Submitter : Dr. Steve Moore **Date:** 02/20/2007

Organization : Condo Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1261-Attach-1.DOC

#1261

March 3, 2007

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

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

My name is Steve Moore and I am an independent pharmacy owner from Plattsburgh, NY. My pharmacy is a major provider of pharmacy services for the greater Plattsburgh area and in 2006 we filled more than 77,000 prescriptions, 65% of which were to Medicare/Medicaid eligible patients. In addition to filling traditional prescriptions we are a provider of durable medical equipment, colostomy/ostomy supplies, post-mastectomy products, and we are the only compounding pharmacy located in this part of the state. We provide medication therapy management, drug utilization review, patient charge accounts, and free prescription delivery (Monday through Friday). The pharmacy provides services to Hospice patients and currently provides blister packed medication for twelve homes operated by Clinton County's Advocacy and Resource Center. We are here for our patients seven days a week.

While more extensive, and certainly more eloquent, comments have been submitted by groups such as the Pharmacists Society of the State of New York (PSSNY), the American Pharmacists Association (APA), and the National Association of Community Pharmacists (NCPA), I would like take the opportunity and submit the following comments regarding the regulation proposed December 20th, 2006 providing a regulatory definition of Average Manufacturer's Price (AMP) and implementing the new Medicaid Federal upper limit (FUL) program for generic drugs.

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

Excluding Pharmacy Benefits Managers and mail order pharmacies recognizes that these are not community pharmacies where the vast majority of Medicaid clients have prescriptions dispensed.

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

These organizations do not dispense medications to the general public and have access to rebates and price concessions that most likely will not be accessible to community pharmacies. AMP must reflect prices paid by community pharmacies.

3. Removal of Medicaid Data

Including these data elements is bootstrapping the AMP calculation and does not recognize that Medicaid pricing (already inadequate to begin with) is heavily regulated by the state and federal governments.

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

The actual implementation of the AMP Regulation could create an avenue for market manipulation. The risk of both price fluctuations and market manipulation, due to timing of manufacturer reporting and the extended ability to revise reported data, are amplified under the proposed structure. Price fluctuations must be promptly addressed by CMS to ensure adequate and fair reimbursement for community pharmacy.

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

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

It is very disheartening that a little more than a year after Medicare Part D was saved by community pharmacy, CMS says thank you with legislation such as this. If nothing else came out of the disaster that was the Medicare D implementation, community pharmacists demonstrated that they are a valuable part of any health care team and CMS does this county a great disservice by rendering us inaccessible to its patients. Make no mistake, if your proposed legislation passes as is, it is your patients who will suffer as community pharmacy will be forced to scale back the services it provides. Any reimbursement model proposed by CMS must take into account the range of services community pharmacy offers your patients as the profession of pharmacy is not one that allows for a reimbursement model focused solely upon the commodity being traded. Community pharmacists are held accountable for prior authorizations, drug utilization review, medication therapy management, and the like. It is unreasonable to expect us to perform these services without compensation for the time and effort spent on behalf of your patients. I ask you to consider what the reaction of your mechanic would be if you tried to pay him (or her) only for the materials he spent 45 minutes installing based upon the price they sold for from a factory in China or India. What about your plumber?

Community pharmacists fully understand and appreciate the rising costs of prescription medication as we, unlike many of our payers, are required to pay for the medication we buy promptly. Prescription medication is indeed expensive and will continue to be

expensive as newer and better medications are brought to market. As CMS is well aware, prescription drugs account for only about 10% of total healthcare spending but make up a disproportionate amount of a consumer's out of pocket spending. CMS must do a better job of educating the public to the true cost of healthcare and really should look to the remaining 90% for additional cost saving measures. Additionally, if CMS has issues with the markup on medication seen by the end users, these issues need to be brought to the pharmaceutical companies and not taken out on community pharmacists. Our reimbursement is largely out of our hands as it determined by insurance companies and community pharmacy is not responsible for tiers, preferred brands, deductibles, and items not on formulary. CMS may also consider using its clout to call for pharmacy benefit manager (PBM) reform. We spent much if 2006 worried about patients having access to the medications they needed, yet these companies reported record profits for their shareholders. We heard about more than one community pharmacy facing hardship or even going out of business due to Medicare D, but interestingly enough there are even more plan offerings in 2007 than there were in 2006.

In conclusion, I support the more extensive comments that are being filed by organizations such as PSSNY, APA, and NCPA regarding this proposed regulation. If CMS is truly interested in paring down the costs associated with prescription medication then you need to work with community pharmacy, not against it. Who better than to help manage these costs of the prescription medication than the professionals who deal with prescription medications on a daily basis? I appreciate your consideration of these comments and I extend to you an open invitation to visit my pharmacy if you would like gain a better understanding of what exactly a community pharmacy does for your patients on a daily basis. I, like many other community pharmacists, will be more than happy to sit down and discuss potential cost saving measures that do not jeopardize patient care. Thank for your time, please contact me with any questions.

Sincerely,

Steve Moore, Pharm. D.

Condo Pharmacy
28 Montcalm Ave
Plattsburgh, NY 12901

Phone: 518-563-3400
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Email: condopharmacy@aol.com

Submitter : Mr. James Quirk **Date:** 02/20/2007

Organization : Alliance of Dedicated Cancer Centers

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-2238-P-1262-Attach-1.PDF

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

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

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

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

Organization : Mr.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

cms file code 2238-p,medicaid program,rx drugs,publication date 12-22-2006.AMP does not even cover the cost of the medication,let alone the cost of a filling a prescription.AMP does not fit and should not be used as an yardstick for paymnets to pharmacies,as this will destroy all the small and medium size pharmacies.An awfull number pharmacies
(25,000 Plus) will lose their lively hood and will en end up on welfare line.Please come up with a reasonable amount payment plan so
that wel can survie and provide services for the poor and needy.

Submitter : Mr. Walter Moore **Date:** 02/20/2007

Organization : Genentech, Inc.

Category : Drug Industry

Issue Areas/Comments

Background

Background

Please see attached comments.

Collection of Information Requirements

Collection of Information Requirements

Please see attached comments.

GENERAL

GENERAL

Please see attached comments.

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

Please see attached comments.

Regulatory Impact Analysis

Regulatory Impact Analysis

Please see attached comments.

Response to Comments

Response to Comments

Please see attached comments.

CMS-2238-P-1264-Attach-1.PDF

1264

Genentech
IN BUSINESS FOR LIFE

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February 20, 2007

VIA ELECTRONIC SUBMISSION

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 21244-1850

CMS File Code: CMS-2238-P

Federal Register Publication Date: December 22, 2006

Dear Ms. Norwalk:

Genentech, Inc. (Genentech) appreciates this opportunity to provide public comments on Proposed Rule CMS-2238-P, "Medicaid Program; Prescription Drugs; Proposed Rule (the "Proposed Rule") published in the *Federal Register* on December 22, 2006.[1]

Genentech is among the worlds leading biotechnology companies, with multiple oncology, immunology, and tissue growth and repair products on the market for serious or life-threatening medical conditions. We also are the leading provider of anti-tumor therapeutics in the United States. Given our expertise in all areas of the drug development process—from research and development to manufacturing and commercialization—we are an important stakeholder in the prescription drug market in the United States, and as such, offer our recommendations on needed revisions to the Proposed Rule for CMS' consideration

As you are aware, Genentech has long wanted more comprehensive, straight-forward directions for properly calculating average manufacturer price (AMP) and determining Best Price under the Medicaid Drug Rebate Program. We support CMS's decision to codify Best Price regulations, and offer our detailed comments on the Proposed Rule below, which are intended to help resolve lingering ambiguities and fill remaining gaps in the regulations that will define the

[1] 71 *Fed. Reg.*77173 (Dec. 22, 2006).

pricing statistics that will be used to determine our Medicaid drug rebate liabilities and that likely will define the reimbursement available to certain of our end-customers.

EXECUTIVE SUMMARY

The following provides a brief summary of our key recommendations:

Definitions:

- *Bona Fide* Service Fees: The Final Rule should reference the discussion of *bona fide* service fees in the preamble to the 2007 Physician Fee Schedule Final Rule[2] and stipulate that CMS intends to apply the *bona fide* service fee definition in the same manner in both the average sales price (ASP) and AMP context.
- Bundled Sales: The definition of bundled sale should be revised to reflect the definition currently included in the Medicaid Drug Rebate Agreement. Absent that change, the Final Rule should limit the definition of bundled sales to arrangements in which rebates and price concessions are contingent upon the purchase of multiple products and include examples illustrating required procedures for allocating price concessions across product bundles.
- Sales in the United States: The existing policy defining sales in the United States as those to entities in the 50 States and the District of Columbia should be codified in the Final Rule.

Determination of AMP:

- Customary Prompt Pay Discounts: The Final Rule should provide guidance clarifying the meaning of the terms "routinely offered" and "prompt payment" in the definition of customary prompt pay discount. It also should explain whether, based on the definition of "wholesaler," prompt pay discounts paid to pharmacies and pharmacy benefit managers (PBMs) are eligible for exclusion from AMP.
- Retail Pharmacy Class of Trade:
    - *Hospital Sales*: Because public access is central to the concept of the retail pharmacy class of trade, hospital sales should be excluded from AMP, regardless of whether the drugs purchased are furnished to patients admitted for inpatient or outpatient services. If CMS chooses to maintain the proposed distinction between inpatient and outpatient hospital sales, manufacturers will need 1 to 2 years to renegotiate existing hospital and group purchasing organization (GPO) contracts. The Final Rule also will need to provide adequate protection for manufacturers that file certified AMP reports in good faith reliance on their hospital customers' appropriate administration of separate inpatient and outpatient contracts.
    - *Health Maintenance Organization (HMO) and Managed Care Organization (MCO) Sales*: The Final Rule should define MCOs. It also should exclude from the calculation of AMP direct and identifiable indirect sales to possession-taking HMOs and MCOs that operate their own pharmacies, but include in the calculation rebates and other price concessions extended to non-possession-taking HMOs and MCOs on retail pharmacy network sales.

[2] 71 *Fed. Reg.* 69623 (Dec. 1, 2006).

- *Outpatient Clinics*: The Final Rule should define outpatient clinics, clarifying whether the term reaches physician offices and addressing how manufacturers are to distinguish freestanding outpatient clinics from hospital-based outpatient departments.
- *Manufacturer Coupons*: Because coupons never reduce a pharmacy's or an insurer's costs for the drugs dispensed to coupon-holders, the value of consumer coupons, regardless of how they are redeemed, always should be excluded from both AMP and Best Price.
- *Returned Goods:* The Final Rule should exclude returned goods from AMP, but the appropriate test of eligibility for the exclusion should be that the return was made in compliance with the manufacturer's return goods policy.

- Non-Retail Class of Trade: Examples of the non-retail class of trade should be included in the Final Rule. Those examples should include goods sold to other manufacturers, academic medical centers and physician investigators for research purposes as well as goods sold to prisons.
- Group Purchasing Organization (GPO) Fees: Because GPOs are neither buyers nor payers, the Final Rule should stipulate that GPO fees may be excluded from AMP and Best Price regardless of whether they satisfy the definition of *bona fide* service fees.
- Lagged Data: The Final Rule should define a methodology for handling lagged unit and lagged price concession data. Genentech endorses adoption of a 12-month rolling percentage methodology based on actual sales in the four quarters prior to the quarter for which monthly and quarterly AMPs are being calculated. We recommend including all price concessions, not just lagged ones, in the discount percentage determination to maximize AMP smoothing and minimize the need for restatements. For clarity, the Final Rule also should provide examples illustrating the methodology, including some that involve bundled sales.

