of rebate claims. MedImmune urges CMS to adopt BIO's position on these critical issues.

Conclusion

MedImmune thanks you for the opportunity to comment on these very important issues and hopes that CMS will take the above comments and suggestions into consideration when finalizing the Proposed Rule. We look forward to publication of a Final Rule that addresses the concerns of manufacturers, States, and CMS and that, most importantly, ensures that patients continue to have access to the drugs that they need.

If you have any questions or would like any additional information on these or any other related topics, please contact me directly at 301-398-4447.

Sincerely,

Caroline York
VP, Reimbursement, Strategic Pricing
and Government Price Reporting

Submitter : kevan page **Date:** 02/20/2007

Organization : Kash and Karry Pharmacy, LLC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

As a new pharmacy onwer I would like to take a moment to comment on the medicare reimbursement reductions tha will take place on July 1st. As a new owner it is very disturbing to read about the cuts. As of now reimbursement rates have already been drastically cut and further cuts seems unbelievable. If this happens not only will our business suffer but well being of our customers will be affected. I am a business man and from a business stand point this will be detramental. More importantly i am a healthcare provider and as a result of these proposed cuts our patients will suffer. As an indepentent community pharmacy we are here to service and care for a community. Many patients depend on their local pharmacy to provide that continuety of care that begins in the physicians office. I would like to strongly urge CMS to take a long look at the proposed cuts and reevaluate these actions. I strongly hope that these changes will not become a reality, as I feel that not only will our business suffer, but our patient care services will fall by the waste side.

Thank you,

Kevan Page PharmD
Kash and Karry Pharmacy
Greenville SC

Submitter : Dr. Rod Wirsching **Date:** 02/20/2007

Organization : Grant Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-2238-P-1257-Attach-1.PDF

1257

February 16. 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 Grant Medical Center, an OhioHealth hospital located in downtown Columbus, Ohio, I am responding to the request for comments on proposed changes to the Deficit Reduction Act of 2005 (DRA) that appear in the December 22, 2006 Federal Registrar. Grant Medical Center is faith-based, not-for-profit 640 licensed bed facility that qualifies as a disproportionate share hospital (DSH) under the Medicare program. Grant Medical Center is currently enrolled as a covered entity under the federal 340B drug discount program.

My concerns as a DSH facility Director of Pharmacy include mandatory NDC reporting for medications administered at our outpatient facilities, average manufacturer price (AMP) impact on 340B formula pricing, and rebate requirements for outpatient clinic drugs. While the changes included in the DRA provide a way to ensure that Medicaid rebates are collected, Grant Medical Center is not able to readily provide NDC information without incredible hardship. The proposed regulations would create administrative and financial burdens associated with reporting NDC information on drugs administered in out outpatient clinics. Our hospital computer systems (pharmacy and billing) are not able to report or track this level of complexity, meaning that this new requirement would necessitate the purchase of a new information system or the establishment of a redundant manual billing system.

The proposed regulations would also decrease the nearly $250,000 savings realized annually by participating in the 340B program, to the extent that the new rules may result in State imposing manufacture rebate obligations on hospital outpatient clinic drugs. Rules relating to the treatment of prompt pay discounts in computing AMP could increase the price we pay for outpatient drugs by adversely affecting the formula for calculating 340B prices.

Overall the proposed changes would negatively impact the central Ohio patient population by decreasing the number of indigent patients served, increasing the price of medications for patients, possibly limiting the number of drugs on formulary, and limiting other services offered by Grant Medical Center.

We hope you will give serious consideration to the issues described above that will lead to the clarification and revision of the proposed regulations published December 22, 2006.

Sincerely,

Rodney G. Wirsching, PharmD., FASHP
Director of Pharmacy

Submitter : Mrs. BARBARA TAYLOR **Date:** 02/20/2007

Organization : TULLAHOMA DRUG STORE INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I AM A PHARMACIST IN AN INDEPENDENT STORE IN TENNESSEE. I HAVE NEVER BEEN AS SCARED OF LOSING MY BUSINESS AS I AM NOW WITH THIS NEW PROPOSAL FOR PHARMACY REIMBURSEMENT. PLEASE CONSIDER THESE OPTIONS.
1.A MINIMUM DESPENSING FEE BASED ON NATIONAL ANNUAL INDEPENDENT ANALYSIS FOR COST OF DISPENSING .
2.PLEASE TELL US THE REAL AMP
3.CONSIDER PBMS REBATES, DISCOUNTS, ETC. WHEN CALCULATING AMP
4.USE 11 DIGIT NDC TO CALCULATE FUL
5.ALLOW INDEPENDENT PHARMACIES TO PROVIDE THE PROFESSIONAL CARE THE MEDICARE PATIENTS DESERVE.