Determination of Best Price:

- Definition of Best Price: The definition of Best Price in the Final Rule should clearly and unambiguously require the pricing statistic to be determined by reference to a customer-specific net price, not a net price derived by aggregating price concessions to different customers in the supply chain.
- Patient Assistance Programs: The Final Rule should clarify that charging a small handling fee on drugs distributed under a Patient Assistance Program does not negate exclusion of those units from Best Price.
- Intra-corporate Transfer Pricing: The Final Rule should stipulate that intra-corporate transfer pricing does not impact AMP or Best Price regardless of the circumstances surrounding the transfer of product manufactured by one member of a corporate family at a discounted book value to another member of the family for distribution.

Manufacturer Requirements:

- Rebasing of AMP: Manufacturers that elect to rebase AMP under the Final Rule should be permitted to factor in the DRA-mandated change in the treatment of customary prompt pay discounts as well as the changes that flow from the regulatory definition of retail pharmacy class of trade. The timeframe for submitting rebased AMPs should be extended to the first four full calendar quarters after publication of the Final Rule.
- Price Report Certifications: To lessen the burden of obtaining certifications, the Final Rule should require manufacturers to submit quarterly Medicaid price report

certifications that speak to the associated monthly AMPs as well as the quarterly filing. The certifications should require company officials to certify only to the accuracy and completeness of reported data to the best of their knowledge.

- Web-Based Reporting: Enrollment in the Drug Data Reporting (DDR) system should be based on company tax identification numbers, not the Social Security numbers of companies' technical contacts. The DDR system also should be modified as soon as possible to allow manufacturers to submit cover letters with their price report filings.
- Web Posting of AMP: CMS should delay posting AMPs on its website until after the Final Rule's effective date.
- Computer System and Programming Requirements: Because of the limited availability of programming and technical support for state-of-the art government pricing systems, the Final Rule should allow manufacturers between 6 months to 1 year at its publication to code, implement, and test required computer system changes.

Physician-Administered Drugs:

- Pro-rating Medicaid Rebates on Drugs Dispensed to Dual Eligible Beneficiaries: The Final Rule should require State Medicaid programs to pro-rate manufacturer rebates on physician-administered drugs and biologics when a State only pays a portion of the cost for dual eligible beneficiaries.
- Limitations on Retrospective Utilization Adjustments: A one-year limit on the time available to States to perform look-back utilization adjustments should be included in the Final Rule.

340B Pricing:

- Dual AMP Reporting: CMS should work with the Department of Health and Human Services (HHS) and the Office of Pharmacy Affairs (OPA) at the Health Resources Services Administration (HRSA) to eliminate the impractical demand issued by OPA in a January 30, 2007 letter directing manufacturers to set 340B prices based on AMPs calculated without regard to DRA-mandated changes.

Average Sales Price (ASP):

- Rebasing the AMP Threshold Percentage: CMS should rebase the threshold percentage used when ASP is compared to AMP to account for the changes in the AMP calculation required in the Final Rule.
- ASP Implications of Changes in the AMP Methodology: The Final Rule should include a discussion of the ASP implications, if any, of the changes made to the AMP calculation methodology.

DETAILED COMMENTS

Definitions – 42 CFR § 447.502

Bona Fide Service Fees

Genentech is pleased the Proposed Rule adopts the definition of *bona fide* service fees included in the average sales price (ASP) regulations at 42 C.F.R. § 414.802. Disparate definitions for Medicare and Medicaid purposes could unduly complicate the design and operation of the internal procedures and oversight systems we have implemented to guard against errors in the pricing statistics we report to CMS.

The Medicare regulation defining *bona fide* service fees for ASP purposes took effect January 1, 2007. When CMS published the regulation as part of the 2007 Physician Fee Schedule Final Rule (the "2007 PFS Final Rule"),[3] it provided commentary elaborating on the elements of the definition. The 2007 PFS Final Rule also acknowledged that proper handling of *bona fide* service fees may differ for price reporting and financial accounting purposes.[4] In contrast, the Proposed Rule fails to offer any substantive discussion of *bona fide* service fees in the preamble interpreting the definition in the AMP and Best Price context.

Genentech urges CMS to adopt the principles and positions applicable to *bona fide* service fees outlined in the 2007 PFS Final Rule for purposes of AMP and Best Price determinations under Medicaid. Please also see our comments, which begin on page 14, addressing the treatment of *bona fide* service fees in the calculation of AMP.

We appreciate the flexibility CMS's approach to fair market value provides manufacturers in the negotiation of service arrangements. We recommend, however, that CMS provide additional guidance in the Final Rule about the nature and scope of the documentation manufacturers should retain to support fair-market-value determinations.

Bundled Sales

Under the Medicaid Drug Rebate Agreement (the "Rebate Agreement"), bundled sales are defined as "the packaging of *drugs of different types* where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately (emphasis added)."[5] Furthermore, the Medicaid Drug Rebate Operational Training Guide provides several examples of how to properly apply this definition in the AMP and Best Price calculations.[6]

The Proposed Rule's definition of a bundled sale expands upon the existing definition in that it contemplates "bundles" involving a single product, not just drugs of different types, without

[3] 71 *Fed. Reg.* 69623, 69666-70 (Dec. 1, 2006).
[4] 71 *Fed. Reg.* at 69669.
[5] Medicaid Rebate Agreement § 1(e).
[6] Medicaid Drug Rebate Operational Training Guide, version 2, p F11a-11c.

providing any rationale for the change. The concept of a bundled sale involving a single drug product is strained and counterintuitive.

The proposed definition also reaches arrangements involving performance criteria contingencies such as the achievement of market share targets or the assignment of preferential formulary placement; yet, beyond these two examples, the intended scope of applicable "performance criteria" remains completely undefined. The fact that the Proposed Rule offers no examples of how the bundled sales definition is to be applied operationally compounds the confusion arising from this lack of definition. The absence of examples also makes if impossible for us to comment on the appropriateness of discount allocations in the context of our contracting practices.

We strongly favor the adoption in the Final Rule of the definition of bundled sales in the Rebate Agreement. Even if a more expansive definition is developed, it should be limited to arrangements in which rebates and price concessions are contingent upon the purchase of multiple products. Finally, regardless of how bundled sales are defined, the Final Rule should include several examples illustrating how discounts and other price concessions are to be allocated across bundles, including, if appropriate, bundles that involve sales occurring during different rebate periods.

Sales in the United States

The definitions of AMP and Best Price in Social Security Act § 1927 turn on product sales "in the United States." The Rebate Agreement interpreted this statutory requirement to mean sales to entities in the 50 States and the District of Columbia. Since the DRA stipulates CMS should promulgate a regulation that "clarifies the requirements for, and manner in which," AMP is calculated,[7] the Final Rule should specify whether sales to Puerto Rico and the other territories are excluded from or included in the calculation of AMP and Best Price. We advocate codifying the existing policy defining sales in the United States as those to entities in the 50 States and the District of Columbia only.

Determination of AMP – 42 CFR § 447.504

Customary Prompt Pay Discounts

We endorse the definition of customary prompt pay discount (CPPD) in the Proposed Rule. Since the definition does not include specific payment levels or time terms, it accommodates existing variability in manufacturer practices. It also allows manufacturers and wholesalers enough flexibility to negotiate payment terms, including CPPDs, appropriate to their particular situation and to changing commercial conditions.

That said, Genentech encourages CMS to discuss in the Final Rule ways in which manufacturers may determine whether their prompt payment policies qualify as "routinely offered."[8] For example, how frequently and consistently does a discount have to be offered to be routine?

[7] DRA § 6001(c)(3)(B).
[8] 41 CFR § 447.504(c).

Similarly, manufacturers need sub-regulatory guidance about how to assess the concept of a "prompt payment." Absent such clarifications, the Final Rule should clarify that manufacturers are permitted to make reasonable assumptions when they apply the proposed definition of CPPDs.

The definition of AMP at 42 C.F.R. § 447.504(a) only permits CPPDs "extended to wholesalers" to be excluded from AMP. That said, the Proposed Rule defines the term "wholesaler" so expansively that it reaches pharmacies and PBMs as well as traditional full-service wholesalers and specialty distributors.[9] The Final Rule should specify whether manufacturers should follow normal rules of construction and read the definition of wholesaler at 42 C.F.R. § 477.504(f) into the instruction to exclude only CPPDs extended to wholesalers from AMP. The clarification is needed because doing so seems at odds with the Proposed Rule's instructions to include in AMP sales to retail pharmacies[10] and mail-order pharmacies[11] net of "cash discounts . . . and any other discounts or price reductions."[12]

The Retail Pharmacy Class of Trade

The DRA tasked the Office of Inspector General (OIG) with making recommendations on needed changes in the instructions available to manufacturers regarding the calculation of AMP. It also directed CMS to take those recommendations into account as it drafted the Proposed Rule.[13] Because the OIG emphasized the need to clarify the definition of the retail pharmacy class of trade,[14] the Proposed Rule includes a definition of this term that is followed by a listing of "[s]ales, rebates, discounts or other price concessions"[15] that CMS has categorized either as included in or excluded from the AMP calculation. Presumably because the statutory definition of AMP at Social Security Act § 1927(k)(1) defines the term as the "average *price paid* to the manufacturer . . . *by wholesalers* for drugs distributed to the retail pharmacy class of trade" (emphasis added), CMS defined wholesaler as well.

We appreciate the inclusion of these definitions in the Proposed Rule because they should provide guidance to manufacturers on the appropriate treatment of transactions not specifically addressed in the list of things included in and excluded from AMP. Our comments are limited to suggestions relating to some of the specific transactions addressed in the Proposed Rule.

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[9] 42 CFR § 447.504(f).
[10] 42 CFR § 447.504(g)(5).
[11] 42 CFR § 447.504(g)(9).
[12] 42 CFR § 447.504(i)(1).
[13] DRA § 602(c)(3).
[14] *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005,* (A-06-06-00063) (May 2006).
[15] 42 CRD §§ 447.504(g) and 447.504(h).

Sales, Rebates and Discounts Excluded from the AMP Calculation

a) Direct and Indirect Sales to Hospitals Where the Drug is Used in the Inpatient Setting[16]

Genentech strongly disagrees with categorizing other prescription drug sales to hospitals as sales to the retail pharmacy class of trade unless the drugs are used in the inpatient setting. Under the Proposed Rule, access to the general public is central to the definition of the retail pharmacy class of trade. Hospital outpatient departments do not fit the definition because they are served by institutional pharmacies that only dispense drugs for patients who have been admitted to the hospital either on an inpatient or an outpatient basis. The Medicare Hospital Conditions of Participation, which apply to the vast majority of acute care hospitals in the United States, support treating inpatient and outpatient sales to hospitals in a uniform fashion for purposes of the AMP calculation in that they require hospital outpatient services to be "appropriately organized and integrated with inpatient services."[17]

From a practical perspective, our experience has shown that unless hospitals are 340B Covered Entities, they do not buy or contract separately with pharmaceutical or biotechnology manufacturers or with GPOs for drugs intended for patients admitted for inpatient care and those admitted for outpatient care. They also do not inventory drugs separately for inpatient and outpatient uses. As a result, Genentech currently does not operate granular enough contract administration systems or drug price reporting systems to permit us to distinguish hospital sales used in the inpatient setting from hospital sales used in the outpatient setting; we suspect other manufacturers are in the same situation.

Before CMS moves forward with a Final Rule that treats hospital sales differently depending upon where in the hospital a particular unit of drug is used, it should assess the impact on the hospital industry. Any increase in costs attributable to hospitals having to negotiate twice as many drug purchase agreements, process twice as many drug purchase orders, and maintain two different drug inventories merely to support the price-reporting needs of their pharmaceutical vendors will flow, in significant measure, to the Medicare and Medicaid programs.

CMS also needs to consider other practical implications of treating inpatient and outpatient hospital sales differently for AMP purposes in the Final Rule. We suspect most manufacturers would be not be able to reliably report on hospital sales in accordance with the provisions of the Proposed Rule for 1 to 2 years because essentially all group purchasing organization (GPO) and hospital contracts for prescription drugs will have to be renegotiated, some of those contracts may not be subject to amendment during their term absent breach, and because data on sales under new contracts will take time to work through the chargeback system.. If CMS insists on maintaining the distinction between inpatient and outpatient hospital sales, it will be imperative for the Final Rule to be delayed to include procedures that manufacturers may use for some period of time after the effective date to estimate the proportion of hospital sales flowing to the inpatient and outpatient setting.

[16] 42 CFR § 447.504(h)(4).
[17] 42 CFR § 482.54.

If the Final Rule requires monthly and quarterly AMP reports to be certified, CMS also should address the potential price-reporting risks associated with manufacturers' required reliance upon their hospital customers to administer separate inpatient and outpatient contracts appropriately. At a minimum, the Final Rule should establish a rebuttable presumption that, absent knowledge by the manufacturer to the contrary, chargeback data flowing from separate hospital inpatient and outpatient contracts is accurate. The treatment of the "no pass through" requirement of the *bona fide* service fee definition in the 2007 PFS Final Rule provides precedent for the adoption of such an approach.

b) Sales to HMOs and Other Managed Care Organizations[18]

The Final Rule should resolve the ambiguities that surround the exclusion of sales to health maintenance organizations (HMOs) and managed care organizations (MCOs) from AMP. A variety of health plan structures incorporate managed care principles to some degree, yet there is no definition of MCOs in the Proposed Rule. The Final Rule should provide a definition or other explanation of the term "managed care organization" detailed enough to permit manufacturers to identify customers that should be assigned to the managed care class of trade.

Perhaps more importantly, the Final Rule should clarify the reach of the HMO and MCO exclusion from AMP. We understand the logic of excluding sales to HMOs and MCOs that operate their own pharmacies because such pharmacies are not open to the general public. We are less clear about the rationale for excluding rebates paid to HMOs or MCOs that do not buy or take possession of drugs but rather require their members to fill prescriptions at a network of retail pharmacies. HMOs and MCOs using this model generally operate their pharmacy benefit through an in-house PBM unit. Some may even contract with an independent PBM. Therefore, we would expect rebates paid to HMOs and MCOs to be handled in the same manner as rebates paid to PBMs whenever their plan enrollees are allowed to fill prescriptions at retail pharmacies.

Regardless of how CMS comes out on the possession-taking versus non-possession-taking question, the Final Rule needs to clarify whether only direct sales to HMOs and MCOs are to be excluded from AMP. The Proposed Rule includes a parenthetical in 42 CFR § 447.504(h)(4) specifying that both direct and indirect sales are to be considered when certain hospital sales are excluded from AMP. It does not use the same parenthetical explanation in the very next sub-paragraph addressing the proper handling of HMO and MCO sales. We see no logical reason why direct and identifiable indirect sales should not be handled in the same matter regardless of the type of entity buying the goods. We also read 42 CFR § 447.504(g)(1), stating that "[s]ales to wholesalers, except for those sales that can be identified with adequate documentation as being subsequently sold to any of the excluded entities as specified in paragraph (h) of this section," as implying that both direct and indirect HMO and MCO sales should be excluded from AMP.

To resolve these last two ambiguities, we urge CMS to promulgate a Final Rule that explicitly includes rebates and other price concessions extended to non-possession-taking HMOs and MCOs on retail network sales in the calculation of AMP and that expressly excludes from that

[18] 42 CFR § 447.504(h)(5).

calculation direct and identifiable indirect sales to possession-taking HMOs and MCOs that operate their own pharmacies.

c) Sales to Wholesalers Where the Drug is Distributed to the Non-Retail Class of Trade[19]

The preamble to the Final Rule should include a discussion that offers examples of the most common types of sales in the non-retail class of trade. We presume sales of product for use in clinical trials to other manufacturers, academic medical centers and physician investigators, regardless of whether those sales are processed through wholesalers or are made direct, would constitute a non-retail sale that should be excluded from AMP. We would appreciate confirmation of this presumption.

We also believe state prisons and federal prisons that do not buy off the Federal Supply Schedule are non-retail customers because their pharmacies are not open to the general public. Given the overall volume of drug sales to correctional facilities by the industry as a whole, it would be appropriate for the Final Rule to clarify that prison sales should be excluded from the calculation of AMP.

d) Manufacturer Coupons Redeemed by a Consumer[20]

We strongly object to the Proposed Rule's treatment of manufacturer coupons for both AMP and Best Price purposes. The distinction that has been drawn between coupons redeemed by the consumer and those redeemed by any entity other than the consumer fails to recognize that coupons are always redeemed by the consumer and always serve to offset the consumer's co-payment obligations for a prescription. Coupons never reduce a pharmacy's or an insurer's cost for the drug dispensed to the coupon-holder. Only patients benefit from use of coupons. Accordingly, the value of consumer coupons should always be excluded from both AMP and Best Price.

Absent a decision to exclude coupon entirely, as an initial matter, the Final Rule should address the mechanics of including certain coupons in the determinations of AMP and Best Price. Specifically, the Final Rule should provide detailed guidance on how manufacturers are to value coupons, particularly those for free goods where there is a choice between the value of the goods to the consumer at market prices and the cost of goods (either marginal or fully loaded) to the manufacturer. In addition, the Final Rule should discuss the precise methodology manufacturers should use when they incorporate coupons into their pricing calculations. Such guidance will be particularly important with respect to Best Price because it is unclear how manufacturers are supposed to match a coupon with a sale.

As the CBO recently recognized,[21] pharmacies either buy drugs from a wholesaler at the wholesaler's normal markup or they purchase them under discounted contracts held directly or indirectly [*i.e.*, through group purchasing organizations (GPOs)] with pharmaceutical

[19] 42 CFR § 447.504(h)(7).
[20] 42 CFR § 447.504(h)(12).
[21] *Prescription Drug Pricing in the Private Sector: A CBO Paper* (January 2007).

manufacturers. They have separate contracts with health plans (or their PBM agents) to sell drugs to plan enrollees at specified prices and in accordance with plan formulary and co-payment requirements. Pricing under the two sets of contracts are completely independent. Regardless of the mechanism used to process a more traditional manufacturer coupon (*e.g.*, submission of the coupon with proof of purchase by the consumer directly to the manufacturer, submission of the coupon with proof of purchase by the consumer to a non-pharmacy vendor hired by the manufacturer to process such submissions, point-of-sale submission of the coupon to the pharmacy, etc.), the value of any coupon accrues entirely to the consumer.

The only "value" a pharmacy would receive from a point-of-sale redemption that it would not ordinarily earn when it fills a prescription is the payment of a fair-market-value handling fee for serving as the manufacturer's vendor for the processing of the coupon. Such a fee should not have to be deducted when AMP and Best Price are determined because of the *bona fide* service fee exclusion applicable to each of these pricing statistics.

Regardless of whether CMS accepts our recommendation to exclude all consumer coupons from AMP, we urge it to clarify the definition of a coupon. Manufacturers use a variety of ways to assist consumers with drug access problems. They may offer coupons that are printed in newspapers, downloadable off the internet, or distributed by physicians. Instead, co-payment assistance for a particular product may take the form of a discount card that may be used to offset co-payments for some specified number of refills or up to some specific dollar amount. These types of more-limited, product-specific consumer co-pay assistance seem more like coupons than the manufacturer-sponsored Drug Discount Care Programs that are excluded from Best Price under 42 CFR § 447.505(d)(7). We would appreciate some guidance on the distinction between the two types of discount cards, if any, from CMS' perspective.

Some manufacturers use coupons for free drugs to effectuate their patient assistance programs. Given that the Proposed Rule stipulates free goods not contingent upon any purchase requirement are excluded from both AMP and Best Price and free goods provided under a manufacturer's patient assistance program are excluded from Best Price, we are perplexed as how to determine Best Price when a patient assistance program is effectuated through a coupon that is redeemed by the patient at the pharmacy. The Final Rule needs to specify which provisions apply--the coupon rules or the non-contingent free goods rules--under these circumstances.

In case the Final Rule does not exclude all coupons from the determination of AMP and Best Price, we also wish to point out one other issue associated with the bifurcated treatment of manufacturer coupons in the Proposed Rule. This issue deals with the reality that few, if any, manufacturers actually process their own consumer coupons. Rather, they outsource the processing to vendors. In recognition of this fact, CMS should amend the language in 42 CFR § 447.504(g)(11) and § 447.505(c)(12) to permit manufacturers to use agents to assist with coupon redemption.

Goods Returned in Good Faith[22]

We strongly support excluding return goods from the AMP calculation. We believe consistency in the treatment of data elements between the AMP and ASP calculations minimizes inadvertent reporting errors. We also believe that eliminating returns will tend to smooth out month-to-month and quarter-to-quarter variations in AMP, minimize the incidence of negative AMPs and make AMP a more appropriate pricing statistic for reimbursement purposes.

The Final Rule should recognize, however, that manufacturers have no control over or knowledge of whether a customer is acting in good faith when goods are returned. We suggest revising the wording of proposed 42 CFR § 447.504(h)(13) to create a returned goods exclusion characterized in a way amenable to manufacturer knowledge and control. For example, the provision could be revised to read: "Returned goods accepted by the manufacturer in accordance with its then-current returned good policy."

Sales, Rebates and Discounts Included in the AMP Calculation

a) Sales to Outpatient Clinics[23]

The Final Rule needs to define the term "outpatient clinic". Although we assume federally qualified health centers, independent diagnostic testing facilities, cancer centers, and the like are outpatient clinics, we are unsure whether the term is also intended to cover physician offices. If it is not, the Proposed Rule is completely silent on the handling of sales to physicians in AMP.

Given CMS' earlier urgings to the States to use crosswalks to collect rebates on physician-administered drugs, the DRA requirements to facilitate rebate collection on infused and injected drugs that are physician administered, and the Proposed Rule provisions effectuating these DRA requirements, it appears CMS views separately billable drugs furnished in a physician office as covered outpatient drugs subject to rebate. The fact that 42 CFR § 447.505 expressly directs the inclusion of prices to providers, including physicians, in the determination of Best Price makes the Proposed Rule's failure to discuss such sales in the context of AMP all the more surprising. In the interest of clarity, we urge CMS to rectify this oversight in the Final Rule by listing physician office sales in 42 CFR § 447.504(g) if they are to be included in AMP or in § 447.504(h) if they are to be excluded.