Submitter : Dr. KEVIN EVETTS **Date:** 02/20/2007

Organization : THE MEDICINE SHOPPE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

2/20/2007

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 on 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,

KEVIN EVETTS
920 ESTATE DRIVE
MEMPHIS TENNESSEE 38119

THE MEDICINE SHOPPE PHARMACY

CMS-2238-P-1260

Submitter : Ms. Ann Berkey **Date:** 02/20/2007

Organization : McKesson Corporation

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see McKesson's attached comments on the proposed rule. Thank you!

CMS-2238-P-1260-Attach-1.PDF

1260

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Senior Vice President
Public Affairs

[redacted]

McKESSON

February 20, 2007

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-2238-P

Dear Ms. Norwalk:

On behalf of McKesson Corporation (hereinafter "McKesson"), I am submitting comments to the Centers for Medicare and Medicaid Services (CMS) on the Medicaid Program; Prescription Drugs: Proposed Rule CMS-2238-P.

For over 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 16 corporation, we deliver vital medicines, medical supplies, care management services, automation, and health information technology solutions that touch the lives of over 100 million patients in healthcare settings that include more than 25,000 retail pharmacies, 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities and 700 home care agencies. McKesson also supplies pharmaceuticals to the entire Department of Veterans Affairs system, as well as to a significant number of Department of Defense and other government facilities.

McKesson is the largest pharmaceutical supply management and health information technology company in the world. Through our recent acquisition of Per-Se Technologies, McKesson is now connected to more than 90% of U.S. pharmacies, and we process approximately 70% of all electronic pharmacy transactions. In that capacity, we also serve as the CMS contractor of TrOOP administration for the Medicare Part D prescription drug benefit.

McKesson was the innovator of electronic prescription coupon programs over 10 years ago with the development of the TrialScript® program, the first alternative sampling program of its kind. Since then, more than 30 million TrialScript transactions, through the participation of over 55,000 pharmacies and 556,000 physicians, have saved millions

of patients more than $400 million annually by providing free or reduced cost access to trial supplies of prescribed medications. Today, McKesson administers over 140 electronic sampling and prescription discount programs, including coupons, rebates, vouchers and discount cards.

Our perspective on the proposed rule is based on our commitment to providing a safe, secure and efficient supply chain for our nation's pharmaceutical products and to ensuring that our pharmacy customers are appropriately and adequately reimbursed for providing needed medications and pharmaceutical therapy to Medicaid patients.

Summary of McKesson Recommendations

As a member of the Healthcare Distribution Management Association (HDMA), McKesson endorses the association's recommendations on this proposed rule and offers the following additional comments on those issues that are most critical to our operations and our customers. Our specific comments are detailed by section; however, we want to emphasize and highlight the following recommendations as critically important to the successful implementation of a final rule:

- ***Refine Average Manufacturer Price (AMP) methodology***
  - Establish the Federal Upper Limit (FUL) based on the weighted average AMP of the therapeutically equivalent products available in the market;
  - Calculate AMPs based on the 11-digit NDC;
  - Reduce variability with a 12-month rolling percentage methodology for lagged data;
  - Postpone the publication of AMP data pending implementation of the Final Rule;

- ***Limit the definition of retail pharmacy class of trade to those channels that are available to the "general public"***
  - Exclude sales to mail order pharmacies;
  - Exclude rebates to Pharmacy Benefit Managers (PBMs);
  - Exclude *all* sales to hospitals;

- ***Clarify the definition and treatment of bona fide service fees*** to ensure consistency with the calculation of the Average Sales Price (ASP) reimbursement methodology;

- ***Exclude customary prompt pay discounts*** from the calculation of Best Price as well as from AMP;

- ***Exclude from AMP and Best Price all manufacturer coupons redeemed by a consumer,*** including electronic programs administered at the point of sale in retail pharmacies;

- ***Confirm the definition of Retail Survey Price (RSP) as stated in the Deficit Reduction Act (DRA) of 2005*** and encourage states to use RSP as an alternative methodology that reflects the average consumer purchase price at retail pharmacies; and

- ***Conform the definition of wholesaler*** to the definitions in the Prescription Drug Marketing Act and FDA regulations thereunder.

We are pleased to provide detailed comments to CMS on the following sections of the proposed rule.

Provisions of the Proposed Regulations

Definitions – Section 447.502

Bona Fide Service Fee

McKesson endorses the definition of "*bona fide* service fee" in the proposed regulations codifying the methodology for calculating AMP and determining Best Price that is identical to the definition included in the Medicare regulations codifying the methodology for calculating ASP. To further assure consistency and operational clarity, we recommend the following:

- In the preamble to the Final Rule, CMS should provide an overview of the types of payments for bona fide service fees that would be acceptable for exclusion from the AMP calculation at this time, but allow for manufacturers and contracting entities to make future interpretations based on the needs of the marketplace. To allow for this flexibility and for innovations to occur in a highly competitive marketplace, the attached list of wholesaler services compiled by HDMA should not be considered as all-inclusive or limiting in any way.

By providing this list in the preamble to the Final Rule, CMS would limit potential inconsistencies by manufacturers, who may otherwise continue to adopt varying interpretations of the types of services for which fees should be excluded. Such a list will help ensure that fees paid by manufacturers to wholesale distributors are treated uniformly in the AMP calculations.