We presume the term "outpatient clinic" is not intended to mean hospital outpatient departments since a different sub-paragraph in 42 CFR § 447.504(g) addresses sales to hospital outpatient pharmacies. That said, it sometimes can be difficult for manufacturers to distinguish between hospital-affiliated freestanding outpatient clinics and true hospital-based outpatient departments. If CMS accepts our recommendation to exclude all hospital sales from AMP, the Final Rule should address this operational issue when it defines outpatient clinic.

[22] 42 CFR § 447.504(h)(13).
[23] 42 CFR § 447.504(g)(8).

b) Sales to Part D, SCHIPs, SPAPs, and Medicaid Programs[24]

The instructions to include Medicaid sales as well as sales and discounts extended to Medicare Part D, State Children's Health Insurance Programs (SCHIPs) and State Pharmaceutical Assistance Programs (SPAPs) in AMP present conceptual and logistical difficulties from our perspective. We presume the "starting point" for the determination of the net sales price to the government programs is wholesale acquisition price and only rebates paid to the SCHIPs, SPAPs, and Part D plans must be deducted in the calculation of AMP. We ask that the Final Rule confirm these presumptions or explain what other starting price should be used.

The Final Rule also must deal with the fact that information on the number of units sold to Medicaid, SCHIPs and SPAPs during a rebate period and the amount of rebates paid to SCHIPs and SPAPs on units dispensed to enrollees in those programs are never available until long after the filing deadline for quarterly AMPs. Frequently, rebate demands from Part D plans also are not received in time for inclusion in quarterly AMPs.

c) Lagged Data in AMP Calculation

Genentech urges CMS to include instructions in the Final Rule for a methodology for handling both lagged unit data and lagged discounts when AMP is calculated. We support the use of a 12-month rolling percentage methodology akin to that in the ASP rule, although we think it appropriate, given the requirement to report monthly AMPs, for CMS to stipulate that, in the AMP context, manufacturers must always use percentages calculated for the four quarters prior to the quarter for which a monthly or quarterly AMP is being determined. We also recommend directing manufacturers to use the same percentage calculated for the prior four quarters in each of the monthly AMP calculations and in the quarterly AMP determination for the next quarter. For example, to calculate January, February and March monthly AMPs as well as the AMP for the first quarter of the year, manufacturers would be instructed to look to actual data from the prior calendar year to determine the unit percentage that should be used to adjust for "missing" utilization data and the discount percentage that should be used to adjust for "missing" price concession information.

We suspect some manufacturers have treated chargebacks as lagged data when they determine ASP and others have not because they receive chargeback reports quickly enough to permit them to file their Medicaid price reports without resorting to use of the lagged methodology. Genentech endorses expanding any lagged methodology instructions to deal more broadly with the timing issues that complicate AMP calculations and contribute to methodological variability between companies. To that end, we suggest the Final Rule require manufacturers to handle all chargebacks, discounts, rebates and other price concessions using a 12-month rolling percentage methodology. The Final Rule also should provide one or more illustrations of how the rolling percentage methodology should be applied so that all parties will have a clear understanding of the process. At least one of those examples should address issues associated with bundled sales.

Such an approach should maximize the smoothing out of period-to-period variability in AMP. Stable AMPs will, in our view, be important if States adopt new reimbursement formulas that are

[24] 42 CFR § 447.504(12).

AMP driven. The approach also should minimize the number of situations in which manufacturers will be required to restate prior period AMPs. We view restatements as problematic from a manufacturer and a State program workload perspective and from a pharmacy reimbursement perspective. We also see frequent restatements as undesirable in the upcoming world of AMP transparency. The frequency of required AMP reporting under the DRA makes the inclusion of provisions in the Final Rule to minimize the need for restatements all the more important.

d) Miscellaneous Transactions on Which the Proposed Rule is Silent

The Proposed Rule provides no instructions on how sales to physician offices, hospices, home health agencies, home infusion companies, or ambulatory surgical centers are to be handled in the AMP calculation. We urge the agency to address these provider types, as well as others that other commenters may identify as "missing," in the Final Rule to minimize ambiguity. Based on our understanding of the Medicare payment methodologies for prescription drugs applicable to these entities as well as the most common payment systems available to them under Medicaid and commercial insurance contracts, we recommend treating hospice and ambulatory surgical center sales like inpatient hospital sales and home health agency and home infusion company sales like outpatient clinic sales.

Clarification of Concessions to Be Deducted When AMP Is Calculated

Proposed 42 CFR § 447.504(i) clarifies which price concessions are to be deducted when AMP is calculated. The provision, read in conjunction with the other provisions of § 447.504, raises a significant questions that require further explanation. That question involves the applicability of the exclusion from AMP of *bona fide* service fees in general and, more specifically, to the proper treatment of GPO fees in the AMP calculation.

Bona Fide Service Fees

We presume that any payment to a purchaser of drug products that qualifies as a *bona fide* service fee should be ignored in accordance with proposed 42 CFR § 447.504(h)(11) when AMP is determined and in accordance with proposed 42 CFR § 447.505(d)(12) when Best Price is determined regardless of whether the payment has been characterized as an administration fee, a distribution fee, a service fee or otherwise. We ask that CMS confirm this conclusion in the Final Rule. Correcting the syntax and punctuation in the 42 CFR § 447.504(i) would help eliminate any potential confusion. We suggest the following:

> AMP includes cash discounts; free goods that are contingent on any purchase requirement; volume discounts; PBM price concessions; chargebacks; incentives; administrative fees, service fees and distribution fees unless such fees quality as *bona fide* service fees; and any other discounts or price reduction and rebates, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to the retail pharmacy class of trade.

Similar corrections are needed in 42 CFR § 447.505(e)(1) with respect to Best Price. Please also see our comments regarding the definition of *bona fide* service fees, which begin on page 5 of this letter.

The GPO Question

We are less clear about CMS' proposed handling of fees paid to GPOs for both AMP and Best Price purposes. The Proposed Rule never specifically mentions GPOs in either the preamble or the text of the regulations. Genentech is of the view that administrative fees paid to GPOs do not constitute price concessions and, therefore, should not be deducted when AMP and Best Price are calculated. We hope the Final Rule will confirm our position and, for the sake of clarity, also stipulate that GPO fees need not satisfy the *bona fide* service fee exception to qualify for exclusion from AMP and Best Price.

GPOs are non-purchasers that represent groups of providers and conduct contract negotiations with pharmaceutical manufacturers on behalf of their assembled members. GPO members are not required to, but rather are merely permitted, at their own discretion, to purchase drugs under the contracts the GPO has negotiated. GPOs stand in a different position than PBMs and non-possessing-taking HMOs and MCOs even though these types of organizations also are non-purchasers with respect to the drugs sold to plan members through their retail pharmacy networks. Unlike GPOs, non-possession-taking HMOs and MCOs, as well as their PBM agents, are payers for drugs. They can confer favorable formulary status on a particular drug and they can move a drug's market share. As a result, it is fair to say they "arrange[] for the purchase" of drugs as that term is used in the retail pharmacy class of trade definition included in the Proposed Rule provision defining AMP.[25] It is also fair to say rebates paid to PBMs and non-possession-taking HMOs and MCOs payers reduce the price realized by a manufacturer on sales through their retail pharmacy networks since these entities pay a significant part of that price.

In contrast, because a GPO is not a payer and does not have the same ability to move market share as a PBM, it does not "arrange[] for the purchase" of drugs. As a result, administrative fees paid to a GPO do not qualify for inclusion in AMP under the Proposed Rule's AMP definition. Similarly, because GPOs are both non-purchasers and non-payers, fees paid to them cannot be said to reduce the drug prices available from manufacturers to buying group members. Accordingly, GPO fees do not neatly fit into the statutory definition of Best Price at Social Security Act § 1927(c)(1)(C) and they should be excluded from the determination of Best Price in the Final Rule just as they should be from the determination of AMP.

In support of this position, we note that GPO fees are paid to third parties that are separate from, and independent of, the purchasing parties (*see* the definition of a GPO at 42 C.F.R. § 1001.952(j)(2)). These fees have long been recognized by Congress and the Inspector General of the Department of Health and Human Services as an integral and non-abusive part of the supply chain. As such, GPO fees have been afforded both statutory and regulatory protection from prosecution under the federal anti-kickback law so long as proper disclosures of the fees are made to the GPO's buying group members. Importantly, protection for GPO fees has not been through the anti-kickback statute's statutory and regulatory exceptions for discounts,[26] but rather under a separate, GPO-specific exception and safe harbor regulation.[27] Indeed, it is precisely

[25] 42 CFR § 447.504(e).
[26] 42 USC § 1320a-7(b)(3)(A) and 42 CFR § 1001.952(h)
[27] 42 USC § 1320a-7(b)(3)(C) and 42 CFR § 1001.952(j).

because GPO fees cannot be protected by the discount exception or safe harbor--because such fees are not price concessions from a "seller" or "offer" to a "buyer"--that the GPO exception and safe harbor are necessary.

42 CFR § 447.505 – Determination of Best Price

The Definition of Best Price

The Proposed Rule defines the sales, discounts and other concessions that must be considered in the determination of Best Price for single source drugs, innovator multiple source drugs, and authorized generics of those products, saying:

> Best price shall be calculated to include all sales and *associated discounts* and other price concessions *provided* by the manufacturer *to any entity* unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation from the rebate calculation (emphasis added).[28]

Unfortunately, this definition is ambiguous. It could be read, as the industry has always read the statutory definition of Best Price, to require reporting of the lowest price net of discounts and concessions offered directly to one particular customer of the manufacturer. On the other hand, the instruction also could be read to imply that CMS expects manufacturers to look beyond the purchase price offered to any particular customer and consider, instead, related transactions with different entities, combining the discounts and other concessions given to all the associated entities involved in the sale to determine Best Price.

To avoid any confusion, we strongly recommend promulgating a Final Rule that clearly and unambiguously requires Best Price to be determined by reference to a customer-specific price, not a price derived by aggregating price concessions to different organizations in the supply chain or otherwise involved with the drug's sale. Genentech is not currently able to track its products as they move through the supply chain and cannot determine Best Price under a definition that contemplates the aggregation of price concessions to different customers. Positioning ourselves to do so would require a renegotiation of many of our distribution contracts to include extensive data reporting elements not now contemplated in the agreements. It would also put us in the untenable position of having to rely on data that we likely could not verify even though we will be required to certify the accuracy of our Best Price reports.

We would like to think the operational impossibility of aggregating discounts to various entities in the supply chain and beyond means that CMS intends the conventional reading of the Best Price definition. However, we are not convinced this is the case because the Proposed Rule stipulates that Best Price includes "prices to any retailer, *including PBM rebates*, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs."[29] Manufacturers are not in a position to match up pharmacy discounts with PBM rebates on retail network sales as the Proposed Rule appears to require. They clearly cannot be expected to track every link in every chain of distribution applicable to each of their products to define a Best

[28] 42 CFR § 447.505(a).
[29] 42 CFR § 447.505(c)(2).

Price that aggregates all discounts extended to any party that touches – physically or figuratively – a particular unit of drug somewhere in the supply chain.

Requiring manufacturers to aggregate discounts associated with different transaction for purposes of Best Price is contrary to Congressional intent. The approach often would expand the spread between AMP and Best Price and could, therefore, move manufacturers' basic rebate liabilities on single source and innovator multiple source drugs from the minimum level of 15.1% of AMP to a higher level tied to the difference between AMP and Best Price. Congress, in contrast, decided to strip provisions from the DRA that would have established higher rebate percentages under the statute. CMS has implicitly acknowledged Congress' decision to not increase manufacturers' rebates by including a provision in the Proposed Rule permitting the rebasing of AMP to prevent an unintended increase in rebate liabilities resulting from the operation of the additional rebate provision at Social Security Act § 1927(c)(2)(A)(ii). It must do the same with respect to Best Price by promulgating a Final Rule that explicitly limits Best Price to the lowest net price offered to any single Best Price-eligible customer.

Exclusion of Goods Provided Free of Charge under a Patient Assistance Program

In Advisory Opinion No. 06-14, the OIG allowed a pharmaceutical manufacturer operating a patient assistance program outside Part D to assess enrollees a nominal handling fee. We ask that CMS clarify in the Final Rule whether imposing such a fee would take free goods offered under a patient assistance program outside the Best Price exclusion for "[g]oods provided free of charge under a manufacturers' patient assistance program."[30] We do not believe it should and we hope the Final Rule will adopt this position.

Best Price Implications of Intra-Corporate Transfers of Goods

We strongly urge CMS to clarify in the Final Rule that intra-corporate transfers of goods are not required to be included in AMP or Best Price or, for that matter, in ASP. Pharmaceutical companies elect to organize themselves in a variety of ways. For example, companies may wish to transfer product manufactured by one member of the corporate family at a discounted book value to another member of the family that will, in turn, function as the exclusive corporate distributor for the product to the market. Such transfers can involve distribution of the transferred product under the labeler code assigned to the manufacturing arm of the organization or under a distinct labeler code assigned to the distribution arm.

Under these circumstances, including transfer prices in AMP, Best Price, and ASP would distort the pricing statistics. AMP and ASP are intended to capture transactional prices available in the marketplace albeit to different classes of customers. Inclusion in AMP and ASP, which are both weighted average prices, of an intra-corporate transfer price applicable to every unit of drug eventually offered to the market by the corporate enterprise would overwhelm the actual market price data and skew AMP and ASP to inappropriately low levels. Such a distortion could penalize State Medicaid programs that collect rebates based, in part, of AMP. It also would penalize providers that are reimbursed by Medicare based on ASP and, potentially, pharmacies that in the future may be reimbursed by Medicaid based, at least in part, on AMP.

[30] 42 CFR § 447.505(d)(9).

The purpose of Best Price is to ensure that State Medicaid programs achieve a net cost commensurate with the price available to a company's most favored commercial customer. If a company were required to set Best Price at its intra-corporate transfer price (or at a price reduced by the aggregate if its transfer price concessions with its customer price concessions), Best Price would cease to serve its intended purposes. Rather, it would either lead to a windfall for the State Medicaid programs or, more likely, create an unnecessary barrier to the effectuation of what otherwise would be preferred corporate structures.

In support of this argument, we note that intra-company transfers are not considered wholesale distribution under the PDMA.[31] Transfers occurring within the same corporate enterprise, therefore, should not be considered a "sale to the retail pharmacy class of trade" for AMP purposes nor should the transfer price be considered a market "price" that warrants inclusion in Best Price. Rather, the pricing statistics reported by the manufacturer should reflect the sales and pricing the corporate enterprise as a whole offers *to the public*. Genentech urges CMS to clarify this point in the Final Rule.

42 CFR § 447.510 – Requirements for Manufacturers

Restating Baseline AMP

Genentech agrees with CMS' decision to allow manufacturers the option of restating baseline AMPs. We agree manufacturers of single source and innovator multiple source drugs should have the opportunity to prevent unintended "creep" in the amount of their additional rebate liability. We also endorse the restatement being voluntary for the reasons discussed in the Proposed Rule.

We are disappointed, however, by the limited scope of the voluntary restatement. The Proposed Rule does not appear to permit manufacturers to consider the statutory change in the treatment of customary prompt pay discounts extended to wholesalers when they rebase. Rather, 42 CFR § 447.510(c)(2) restricts restatements to changes reflective of the revised definition of retail pharmacy class of trade at § 447.504(e). Unless this restriction is eliminated, many manufacturers will still pay higher additional rebates under the Final Rule. Congress rejected proposals to increase the rebate percentages during the debate over the DRA. To support Congress' intent to hold the line on Medicaid rebates, CMS must promulgate a price reporting regulation that expressly allows manufacturers to incorporate the DRA-mandated changes in the handling of CPPDs in their rebasing of AMP.

Based on the explanation for making rebasing optional, CMS appears to understand the data gathering that must support any AMP restatement. Therefore, we are surprised the Proposed Rule only allows manufacturers one quarter to accomplish a voluntary rebasing. The short timeline is all the more troubling since some manufacturers may have to make significant systems and data collection changes to comply with price reporting procedures outlined in the Final Rule. Accordingly, we urge CMS to permit manufacturers to submit rebased AMPs with price reports filed during the first four quarters after the publication date of the Final Rule.

[31] 21 CFR § 203.3(cc).

Furthermore, the Final Rule should give manufacturers the option of phasing in rebasing so long as revised baseline AMPs for all of the products the company elects to rebase are filed within the stipulated timeframe.

We appreciate the operational challenges CMS will face as it begins posting monthly AMPs and using them to calculate and disseminate monthly Federal Upper Limits (FULs). Nonetheless, it seems inappropriate to prohibit restatements of monthly AMPs except in extraordinary circumstances and even then only with permission of the Secretary of Health and Human Services. For many manufacturers, even those with sophisticated computerized government pricing systems, the determination of AMP and Best Price can be a time-consuming, detail-oriented process that will now have to be repeated at least 16 times a year. As CMS should know from the prevalence of ASP restatements deemed significant enough to transmit to the carriers, mistakes do occur on occasion despite manufacturers' best efforts.

Manufacturers should not be denied the opportunity to correct significant mistakes in their monthly AMP filings in a world where those reports will be publicly available. A prohibition against restatements could have financial consequences for manufacturers as well. We are aware of at least one state supplemental rebate program that is contemplating tying rebates on the AMPs participating manufacturers report for the last month of each quarter. A prohibition against restatement also seems unfair to pharmacies, physicians and hospital outpatient departments that may have been reimbursed for covered outpatient drugs by state Medicaid programs based on monthly AMPs that later turn out to be erroneously low.

Monthly AMP Reporting

The Proposed Rule provides scanty guidance on how manufacturers should determine monthly AMP values. It is problematic, in our view, to instruct manufacturers to devise their own procedures for estimating end-of-quarter rebates and allocating them to each month in the quarter. Such an approach puts manufacturers at risk of enforcement actions for estimation and allocation methodologies deemed inappropriate by government authorities after years of consistent good faith use. Moreover, the approach in the Proposed Rule fosters the very type of methodological variability from company to company that Congress intended to eliminate when it mandated the promulgation of an AMP regulation in the DRA. We offer as a reasonable solution the 12-month rolling average methodology discussed in our comments above about the inclusion of sales to Part D, SCHIPs, SPAPs and Medicaid programs in the determination of AMP under 42 CFR § 447.504.

Certification of Price Reports

The Proposed Rule would require manufacturers to certify both their monthly AMP reports and their quarterly AMP and Best Price filings. The logistical difficulties of obtaining certifications from a company's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or direct report designee can, at times, be daunting. We recommend requiring only a quarterly certification that speaks to the associated monthly AMPs as well as the quarterly filing itself.

Neither the Proposed Rule nor the forms CMS has made available to guide the submission of January AMPs contain the text of the proposed certification. We are familiar with the certification used with the quarterly ASP reports some pharmaceutical manufacturers must file with Medicare. That certification requires manufacturers to acknowledge without qualification that ASPs were "calculated accurately" because the applicable civil monetary penalty provision at Social Security Act § 1847A(d)(4) contains no explicit knowledge requirement. It would be inappropriate for the Final Rule, or for CMS through sub-regulatory guidance, to adopt identical certification language for AMP and Best Price purposes. The civil monetary penalty provision at Social Security Act § 1927(b)(3)(C)(ii) governing Medicaid price reporting is only triggered if a manufacturer "knowingly" provides false information. Accordingly, AMP and Best Price certifications only should require company officials to stipulate to the accuracy and completeness of reported data to the best of their knowledge and belief.

Web-Based Reporting

Genentech supports the move to electronic filing of AMP and Best Price reports. We understand that, beginning January 1, 2007, CMS will only accept such reports filed electronically through Medicaid's new Drug Data Reporting (DDR) system. We hope Medicare will move expeditiously to a similar system for ASP reporting.

That said, we are troubled by one administrative aspect of the DDR implementation. Manufacturer Release No. 76, which CMS distributed in mid-December to the technical contacts for each manufacturer that participates in Medicaid, instructs those contacts to apply for identification numbers and passwords for the DDR system. To do so, they must use an application form that requires them to submit their Social Security numbers to enroll their companies in the system. This request represents an abuse of the Social Security number system. Those numbers are supposed to be used only to track an individual's Social Security benefits, not to identify the individual in other contexts.

We see absolutely no reason why CMS cannot accept company tax identification numbers in lieu of an employee's Social Security number to effectuate a company's enrollment in the DDR system. We strongly urge CMS to adopt company tax identification numbers as the identifiers for the DDR system immediately even if doing so requires some companies to reenroll. CMS also should destroy all records of employee Social Security numbers provided by technical contacts once a company has been enrolled under its tax identification number and notify the technical contacts of the destruction.

We note the DDR system does not appear to permit manufacturers to submit a text document along with their AMP and Best Price reports. We strongly encourage CMS make this function available as soon as possible. We anticipate some manufacturers may wish to submit a letter with their price reports explaining assumptions used in making the calculations. Companies likely will find the submission of such explanations attractive during the limbo period between January 1 and the effective date of the Final Rule. Many likely will want to continue submitting explanatory letters once AMP and Best Price reports have to be certified. Adaptation of the DDR system for use by Medicare will necessitate a function allowing the submission of cover letters as well since CMS asks companies to provide assumption letters with their ASP reports.

Finally, if the DDR system will be available for communicating restatements of quarterly pricing statistics, the ability to add a letter explaining the restatement will be essential.

Posting of AMP Data

We realize the DRA sets an effective date of January 1, 2007 for the public posting of AMP data. We appreciate CMS's decision to read the law as applying to data related to sales occurring on or after the statute's effective date and its commitment not to post AMP data until it can process January monthly AMPs due to be filed by March 2, 2007. This approach ensures that posted AMPs at least will be reflective of the DRA's removal of CPPDs extended to wholesalers from the calculation.

We understand CMS believes it does not have the statutory authority to delay posting AMP data beyond the point when it has January AMPs in hand. Nonetheless, we realize executive branch agencies occasionally have missed statutory deadlines without suffering legal repercussions, particularly when there is a valid reason for delay and the delay is reasonably short. CMS itself failed to meet the statutory deadline included in the Medicare Modernization Act for implementing the competitive acquisition program (CAP) for drugs covered under Medicare Part B because it needed to work out problems with initial program design and attract a CAP vendor.

CMS should likewise delay posting of AMP values on its website until all the regulatory changes have been finalized and manufacturers given sufficient time to update their systems. Premature postings could mislead consumers about the appropriateness of the prices they are charged for drugs at retail pharmacies. It also could mislead commercial carriers about drug costs to retail outlets. The simplest way to avoid possible confusion and data misuse would be to delay website postings until the Final Rule becomes effective. Alternatively, web postings of AMP values should be prefaced by an introductory discussion explaining the current shortcomings of AMP as a measure of both retail prices and pharmacy acquisition costs and highlighting the potential for changes in the calculation methodology underlying AMP over the next year. We applaud the caveats about the AMP data currently being downloaded to the States that CMS included in Medicaid State Director Letter No. 144 released in mid-December. We also encourage reiterating the warning when the January AMPs are downloaded to the States.