Dispensing Fee

McKesson commends CMS for including a definition of dispensing fees in the proposed rule; however, we remain concerned that states may not fully incorporate and account for the actual cost of dispensing services in establishing the new AMP-based FULs. In addition to reflecting reasonable costs of dispensing, dispensing fees should also be viewed as compensating the pharmacist for professional services associated with counseling providers, prescribers and patients on drug safety, effectiveness, compatibility and cost. Because this proposed rule intends to assure appropriate reimbursement for Medicaid prescriptions, McKesson recommends that the definition of dispensing fee explicitly include the need to incorporate pharmacists' "professional fees" to ensure that the professional services of the pharmacist are considered and included by state programs in setting their dispensing fees.

Many organizations have documented the cost of dispensing a drug in national dispensing cost surveys, including the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA). A January 2007 study,

conducted by the accounting firm, Grant Thornton, on behalf of the Coalition for Community Pharmacy Action (CCPA), documents a mean dispensing cost of $10.50 per prescription. This figure stands in stark contrast to the average dispensing fee paid by Medicaid, which reimburses pharmacies on average approximately $4.50. We suggest that CMS use these reference studies as a guide to appropriately evaluate the cost of dispensing a drug. Additionally, we urge CMS to closely examine states' new reimbursement formulas to ensure that states have appropriately included the costs and associated services in their definition of dispensing fees, including a reasonable return for a retail pharmacy.

National Drug Code

McKesson recommends that the final regulation stipulate that manufacturers must calculate and report AMP at the 11-digit NDC level. The 11-digit NDC is the universally used industry standard which differentiates among specific package forms and sizes. Utilizing 9-digit NDC codes could result in an AMP that is based on package forms not customarily used in a retail pharmacy or bulk package sizes that are uneconomical for, and therefore not generally purchased by, a retail pharmacy. Additionally, the ASP regulations require manufacturers to calculate and report ASPs based on the 11-digit NDC. In order to base reimbursement on package forms and sizes appropriate for retail pharmacies and to assure consistency with the universal industry standard, we recommend that CMS require use of the 11-digit NDC for purposes of calculating and reporting AMP.

Determination of Average Manufacturer Price – Section 447.504

Mail Order

McKesson strongly recommends that sales to mail order pharmacies be excluded from the definition of retail pharmacy class of trade, which would be consistent with the CMS position to exclude sales to managed care entities and HMOs from the retail pharmacy class of trade. We believe that sales to mail order pharmacies should be treated in the same fashion as sales to long-term care (LTC) pharmacies, which CMS has also excluded from the definition of retail pharmacy class of trade. Neither mail order nor LTC pharmacies serve the acute care pharmacy needs of consumers; they do not fill prescriptions for immediate and same day use; and, they are not accessible to the general public. Additionally, mail order pharmacies typically fill and are reimbursed for 90-day prescriptions. Traditional retail pharmacies do not have access to the discounts and rebates offered to mail order and are not reimbursed for prescriptions filled for a supply greater than 30 days.

PBM Rebates, Discounts and Other Price Concessions

We recommend that PBM rebates, discounts, or other price concessions be excluded from the calculation of AMP. We believe that it is inappropriate to include such PBM price concessions in the calculation of AMP for the following reasons:

- We concur with the CMS "general public" standard, which is used to determine channels within the retail pharmacy class of trade. As CMS has noted in the proposed rule, PBMs do not meet this standard. Patients have to belong to a

specific health plan in order to access drugs through a particular PBM. Consequently, discounts and rebates to PBMs are not typically available to the "general public".

- Discounts and rebates offered to PBMs typically are based on relationships between the PBM and a Health Maintenance Organization (HMO) or, more generally, a Managed Care Organization (MCO). Given that CMS is proposing to expressly exclude rebates and discounts to HMOs and MCOs from the calculation of AMP, we believe that rebates and discounts to their associated PBMs should be excluded as well.

- PBM rebates and discounts are rarely, if ever, passed on to pharmacists. Therefore, pharmacists may be adversely and inappropriately affected if PBM rebates and discounts are included in the calculation of AMP.

Retail Pharmacy Class of Trade

We concur with CMS that the retail pharmacy class of trade is characterized by public access. Independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarkets are all pharmacies that are "open to the public". Mail order pharmacies and PBMs are not accessible to the general public and should be excluded from the retail pharmacy class of trade.

Customary Prompt Pay Discounts

McKesson applauds CMS for excluding from the calculation of AMP the customary prompt pay discounts extended to wholesalers. Since the term "cash discounts" is used interchangeably with "customary prompt pay discounts" in the industry, we further encourage the agency to combine the two terms into "customary prompt pay discounts/cash discounts".

Definition of Wholesaler

McKesson strongly recommends that CMS adopt the definition of wholesaler as outlined in the Prescription Drug Marketing Act (PDMA). The definition of wholesaler is overly broad in the proposed rule and should exclude PBMs. PBMs are administrative service organizations that provide prescription drug benefits to health plans and MCOs on a contractual basis. PBMs do not perform wholesaler functions and should not be considered wholesalers. Specifically, we suggest the definitions of "wholesaler", "wholesale distribution" and "distribute" be consistent with the FDA regulations implementing the PDMA.

Outpatient Hospital Sales

For both policy and operational reasons, McKesson strongly recommends that *all* sales to hospital pharmacies be excluded from the calculation of AMP. Outpatient hospital pharmacies fill prescriptions for hospital employees and the initial prescriptions for patients who have undergone outpatient procedures; the general public typically has no access to these types of pharmacies. The proposed rule would *include* such outpatient sales – and *exclude* inpatient hospital sales – from the AMP calculation. This distinction would create an administratively impractical requirement that would force hospitals to maintain separate inventories of pharmaceutical products for inpatient and outpatient use.

Manufacturer Coupons

McKesson strongly supports the language of the proposed rule which specifies that manufacturer coupons redeemed by a consumer should be excluded from AMP as well as from Best Price. These programs provide a direct benefit to the consumer and do not affect prices paid by the retail pharmacy class of trade.

While McKesson supports the coupon exclusion, we request clarification regarding the scope of the term "coupon" in the language of the proposed rule, particularly in light of CMS' statement that it "believe[s] that the redemption of coupons by the consumer *directly* to the manufacturer is not included in the retail pharmacy class of trade." [Emphasis added] Electronic sampling and prescription discount coupons, rebates, cards, vouchers, and similar programs function as technologically advanced versions of a manufacturer mail-in coupon redeemed by a consumer. As in the case of standard manufacturer coupons, these electronic programs are all structured to provide direct savings to the consumer from the manufacturer. Accordingly, although adjudicated in real time at the point of sale, these programs do not entail any economic relationship between the retail pharmacy and the manufacturer.

It is McKesson's position that alternative sampling and prescription discount coupons, cards, vouchers, rebates, and similar programs *which are redeemed by or on behalf of the consumer* should all be excluded from the Best Price and Average Manufacturer Price calculations. We urge CMS to clarify that these alternative sampling and prescription discount programs are a "coupon" for purposes of exclusion from both AMP and Best Price calculations.

Electronic sampling and prescription discount programs provide a safe and effective alternative to the distribution of free drug samples in a physician's office. Without clarification, we expect that manufacturers will be reluctant to continue these kinds of electronic programs. A major benefit of these programs is the coordination of both the physician and the pharmacist in the patient's care. Unlike traditional samples given out at the physician's office, electronic sampling and discount programs allow a pharmacist to provide drug utilization review for potential harmful interactions, therapeutic duplication, and adverse reactions. As a result, these programs promote enhanced patient safety and provide a direct benefit to the consumer.

Determination of Best Price – Section 447.505

Customary Prompt Pay Discounts

We applaud CMS for excluding customary prompt pay discounts/cash discounts from the calculation of AMP, as specified in the DRA, and urge the agency to exclude customary prompt pay discounts/cash discounts from Best Price as well. Congress explicitly excluded prompt pay discounts from AMP, where such terms could have a material effect on the calculation.

We believe that customary prompt pay discounts/cash discounts should also be excluded from Best Price. As written in the proposed rule, manufacturers would have to treat customary prompt pay discounts/cash discounts differently when calculating AMP versus

Best Price. Prompt pay discounts average 2-3% and will not be material enough to establish a new Best Price. Therefore, we urge CMS to use its regulatory authority to require consistent treatment of customary prompt pay discounts/cash discounts by excluding them from the calculation of *both* AMP and Best Price.

PBM Rebates, Discounts and Other Price Concessions

McKesson recommends that CMS exclude PBM price concessions from the calculation of Best Price for the same reasons that PBM rebates, discounts and other price concessions should be excluded from the calculation of AMP. As previously stated, PBM price concessions are not available to, nor do they impact prices paid by, the retail pharmacy class of trade.

Administrative, Service and Distribution Fees

McKesson recommends that administrative and distribution fees be excluded from the calculation of Best Price. As the proposed rule provides, manufacturers should exclude all payments or fees for bona fide services from the calculation of Best Price. In the Final Rule, we urge CMS to clarify that administrative and distribution fees qualify as bona fide service fees as long as the base criteria for bona fide services are met. Further, we recommend that fees for all bona fide services performed on behalf of a manufacturer should be excluded from Best Price.

Manufacturer Coupons

As we have previously stated, McKesson strongly supports the language of the proposed rule which specifies that manufacturer coupons redeemed by a consumer should be excluded from AMP and from Best Price. These programs provide a direct benefit to the consumer and do not affect prices paid by the retail pharmacy class of trade.