Computer System and Programming Requirements

There are only two major vendors of the government pricing computer systems used by most major manufacturers to process Medicaid rebate invoices and store the data required to be retained to support rebate payments under 42 C.F.R. § 447.534(h). Installation of both of the available systems requires extensive systems support from the vendor because the systems must be mapped to a company's existing sales tracking, contract management, and financial accounting systems. Further, the government pricing systems have to be set up to properly reflect the specific details of the AMP and Best Price methodologies adopted by each company using the program. Vendor assistance is also needed to deal with program requirements and systems changes that directly affect either a company's government pricing system or the computer systems that "feed" it.

In our experience, the government pricing system vendors have a limited number of programmers and other technical support personnel available to assist manufacturers with installations of or adjustments to their government pricing systems. As a result, the implementation timeline for the Final Rule must take into account the time manufacturers will need to arrange for vendor support, wait for their scheduled work slot, and put in place and test the system changes required by the new regulations. We estimate that, collectively, manufacturers using state-of-the art government pricing systems will need between 6 months to 1 year after the Final Rule is issued to code, implement and test the required computer system changes.

42 CFR § 447.520 – Conditions Relating to Physician-Administered Drugs

The Proposed Rule confirms that States will have to require submission of National Drug Code (NDC) numbers on physician claims for the "incident-to" administration of single source drugs in 2007 to obtain federal financial participation in program costs associated with those claims. The same applies to hospital outpatient departments filing claims for such drugs. These requirements were mandated by DRA § 6002 in an effort to ensure that State Medicaid programs collect rebates on physician-administered drugs.

Pro-rating Rebates Due on Part B Drugs Furnished to Dual Eligible Beneficiaries

We are disappointed the Proposed Rule does not require States Medicaid programs to pro-rate manufacturer rebates on physician-administered drugs and biologics when the State only pays a portion of the cost for dually eligible beneficiaries. We had expected such a provision in the wake of Senator Grassley's August 14, 2006 to Dr. McClellan clarifying Congressional intent regarding DRA § 6002. That letter declared flatly:

> The goal of the provision [DRA § 6002] is for states to be able to collect only for the proportion of the Medicaid rebate that equates to the proportion of the Medicaid payment for the drug. Federal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program.

It is patently unfair to expect manufacturers to pay a State the full rebate amount on a product reimbursed by Medicare as the primary payer when the State pays only the residual co-payment or less for the drug furnished to a dually eligible patient. In many instances, States receive significantly more in rebates than they spend on co-payments. The intent of the Medicaid drug rebate statute is to ensure that State Medicaid programs get the full benefit of a manufacturer's best pricing. It is not to generate windfall profits for States. To avoid any ambiguity stemming from an old CMS State Medicaid Director Letter[32] on the subject--a letter issued before Part D and before States were invoicing for rebates on physician-administered drugs where the dual-eligible issue still arises--the Final Rule should affirmatively limit manufacturers' rebate liability on physician-administered drugs to the proportion of the cost actually assumed by the State Medicaid program.

[32] State Medicaid Director Letter No. 64 (1996), stating "[i]f a Medicaid agency paid any portion of a drug claim, including the dispensing fee, then, for purposes of the rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug."

Time Limit on Retrospective Utilization Adjustments

We note some State programs have been using crosswalks to collect rebates on physician-administered drugs for a number of years. Many have even reprocessed claims from prior years and presented manufacturers with invoices containing utilization adjustments for numerous quarters to capture additional rebates. We have received invoices for drugs administered as far back as the first quarter of 1999.

We understand States are of the view they may collect rebates on claims going as far back as they have the data to identify the product administered. Neither existing regulations nor the Proposed Rule impose time limits on the States' ability to engage in this practice. The Medicaid Drug Rebate Statute does require States to submit drug utilization data to manufacturers "not later than 60 days after the end of each rebate period."[33] Despite this, CMS has always permitted States to adjust utilization demands in later quarters. Although the 1995 proposed rule designed to codify requirements of the Medicaid drug rebate program would have limited States to a one-year look-back period,[34] that rule was never finalized. In the interest of finality, we encourage CMS to add a provision to 42 CFR § 447.520 imposing a one-year time limit on States' look-back utilization adjustments when it publishes the Final Rule.

Implications of AMP Changes for 340B Pricing

Social Security Act § 1927(a) prohibits the Department of Health and Human Services from making federal financial participation available to State Medicaid programs on a manufacturers' products and from paying for those products under Part B of Medicare unless the manufacturer has entered into a Pharmaceutical Pricing Agreement (PPA) with the Office of Pharmacy Affairs (OPA) at the Health Resources and Services Administration agreeing to make discounted pricing available to 340B Covered Entities. Social Security Act § 1927(a)(5)(D) stipulates that "[i]n determining whether an agreement under subparagraph (A) [referring to a manufacturer's PPA with OPA] meets the requirements of section 340B of the Public Health Service Act, the Secretary [of HHS] may not take into account any amendments to such section [referring to section 340B of the Public Health Service Act] enacted after the enactment of title VI of the Veterans Health Care Act of 1992."[35]

We note that the DRA makes absolutely no changes to the Public Health Service Act or to Social Security Act § 1927(b)(3). Yet, despite the fact that the model PPA in Article II requires manufacturers of single source and innovator multiple source drugs "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug *reported . . . to* the Secretary in accordance with the manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage (emphasis added)," we received a letter from the Director of OPA dated January 30, 2007 stating that we must "continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts." This instruction is contrary

[33] Social Security Act § 1927(b)(2)(A).
[34] 60 *Fed. Reg.* 48442-48490 (Sept. 19, 1995).
[35] Pub. L. 102-585 (Nov. 4, 1992).

to the requirements of our PPA. It is also inconsistent with the Proposed Rule's requirement to exclude CPPDs from AMP.

More importantly, OPA's position is operationally impractical. Manufacturers have no obligation to report pricing data to OPA. Rather, we are only required to report to pricing statistics to CMS, including AMP reflective of the DRA direction to exclude prompt pay discounts and, eventually, other elements of the Final Rule specifying additional requirements for the determination of AMP. We cannot imagine CMS wants to receive records from manufacturers detailing AMPs calculated in two different ways. Moreover, we have no idea how OPA expects manufacturers and CMS will deal with the rebasing of AMP provided from in the Proposed Rule since the rebasing will affect the Unit Rebate Amounts (URAs) calculated by CMS and used by manufacturers to calculate the 340B ceiling price. We urge CMS to notify OPA of its refusal to require reporting of two AMPs and we ask that CMS coordinate with the Secretary of HHS and OPA to ensure that manufacturers will not be subjected to the requirement to calculate and report two AMPs--a requirement which would impose additional recordkeeping requirements on manufacturers as well as overburden manufacturer price reporting staffs that are already facing a quadrupling of their reporting workloads because of the DRA's requirement for monthly AMP reporting.

Implications of AMP Changes for ASP

Rebasing the AMP Threshold Percentage

Under the Medicare Modernization Act, CMS has the authority to reduce ASP-based payments for Part B covered drugs if ASP exceeds AMP by 5%. This AMP-based trigger for Part B reimbursement cuts needs to be adjusted to account for the exclusion of CPPDs from the calculation of AMP under the DRA. CMS has the statutory authority to make the adjustment simply by changing the existing threshold percentage that applies when comparisons between ASP and AMP are carried out.[36] The Impact Analysis of the Proposed Rule estimates AMPs will increase by approximately 2% because of the change in treatment of CPPDs. That estimate suggests the appropriate threshold percentage for 2008 should be in the range of 7%. Nonetheless, we urge CMS to base the threshold percentage to be published in the 2008 Physician Fee Schedule Final Rule based on an analysis of AMP data received pre- and post-promulgation of the Final Rule. We recognize CMS has made no adjustments to ASP to date because of concerns about the currency of data in OIG reports urging such reductions. We trust CMS will continue to show the same restraint when it assesses ASP data under the 2007 threshold percentage after implementation of the Final Rule.

Implications of AMP Changes for ASP Calculations

When ASP reporting first began, CMS held an Open Door Forum to discuss the new pricing metric. During that forum, the agency advised manufacturers to look to their customary business practices and their AMP procedures for guidance whenever the Social Security Act and the ASP regulations left doubts about the proper handling of a particular issue. The Proposed Rule addresses a number of issues publicly for the first time, for example, coupons and direct patient

[36] 42 USC 1847A(d)(3)(B)(ii).

sales. Given the similarities between the calculation methodologies for AMP and ASP, CMS should consider including a discussion in the preamble to the Final Rule explaining when, or whether, manufacturers should apply new teachings from the AMP regulation to their ASP policies.

* * * * * * * *

Genentech, Inc. appreciates the opportunity to provide comments and recommendations regarding Proposed Rule CMS-2238-P. As always, we stand prepared to address any questions you may have about the issues, concerns, and suggestions discussed above.

Sincerely,

Walter Moore
Vice President, Government Affairs

Submitter : Mel Brodsky **Date:** 02/20/2007

Organization : Keystone Pharmacy Purchasing Alliance, Inc.

Category : Pharmacist

Issue Areas/Comments

Background

Background

See Attached

Collection of Information Requirements

Collection of Information Requirements

See Attached

GENERAL

GENERAL

See Attached

Provisions of the Proposed Regulations

Provisions of the Proposed Regulations

See Attached

Regulatory Impact Analysis

Regulatory Impact Analysis

See Attached

Response to Comments

Response to Comments

See Attached

CMS-2238-P-1266-Attach-1.DOC

#1266.

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

Dear Acting Administrator Norwalk:

I thank you for the opportunity to comment on the proposed rule changes that will implement the Medicaid provisions of the Deficit Reduction Act of 2005 (DRA).

It appears that many parts of this proposed rule were written without an understanding of the pharmacy community and its day-to-day operations. The impact of the proposed rule will determine whether Medicaid patients continue to receive counseling and Medicaid drugs from their community pharmacies. In addition, CMS should reconsider the GAO report, "*Medicaid Drug Rebate Program – "Inadequate Oversight Raises Concerns about Rebates Paid to States"* (GAO-05-102), dated February 2005

In CMS press releases throughout the implementation of Medicare Part D, Dr. McClellan personally praised the "heroic" efforts of Community Pharmacy (Chain Store & Independent) for the help they provided seniors during the implementation period. Due to those efforts, millions of seniors have better access to their pharmaceutical needs and billions of dollars have already been saved by the Federal Government. After spending countless hours explaining and helping seniors to choose their Part D plans, waiting months for reimbursements, and continuing to receive lower reimbursement amounts, bleeding $8.4 Billion additional dollars from Community Pharmacy may break the backbone of our prescription care system.

Here are two overall comments regarding the proposed rule:

1) Need more frequent price updates

The reimbursement cuts come entirely from multiple source drugs (generics), whose prices fluctuate on a daily basis due to market place availability and the number of manufacturers supplying the product. Updating pricing monthly, with a 30 day window for the manufactures to supply pricing data means that pricing will lag as much as 60 days behind the market place.