While McKesson supports the coupon exclusion, we request clarification regarding the scope of the term "coupon" in the language of the proposed rule, particularly in light of CMS' statement that it "believe[s] that the redemption of coupons by the consumer *directly* to the manufacturer is not included in the retail pharmacy class of trade." [Emphasis added] Electronic sampling and prescription discount coupons, rebates, cards, vouchers, and similar programs function as technologically advanced versions of a manufacturer mail-in coupon redeemed by a consumer. As in the case of standard manufacturer coupons, these electronic programs are all structured to provide direct savings to the consumer from the manufacturer. Accordingly, although adjudicated in real time at the point of sale, these programs do not entail any economic relationship between the retail pharmacy and the manufacturer.

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Requirements for Manufacturers – Section 447.510

Monthly AMP Calculation Methodology

To assure that AMP calculations generate sensible and practical results, McKesson recommends that CMS propose and adopt a smoothing methodology, such as a 12-month rolling percentage methodology, for manufacturers to use in reporting AMP. This methodology is necessary to account for data, such as discounts, rebates, chargebacks and other price adjustments, that may be delayed or otherwise "lag" if AMP is to be calculated on a monthly basis. Absent such a methodology, the calculations of AMP will vary significantly from month to month, and generate confusion in the marketplace.

Posting of AMP Data

To ensure that data accessible to the public is accurate, McKesson recommends that the public disclosure or reporting of AMP data not occur until after the regulations have been fully implemented. A delay in the publication of AMP data will provide both manufacturers and CMS with the time necessary to address and adjust for any variations in the quality and consistency of AMP calculations.

Upper Limits for Multiple Source Drugs – Section 447.514

FULs Representative of the Most Commonly Purchased Package Size

McKesson strongly recommends that CMS base the reimbursement metric for Federal Upper Limits (FULs) on the 11-digit NDC, which is used to differentiate among specific package forms and sizes. Utilizing 9-digit NDC codes could result in an AMP that is based on package forms not customarily used by retail pharmacy or bulk package sizes that are uneconomical for, and therefore not generally purchased by, retail pharmacies. As CMS stated in the proposed regulation, using the 11-digit NDC "would also align with State Medicaid drug payments that are based on the package size." Therefore, in order to base reimbursement on package forms and sizes appropriate for retail pharmacies and to assure consistency with state Medicaid drug payment calculations, we recommend that CMS require use of the 11-digit NDC for purposes of calculating and reporting AMP.

National Drug Code

McKesson recommends that the final regulation require manufacturers to calculate and report AMP at the 11-digit NDC level. The 11-digit NDC is the universally used industry standard. The ASP regulations require manufacturers to calculate and report ASPs based on the 11-digit NDC; therefore, to ensure consistency, we recommend that CMS require use of the 11-digit NDC for purposes of calculating and reporting AMP.

Eliminating Outliers from FUL Calculations

In lieu of an outlier methodology, McKesson strongly recommends that the Final Rule should set FULs based on the weighted average AMP of the therapeutically equivalent products available in the market, and not the AMP of the least costly product. This metric is based on the unit volume reported by manufacturers and most appropriately represents the price paid for drugs in a therapeutic class based on their availability. By utilizing this approach, CMS would avoid basing AMP on any of the following: regional pricing that may not be widely available for a specific product, fire sale pricing on short dated products, and prices that are not sustainable over a consistent period of time.

The table below depicts weighted average price based on unit volume for five therapeutically equivalent products across manufacturers.

Weighted Average AMP:

Product at the 11-Digit Equivalents	AMP	Unit Volume	Sales
A	$ 2.00	100	$200
B	$ 4.00	200	$800
C	$ 6.00	200	$1,200
D	$ 8.00	280	$2,240
E	$ 9.00	220	$1,980
Total		1,000	$6,420

Lowest AMP = $2.00
Weighted Average AMP = Sales ÷ Unit Volume = $6.40

Alternatively, rather than using the lowest AMP with a provision for price outliers to set FUL for a product class, we recommend that CMS use a different outlier to reflect a reasonable market share threshold. This approach is intended to help ensure that the price is based on product that is widely available in the marketplace. Specifically, we recommend that manufacturers report AMPs at the 11-digit level with their respective unit volume. The Final Rule should include an FUL outlier methodology that examines AMPs on a cumulative market share basis, starting with the lowest AMP, then the next highest and so on, rejecting AMPs until a cumulative market share of 50% has been reached. This approach would allow CMS to set FULs based on a criterion that distinguishes between low-priced NDCs available only on a limited basis and NDCs priced at true market levels and available in quantities sufficient to satisfy retail pharmacy demand. Absent such a "market share" approach, it is likely that the FUL will be established using pricing data that is not widely available.

To illustrate this approach, tables 1 and 2 compare AMPs and unit volume for five therapeutically equivalent products at the 11- digit NDC level. The table is sorted from lowest to highest AMP. Each product's market share is calculated based on the product's respective unit volume compared to total unit volume in the therapeutic class. Cumulative market share is then determined at each level of AMP.

Market Share-Based AMP: Example 1

Product at the 11-Digit Equivalent	AMP	Unit Volume	Market Share	Cumulative Market Share
A	$ 2.00	100	10%	10%
B	$ 4.00	200	20%	30%
C	$ 6.00	200	20%	50%
D	$ 8.00	280	28%	78%
E	$ 9.00	220	22%	100%
Total		1,000	100%	

Lowest AMP = $2.00
Market Share-based AMP = $6.00 (lowest AMP at 50% cumulative market share)

Market Share-Based AMP: Example 2

Product at the 11-Digit Equivalent	AMP	Unit Volume	Market Share	Cumulative Market Share
A	$ 3.00	100	10%	10%
B	$ 3.50	150	15%	25%
C	$ 4.25	200	20%	45%
D	$ 5.00	200	20%	65%
E	$ 9.00	350	35%	100%
Total		1,000	100%	

Lowest AMP = $3.00
Market Share-based AMP = $5.00 (lowest AMP at 50% cumulative market share)

Both tables illustrate the merits of this methodology, which reflects a sustainable AMP on widely available product at a 50% cumulative market share.

As the agency is aware, the AMP-based reimbursement metric is critical to the pharmacy community. Therefore, we urge CMS to include an appeals mechanism in the Final Rule. Such a mechanism would allow providers, manufacturers and states to have an opportunity to review and seek removal or modification of an FUL which is not consistent with rapidly-changing market conditions or the goal of the program.

Retail Survey Price

As we have expressed in this letter, McKesson remains concerned that the use of AMP, even if defined as we have recommended, is likely to reduce reimbursement for pharmacies and pharmacists and potentially jeopardize access to prescription drugs for Medicaid patients. As an alternative, McKesson urges CMS to consider and further explore Retail Survey Price (RSP) as an appropriate reimbursement metric.

In late 2005, our industry proposed RSP as an alternative reimbursement methodology. RSP has been defined as the nationwide average of consumer purchase prices, net of all discounts and rebates, for prescription drugs from the retail pharmacy. RSP was intended to reflect the "out-the-door cost" of the ingredient, distribution and pharmacy costs of a prescription drug from manufacturer to patient in a retail pharmacy. As a result of Congressional interest in an alternative to AMP, the DRA included a requirement that CMS determine retail survey prices and provide the information to states on at least a monthly basis.

We understand that CMS has already issued a contract to a vendor to conduct the RSP surveys. Without an accurate and appropriate definition of RSP, we are concerned that RSP data collected by the vendor may not reflect the consumer purchase price at the retail pharmacy, as defined by Congress. We strongly urge CMS to work with stakeholders to develop a consistent, reliable, accurate, and timely methodology for collecting and disseminating RSP data to states. The distribution of appropriate RSP data to the states could be critical in assuring that Medicaid drug reimbursement rates represent pharmacists' true costs, thus protecting patient access.

Conclusion

McKesson recognizes the need to achieve consistency and accuracy in price reporting and metrics for Medicaid pharmaceutical reimbursement. Based on our extensive experience in the pharmaceutical distribution business, we are pleased to provide comments to CMS on the proposed rule.

In summary, we recommend that the Final Rule include the following modifications:

1. ***Refine AMP methodology***
    a. Establish the Federal Upper Limit (FUL) based on the weighted average AMP of the therapeutically equivalent products available in the market;
    b. Calculate AMPs based on the 11-digit NDC;
    c. Reduce variability with a 12-month rolling percentage methodology for lagged data;
    d. Postpone the publication of AMP data pending implementation of the Final Rule;

2. ***Limit the definition of retail class of trade to those channels that are available to the "general public"***
    a. Exclude sales to mail order pharmacies;
    b. Exclude rebates to Pharmacy Benefit Managers (PBMs);
    c. Exclude *all* sales to hospitals;

3. ***Clarify the definition and treatment of bona fide service fees*** to ensure consistency with the calculation of the ASP reimbursement methodology;

4. ***Exclude customary prompt pay discounts*** from the calculation of Best Price as well as from AMP;

5. ***Exclude from AMP and Best Price all manufacturer coupons redeemed by a consumer,*** including electronic programs administered at the point of sale in retail pharmacies;

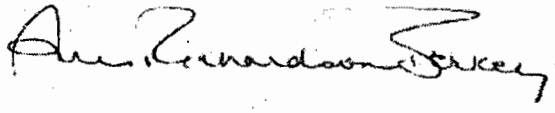
6. ***Confirm the definition of Retail Survey Price (RSP) as stated in the Deficit Reduction Act (DRA) of 2005*** and encourage states to use RSP as an alternative methodology that reflects the average consumer purchase price at retail pharmacy; and

7. ***Conform the definition of wholesaler*** to the definitions in the Prescription Drug Marketing Act and subsequent FDA regulations.