2) AMP definition includes price concessions not available to community pharmacy

Everyone agrees that Average Wholesale Price (AWP) is no longer an accurate basis for pricing, however, Average Manufacturer's Price (AMP) is hardly an accurate replacement. The primary flaw I see in your calculation for determining Federal Upper Limit (FUL) using AMP is that distribution costs added to this price by Wholesalers & Distributors is not considered in your formula. While CMS may feel that this is a minimal mark-up (as with Brand Name Products), in reality this figure ranges from a low of 15% to a high of about 35%.

Independents purchase 95% of their generics through Wholesalers & Distributors. Chain stores purchase fewer generics through Wholesalers & Distributors, but their net price (after direct purchase from manufacturers and handling warehousing and distribution internally) is similar to independent pharmacy's invoice pricing. Wholesalers in the United States enable timely delivery of prescription care and are very important in the day-to-day pharmacy operation.

In light of their contribution of prescription care, I urge CMS to consider the addition of wholesaler markups into the computation of the FUL.

In response to CMS's specific requests for comments:

Including mail-order pricing into the pricing formula to calculate FUL's –

The fact that manufacturers have instituted different prices for different categories is discriminatory. This issue has been litigated in Federal Court for the past 11 years. The inclusion of mail-order pricing in the formula seriously disadvantages brick and mortar retail pharmacy. The Federal Government should mandate a "One Price Policy" by all manufacturers to all categories, thereby lowering the price to the consumer, leveling the playing field and ending discriminatory pricing. It seems to work in Europe and Canada – but influential lobbying interests have spent millions to prevent this from occurring in the United States.

At a minimum, CMS should create a Retail Average Manufacturers Price (RAMP) and a Mail-Order Average Manufacturers Price (MAMP) for reimbursement to these two entities.

Including rebates to PBM's in the calculation of AMP –

CMS states in the proposed rule that it has no way of knowing what portion of these rebates are passed onto Community Pharmacy or the consumer. I want to be completely clear on this point: ***NONE OF THESE DOLLARS ARE PASSED ONTO COMMUNITY PHARMACY OR THE CONSUMER.*** The present day PBM's (which are no longer just an administrator) are big businesses and their astronomical profits are to the point where they are unconscionably increasing the costs of health care. I include an article in the December 29, 2006 issue of the Wall Street Journal for your reference. Additionally, there are frequent newspaper reports on the "settlements" made by PBM's to the States, HMO's, etc for various legal infractions. For your reference, I have attached a review of PBM litigation [the Balto piece or my summary of the Balto piece broken down into pending and settled litigation].

The proposed rule will discourage the generic dispensing

Over the past few years, generic utilization has greatly increased, thus saving the government billions of dollars. This utilization has increased from about 30% of all drugs ten years ago to approximately 55% now. Cutting reimbursement for generics will reverse this increase in utilization very quickly and more than offset any estimated savings.

PBMs use the "charge-back" system to unfairly increase profits

Many PBMs own their own Mail-Order houses, and mail order is done almost exclusively through these PBM-run entities. PBMs mandate the use of the mail-order by consumers though unfair business practices (co-pay differentials) and take advantage of their mail-order category to obtain discriminatory pricing -- which they do not pass on to consumer or the end payor. They do not actually act as a wholesaler, but use the "charge-back system" developed by the wholesalers and manufacturers to greatly increase their profits. They also spend millions of dollars fighting "transparency" lawsuits throughout the country, rather than allowing anyone the ability to see "the money trail."

Allowing each State to set Professional Fees

Many cost surveys over the past few years show that the actual costs by the pharmacy community to dispense a prescription are approximately $9.50. One widely cited study – done by the University of Texas – estimates the dispensing cost at $9.62 per prescription. There is no

reason to think that the States will enact a reimbursement formula that covers these costs directly.

This would be an excellent opportunity for CMS to mandate a $10.00 professional fee for brand products and a $15.00 professional fee for generics. This would assure that generic utilization increases and patient access to prescription care would not be seriously affected. [Also, states should be encouraged to use Wholesale Acquisition Cost (WAC), which provides an accurate measure of pharmacy's acquisition cost, is published by the pricing guides, and is publicly available. Of course, adequate professional fees must also be included in the formula.]

Items Included in AMP Calculation

CMS proposes to exclude rebates to Medicaid, DoD, HIS, and DVA because prices to these entities are not available to the retail pharmacy class of trade. To be consistent in that reasoning, however, rebates offered to SCHIP, Medicare Part D Plans, PBMs and SPAP Plans should also be excluded as they are also not available to the retail pharmacy class of trade. I would respectfully ask CMS to revisit its assumptions in this portion of the proposed rule.

Initiation of the Definition of Fair Market Value

In this section, CMS discusses Medicare Part B initiating a Fair Market Value for their limited number of drugs and whether this method should be instituted for this rule. My response is that in many cases Part B drugs can not be bought by the pharmacy community at the prices set. Initiating this method would make chain pharmacy stores into variety stores and independent pharmacy would cease to exist. Access to prescription drugs would decrease and hospital emergency rooms would become understaffed clinics. This approach does not make sense.

Pricing for new generic Products entering the Market-Place:

When a brand name product nears the end of its patent, the manufacturer works out a deal with one generic manufacturer to have exclusive rights for a period of about 6 months. In many cases, the brand manufacturer has an equity ownership in the generic manufacturer or the nrand name manufacturer shares in the profits during this period through a licensing agreement. Invoice pricing does not fall by any more than 20 – 25% below the branded product during this period. Therefore, an FUL price should not be permitted until at least 2, or preferably 3 manufacturers make it available and affect market-place pricing.

Inclusion of Administration Fees or Service Fees paid to Wholesalers, PBMs or HMOs

These fees are not available to the retail pharmacy class of trade and should be excluded from the calculation. They are kept by the above entities and have no effect on invoice pricing to retail pharmacy.

Nominal Pricing

This pricing is also not available to the Retail Pharmacy Trade and should be excluded from any AMP calculation..

Use of 9-digits NDC versus the 11-digits NDC

Every pharmacy's inventory of a product is determined by actual usage of a product. Proper control of inventory is very important to a store's bottom line. As CMS agrees that keeping the 11-digits NDC is no more work than keeping the 9 digits, I would suggest that the

the country.

Outlier Price

When a manufacturer stops manufacturing a product, the pricing services do not necessarily remove the product. In fact, many remain for quite some time. There are many instances where many manufacturers decide to stop producing a drug and the price from the remaining manufacturers increase sharply. The proposed rule does not take into account this very common practice. Under the proposed rule, it could take well over 90 days for CMS to "catch up" while stores would lose money filling these prescriptions.

I respectfully submit that CMS must set up a process whereby pharmacies can fill out a form showing that a product is not available from their distributors at the price CMS is paying. This information can be verified quickly and pricing changed in a timely manner. We presently have a successful program in effect in Pennsylvania with most of the Third Party Plans, including Medicaid Programs and Part D Programs, and have had great success.

Savings Estimates developed by the Office of the Actuary in CMS

In this section CMS mentions the impact on just 3 types of small businesses: (1) small pharmaceutical companies participating in the Medicaid Drug Rebate Program, (2) small retail pharmacies & (3) physicians and other practitioners (including small hospitals or other entities such as non-profit providers) that bill Medicaid for physician administered drugs. First, it should be noted that the proposed rule will affect all of Pharmacy, including the large Chain Stores, Wholesalers, Distributors, and most importantly will affect patient ACCESS to prescriptions.

According to the Pfizer/NCPA digest for the year 2005, the average sales in an independent pharmacy are over $3 million a year. Independent pharmacies provide important, personalized counseling services to Medicaid and Medicare patients and are a vital part of their local economies.

In the summary of this section, CMS states that the reimbursement cuts will result in only a 1% decrease in pharmacy revenue. From what I have seen and heard from others with much more information in hand, however, is that AMP pricing will decrease reimbursement by $3.00 to $4.00 per prescription which will decrease gross profits by approximately 15 – 20% for an industry that is seeing its profits decreasing yearly. This is a huge negative impact upon community pharmacies. The loss of patient access to medications when more Independents close their doors CANNOT be picked up by the Chains or mail-order who do not offer the personal services provided by Independent Pharmacy (counseling, pick-up & delivery, house charges, third party administrative help, and the knowledge of their patient needs to name just a few). These closures will put patient health in jeopardy. Antibiotics, to state but one example, are a medicine that should and can be accessed immediately from community pharmacies, instead of having to wait for the drugs through mail order.

III. Additional suggestions:

Include the pharmacy profession in your meetings and allow our national groups to sit in and express their feelings at your meetings before CMS decides on a final rule. Include managers of Chain Stores & owners of Independent Stores that "live" the day-to-day operations of a pharmacy.

With Gross Profits so low in this industry, a fair Federally Mandated Professional Fee must be included in your final rulings. Do the calculations on a drug where a 30 day supply may cost 50 cents, $5, $10 etc. One price does not fit all prescriptions-- it never did and it never will. At least a Minimum Professional Fee must be mandated that will allow stores some type of return on investment.

Include Wholesaler & Distributors Mark-Ups in your calculations.

Insist that your employees spend a full day in a Pharmacy before they write up rules.

Members of PHRMA are not affected by these rulings while their products still account for **85%** of your drug costs. Have them explain the much lower pricing they offer other countries. Have them explain why they spend more on TV advertising than they do on Research & Development.

A 5% decrease in pricing from PHRMA will save much more than $8.4 Billion.

III. Summary

Although this proposed rule will have a devastating effect on many independent pharmacies, I do not know how many pharmacists will submit comments to CMS. In many instances, the implementation of Part D forced community pharmacies to close. Medicare Part D has placed such a burden on Pharmacy that only a very few have the time to read over these 150 pages & express their concerns. I hope my comments and suggestions are considered.

I believe CMS should understand that from the perspective of independent pharmacy, it seems that we are the easiest group to attack and extract money from in order to meet budget cut numbers. Federal Antitrust laws prevent us from working together to battle so what can a "small" Independent do to fight back with any success?

I thank you for this opportunity to express my concerns:

Sincerely,

Mel Brodsky R.Ph.
CEO
Keystone Pharmacy Purchasing Alliance, Inc.
7425 Frankford Ave 2nd Floor
Philadelphia, Pa 19136

Submitter : **Mr. Jeffrey Handwerker** **Date: 02/20/2007**

Organization : **Arnold & Porter LLP**

Category : **Attorney/Law Firm**

Issue Areas/Comments

Background

Background

Attached please find comments on the Proposed Rule (Docket No. CMS-2238-P) submitted on behalf of Merck/Schering-Plough Pharmaceuticals. If you have any questions about this filing, please do not hesitate to contact me.

Jeff Handwerker

GENERAL

GENERAL

Comment letter is attached as a PDF.

CMS-2238-P-1267-Attach-1.PDF

1267

February 20, 2007

VIA EXPRESS MAIL AND ELECTRONIC SUBMISSION
(http://www.cms.hhs.gov/eRulemaking)

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–2238–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–8015.

Re: **Comments on Proposed Rule Related to the Deficit Reduction Act and the Medicaid Drug Rebate Program, MS-2238-P**

Dear Acting Administrator Norwalk:

Merck/Schering-Plough Pharmaceuticals ("MSP") is pleased to submit the following comments regarding the Proposed Rule to implement provisions of the Deficit Reduction Act of 2005 ("DRA") that was published by the Centers for Medicare and Medicaid Services ("CMS") in the *Federal Register* on December 22, 2006 (the "Proposed Rule").[1] MSP appreciates the opportunity to submit these comments on the Proposed Rule and joins in the comment letters submitted today by the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO"). MSP submits this additional comment letter concerning two issues that it believes are of particular importance to ensuring a well-managed and efficient Medicaid Drug Rebate Program. MSP remains willing to assist CMS in any way deemed helpful by CMS as it develops the Final Rule.