We applaud CMS for seeking feedback from stakeholders on proposed changes to the methodology for Medicaid reimbursement for pharmaceuticals. However, we remain concerned about the potentially significant and negative economic impact of this proposed regulation on retail pharmacy. The final determination of AMP may not be a sufficiently accurate benchmark of retail pharmacy costs. The proposed inclusion of PBM rebates and all mail order pharmacy sales in calculating AMP would further reduce reimbursement to our vital independent and chain retail pharmacies across the country and is not likely to be sufficient to cover a retail pharmacist's costs of doing business. Without appropriate reimbursement to pharmacies for their cost to dispense Medicaid prescriptions, the ability of retail pharmacies to continue to serve this most needy and most vulnerable segment of our population may be in jeopardy.

We appreciate the opportunity to provide our comments on Proposed Rule CMS-2238-P. We look forward to working with you as you develop an Average Manufacturer Price calculation that represents an equitable and reasonable approach to reimbursement for the products we distribute. Should you have questions or need further information, please contact me at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey

ATTACHMENT

List of Wholesaler Services As Compiled by HDMA

The following discussion of the types of bona fide services offered by HDMA wholesalers is intended to be dynamic and flexible. New services categories will likely evolve as drug products and distribution technologies emerge. Many specific services, including some not yet contemplated, may fit within each service category. The six headings referenced are provided as general categories to organize the list; however, by their nature many of the services overlap among the general categories.

Note: The following list of services is not intended to be all-inclusive. Any other service would qualify as a bona fide service that is agreed to in an arms-length negotiation between the manufacturer and the wholesaler. Statistical references found herein are based on the experience of HDMA members only, and is not intended to reflect the experience of the entire wholesale industry.

1. Logistic Support Services

The US has the most efficient pharmaceutical supply chain in the world, due in large part to the continuous improvement by wholesalers in the logistics activities of ordering, receiving, stocking, picking, packing and shipping pharmaceutical products to the nation's physicians, hospitals and drug stores. The implementation of logistic support services programs enables the warehousing of a broad assortment of branded and generic prescription drugs, next day or same day delivery, the aggregation of shipments into customer stores and warehouses, and the special handling of controlled substances. Aggregation of delivery volume reduces shipping and delivery costs, therefore marginal delivery cost per item declines with increased delivery volume.

The ongoing refinement of the industry's logistical support services has also enabled the rapid distribution of new products as they are introduced into the marketplace. Lesser known logistical services such as emergency logistic support permit the reallocation of scarce inventory during crises. Wholesalers are committed to continuously improving supply chain practices to aggressively combat counterfeit drugs on behalf of patient safety. These improvements include, for example, technical improvements such as electronic track and trace solutions.

Wholesalers maintain distribution facilities that are in strict compliance with the Prescription Drug Marketing Act (PDMA) providing for the secure warehousing of drug products, and ensuring the integrity, efficacy and safe handling of all prescription drugs. Additionally, wholesalers monitor the regulatory environment to assure that the handling, storage, and shipment of manufacturers' products are compliant with FDA and DEA requirements, as well as all applicable state and federal law. Wholesalers are licensed in every state or territory where they distribute product. All products are shipped in containers that protect and maintain product safety and integrity, pursuant to applicable legal requirements.

Typical logistical support services provided by wholesalers include but are not limited to:

- Ordering, receiving and storing a manufacturer's products in PDMA-compliant facilities;
- Picking and packing customer-specific orders;
- Single destination shipping to over 144,000[1] points of care on a daily basis;
- Special handling for refrigerated and frozen drugs, biologics, cytotoxins, flammable products and controlled substances;
- Managing advanced allocation systems for items in short supply;
- Carrying out manufacturer-specific logistics;
- Ensuring that state licensing guidelines are implemented;
- Following HDMA's Recommended Guidelines for Pharmaceutical Distribution System Integrity, a set of business practices for appropriate due diligence.

2. Order Processing Services

The aggregation of customer orders provided by wholesalers reduces order processing costs for manufacturers and pharmacies. Typically, pharmacies need to order from only one or two wholesalers, as opposed to hundreds of manufacturers that supply prescription drugs (branded and generic), over-the-counter (OTC), medical supplies and health and beauty care products. Aggregation of orders significantly reduces order management costs for both pharmacies and manufacturers.

Typical order processing services provided by wholesalers include but are not limited to:

- Providing real-time product availability information to customers on a 7/24/365 basis, so patients have access to needed drugs immediately; achieving high services levels;
- Establishing a single point of contact for customer service and support, handling over 40 million[2] calls per year;
- Managing customer-specific contracts with multiple manufacturers allowing customers to comply with their contracts and reduce their overall pharmaceutical costs;
- Offering sophisticated hardware and software systems for customer ordering;
- Issuing recall notices on behalf of manufacturers as well as providing further administrative services and logistics as required by the FDA.

3. Financial Management Services

Because wholesalers take ownership of the pharmaceutical products and manage the financial relationship with the providers, manufacturers have effectively shifted credit risk from themselves to the wholesalers avoiding a cost that would otherwise be borne by the manufacturer. This downstream shift in risk provides appreciable savings to the

[1] Industry Overview: IMS National Sales Perspective™

[2] HDMA The Role of Distributors in the U.S. Healthcare Industry: Booz Allen Hamilton

manufacturer and is a fundamental basis for prompt pay discounts provided by manufacturers to wholesalers.

The manufacturer sells product to the wholesaler at negotiated terms. The wholesaler generally pays the manufacturer for the product within 30 days. The wholesalers then store the product in PDMA-compliant facilities until it is ordered by a customer. The wholesaler accepts the responsibility of billing the customer for the product. Since the wholesaler is able to aggregate quantities of product across multiple manufacturers, the bill is also consolidated, significantly increasing the efficiency for the customer. The wholesalers must wait for the customer to pay them, a process which may take from 1 – 60 days. In the event of customer bankruptcy, the wholesalers are left with a potentially uncollectible debt, thereby assuming a great deal of credit risk.

Typical financial services provided by wholesalers include but are not limited to:

- Conducting complex and multi-tiered contract administration and chargeback management services;
- Aggregating billing for products across all manufacturers, significantly increasing efficiency for customers and manufacturers;
- Processing returns and related compensation on behalf of the manufacturer (e.g., when a product is mis-ordered, damaged, or otherwise unsuitable);
- Aggregating collection services for products across all manufacturers;
- Aggregating the credit risk for pharmacy receivables resulting in deferring the customer credit risk away from the supplier to the wholesaler;
- Customer-facing services such as performance guaranty, extension of credit, insurance and risk management;
- Actively managing the manufacturer/wholesaler transactions, including deductions for incorrect quantities, pricing, chargebacks or orders of drugs shipped to the wholesalers;
- Maintaining approximately $9 billion in working inventories; available for same-day and next-day delivery.

Additional Background Information:

These financial arrangements result in other efficiencies. For example, members of the supply chain are able to simplify their working capital arrangements by using "Just-in-Time" shipments, so that they do not need to pay for any more storage space than is needed at any one time.

4. Inventory Management

Wholesalers work closely with manufacturers to manage inventories and ensure a sufficient supply of pharmaceutical products in the supply chain to meet provider and patient demands. These pharmaceutical products are stored in PDMA-compliant facilities and every effort is made to ensure supply chain integrity and to comply with all regulatory requirements.

Highly developed inventory management systems are critical for an efficient pharmaceutical supply chain and for preventing counterfeit product from entering the channel. These systems also ensure that product in the channel is in line with true demand; an area of key focus to the SEC and for Sarbanes Oxley reporting.

Typical inventory management services provided by wholesalers include but are not limited to:

- Inventory level commitment - implement purchase limits to reflect negotiated commitment level;
- Providing committed inventory service-levels to customers;
- Managing demand variability resulting in additional control over the supply chain and allowing manufacturers a smooth "just-in-time" manufacturing process;
- Filtering and monitoring customer orders to prevent speculative buying and to maintain inventory levels that reflect genuine customer demand.

5. Data Management and Reporting Services

Wholesalers supply vital data feeds and aggregated information that assist manufacturers in developing their production schedules based on genuine future demand. A variety of ancillary processes are also needed to ensure that data tracking is efficient and accurate so that information about the manufacturer's products make its way into the appropriate data bases rapidly and completely (e.g., product bar coding, storage shelf labeling, electronic entry, etc.).

Typical data management services provided by wholesalers include but are not limited to:

- Product returns data points;
- Product inventory levels;
- Sales data for the manufacturers products;
- Provide data on outdated and damaged products;
- Ad hoc data and reports as requested by individual manufacturers.

Additional Background Information:

Wholesalers typically feed the data to manufacturers on an automated and scheduled basis (e.g., daily, weekly, monthly). Manufacturers use this critical data to forecast future demand and establish production schedules to estimate the volume of product needed to re-supply the warehouses. Ultimately, this helps ensure that product in the supply channel is in line with true patient demand.

6. Sales and Marketing Services

The role of wholesalers often includes providing product sales and promotional materials on behalf of manufacturers. Distributing in-store displays, promotional and marketing materials, as well as educating customers on manufacturer programs, and product promotions are some of the services available to manufacturers.

Typical sales and marketing services provided by wholesalers include but are not limited to:

- Educating customers on available manufacturer sponsored marketing programs, providing promotional materials, displays, and services;
- Making sales calls for suppliers' products, e.g., 1.8 million[3] pharmacy calls per year;
- Providing new product launch support, ensuring that pharmacies have access to newly FDA-approved drugs within 24 hours;
- Providing rapid and efficient industry information to manufacturers regarding product announcements, recalls, notices, etc.

The fee-for-service wholesale distribution system has evolved in a dynamic manner over the last several years. Wholesalers have adapted to changes in the industry by offering new services, driven by manufacturers' business models, legislative initiatives, patient safety and risk management initiatives, and innovations in technology affecting manufacturers and other customers. Wholesale industry members shall continue to maintain the highest standards of safety and efficiency in the marketplace in order to meet their service obligations to their customers.

[3] HDMA The Role of Distributors in the U.S. Healthcare Industry: Booz Allen Hamilton