A. Coupon Programs (447.504(g)(11) and 447.505(c)(12))

MSP offers both coupon and voucher programs for the benefit of patients. Although "coupon" and "voucher" programs may appear similar, they are different in purpose and function. In MSP's terminology, "coupons" are certificates or preprogrammed cards provided to patients that entitle them to discounts on their prescription drug purchases, either at the point-of-sale or subsequent to the purchase through obtaining a rebate from MSP or a vendor that we have retained to administer the program. In either case, the amount of the discount to the consumer

[1] Medicaid Program; Prescription Drugs, Proposed Rule, 71 Fed. Reg. 77174 (Dec. 22, 2006).

provides a dollar-for-dollar reduction in the amount that the consumer pays for the drug out-of-pocket. Whether the coupons are redeemed to us by the dispensing pharmacy or directly by the consumer, the entire discount represented by the coupon goes to the consumer.

In point-of-sale coupons, the dispensing pharmacy is compensated for the value of the discount passed on to the consumer plus a small handling fee for administering the transaction.[2] The pharmacy receives no part of the discount and is prohibited from charging more than its usual and customary price less the discount. If the consumer is a member of a managed care plan, the discount on the product is limited to the amount of the consumer's copayment or coinsurance.

"Vouchers" entitle a consumer to receive a specified number of units of a drug free-of-charge. MSP contracts with a vendor, which in turn contracts with the pharmacy. The pharmacy dispenses the drug free-of-charge to the consumer and is then reimbursed by the vendor according to a formula that the vendor negotiates with the pharmacy, plus a dispensing fee. The vendor bills MSP for this reimbursement expense (which is designed to be revenue neutral to the pharmacy) plus a service fee.[3] Because MSP indirectly reimburses the dispensing pharmacy through the negotiated formula, the dispensing pharmacy does not submit a reimbursement claim for those units to any public or private insurance program of which the consumer may be a beneficiary. Although vouchers are submitted for redemption through a pharmacy, the discount has no effect on the acquisition price paid by the pharmacy for the prescription drug that is dispensed upon the presentation of a voucher.

Under the Proposed Rule, CMS would require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of AMP," but "to include coupons redeemed by any entity other than the consumer in the calculation of AMP." 71 Fed. Reg. 77174, 77181 (Dec. 22, 2006); see also id. at 77197 (to be codified at 42 C.F.R. §§ 447.504(g)(11) & (h)(9)). Similarly, CMS would require manufacturers "to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price," but "to include coupons redeemed by any entity other than the consumer in the calculation of best price." Id. at 77183; see also id. at 77197 (to be codified at 42 C.F.R. §§ 447.505(c)(12) & (d)(8)).

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[2] The impact of the handling fee on MSP's AMP calculation and Best Price determination should be evaluated under the rules that CMS establishes for determining bona fide service fees.

[3] As with the fees involved in coupon programs, this service fee also should be evaluated under the definition of "bona fide service fee" adopted in the Final Rule.

In the context of Best Price determinations, CMS premises its proposal on its belief that "the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose sales are included in best price," but that "the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (*e.g.*, retail pharmacy)." Id. at 77183. This rationale presumably underlies CMS's proposed treatment of manufacturer coupons in AMP calculations as well.

MSP is concerned that "vouchers" may also be included in potential interpretations of the term "coupon," whether or not this was CMS's intent. MSP believes that CMS's proposed treatment of coupons (and possibly vouchers) in AMP and Best Price calculations is not appropriate. In our view, coupons redeemed directly by patients to the manufacturer should not be treated any differently from coupons redeemed to the manufacturer through other parties. CMS appears to believe that pharmacies that accept coupons/vouchers and receive reimbursement from the manufacturer for doing so obtain a concession on the acquisition price that the pharmacy paid for the drug. As noted above, however, this is not consistent with the manner in which MSP's programs are structured, where coupons and vouchers are intended solely for the financial benefit of patients, regardless of the means by which the coupon or voucher is redeemed.

Under MSP's programs, the reimbursement amount for coupons or vouchers redeemed at the pharmacy "passes through" the redeeming entity directly to the patient and is unrelated to the price the redeeming entity paid to purchase the units of the drug dispensed subject to the coupon or voucher. The transaction that establishes the price the redeeming entity paid to acquire the drug takes place well before the patient ever presents the coupon or voucher to the redeeming entity. Indeed, that transaction often involves only a wholesaler and a retail pharmacy; the manufacturer may not even be a party.[4] Because the redeeming entity in the case of both coupons and vouchers does not retain any portion of the discount conferred to the patient, the coupon or voucher has no effect on the price the entity paid for the prescription drugs it dispenses to the patient. The coupon/voucher, accordingly, should not be included in a manufacturer's calculation of AMP or determination of Best Price.

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[4] If coupon or voucher programs were "relevant" to AMP or Best Price, it is not clear how the manufacturer should account for the value of such a program in its price calculations. If the pharmacy buys the drugs from a wholesaler, the manufacturer would not: (a) know the acquisition price for the drug that the pharmacy paid (because it is not a party to the agreement between the distributor and the pharmacy); or (b) have the ability to trace the units dispensed to the patient using a coupon or voucher to a sale from the manufacturer to a wholesaler.

Moreover, CMS's proposed approach could have unintended consequences on both coupon and voucher programs, which offer substantial benefits to patients. This is especially true with regard to voucher programs, if CMS considers vouchers as "manufacturer coupons." Although vouchers function similarly to product samples (like samples, vouchers allow a patient to test a drug without cost for a limited time to enable the patient's physician to determine the safety and efficacy of the drug for the particular patient), they have many advantages over product samples. From the physician's standpoint, vouchers are easier to safeguard, store and distribute to patients. For the patient, vouchers also offer considerable advantages because they require a prescription before they can be used and a pharmacist must fill the prescription. Thus, vouchers allow the dispensing pharmacy an additional opportunity to track prescription drug use and thereby monitor for adverse drug interactions and provide another opportunity for the patient to ask questions of a healthcare practitioner.

With regard to coupon programs, CMS's proposed approach could also result in manufacturers requiring patients to redeem coupons directly to them. This would burden patients by requiring them to put forth the full out-of-pocket cost of the prescription and wait for reimbursement after mailing proof-of-purchase forms to the manufacturer. It also could require manufacturers to pay for additional infrastructure to administer such coupon programs. MSP does not believe that such additional steps are necessary or warranted. Coupons serve the valuable purpose of encouraging patients to obtain the medications their physicians have prescribed by reducing the cost of such medications to the patients, and we are concerned that CMS's proposal could reduce or unduly burden patient participation in those programs.

For these reasons, MSP respectfully requests that CMS take the following steps in the Final Rule.

1. Adopt a definition of "manufacturer coupon" and define the term to mean:

> any certificate provided to a consumer that provides by its terms that the consumer is entitled to a discount on his or her purchase of drugs, either: (A) at the point-of-purchase, through a reduction equal to the face value of the coupon up to the amount the consumer is required to pay the entity that dispenses the drugs, or (B) subsequent to the purchase, through receipt of a cash reimbursement from the manufacturer (or a vendor under contract to the manufacturer to administer the coupon program) where the reimbursement amount is equal to the lesser of the amount the

consumer paid to the dispensing entity or the face value of the coupon.

2. Require manufacturers to exclude from their AMP and Best Price calculations: (A) any manufacturer coupon redeemed by a consumer either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program; or (B) any manufacturer coupon redeemed by an entity other than a consumer (after being presented by the consumer and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the coupon program.

3. Specify that manufacturers should also exclude from their AMP and Best Price calculations any fee paid to an entity other than a consumer that redeems a manufacturer coupon where the fee satisfies the definition of "bona fide service fee" adopted by CMS the Final Rule.

4. Confirm that CMS does not consider manufacturer vouchers to be "manufacturer coupons."

5. In the alternative to recommendation 4, if CMS does decide to treat manufacturer vouchers separately from, or as part of, its guidance concerning manufacturer coupons in the Final Rule:

   (A) adopt a definition of "manufacturer voucher," and define the term to mean:

   any certificate provided to a consumer that provides by its terms that the consumer is entitled to a specified number of units of a drug free-of-charge, without (A) any co-payment from the consumer, or (B) reimbursement to the entity that dispenses the drug from any insurance program of which the consumer may be a beneficiary.

   (B) require manufacturers to exclude from their AMP and Best Price calculations: (i) Any manufacturer voucher redeemed by a consumer either directly to the manufacturer or to a vendor under contract to the

manufacturer to administer the voucher program; and (ii) Any manufacturer voucher redeemed by an entity other than a consumer (after being presented by the consumer and honored by such entity) either directly to the manufacturer or to a vendor under contract to the manufacturer to administer the voucher program; and

(C) specify that manufacturers should also exclude from their AMP and Best Price calculations: (i) the reimbursement amount paid for any manufacturer vouchers; and (ii) any fees paid to an entity other than a consumer that redeems a manufacturer voucher where the fee satisfies the definition of "bona fide service fee" adopted by CMS the Final Rule.

6. If CMS does not adopt the approach to treating coupon and voucher programs that MSP has suggested, MSP respectfully requests clear guidance from CMS as to how manufacturers should account for the value of point-of-sale coupons and vouchers in their calculations of AMP and Best Price, including specific mathematical examples as to how the value of such coupon and voucher programs should be accounted for in AMP and Best Price.

B. Effective Date

The DRA required CMS to promulgate rules concerning AMP by no later than July 1, 2007. Many of the changes that would result from promulgation of the Final Rule, including the coupon/voucher changes discussed above, will require time for manufacturers to implement. Accordingly, MSP recommends that CMS allow manufacturers four calendar quarters, that is, until July 1, 2008, before manufacturers are required to implement any changes made in the Final Rule that are not required by the DRA, including any guidance provided concerning coupon and voucher programs. This four-quarter period would allow both manufacturers and CMS sufficient time to prepare, program and test their information technology systems for the changes that the Final Rule will require.

* * * *

MSP appreciates the opportunity to comment on the Proposed Rule. MSP also acknowledges the considerable effort that CMS put into the development of the Proposed Rule,

and we hope that our comments will be useful to CMS as it develops the Final Rule. MSP would be pleased to provide any additional information upon request.

Sincerely,

Deepak K. Khanna
Vice President & General Manager
Merck/Schering-Plough Pharmaceuticals

Submitter : Ms. Jeanne LaBrecque **Date:** 02/20/2007

Organization : Indiana Office of Medicaid Policy and Planning

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-2238-P-1268-Attach-1.DOC

#1268

February 20th, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: **CMS-2238-P**

Dear Ms. Norwalk:

The State of Indiana's Office of Medicaid Policy and Planning is submitting comments on the proposed rule pertaining to 42 CFR Part 447, Medicaid Program; Prescription Drugs. The Office has a vested interest in ensuring that CMS carefully considers the merits of all comments prior to issuing a final rule. These comments have been provided to CMS to assist CMS in evaluating the best course of action to pursue while meeting the Congressional intent of the legislation. Should questions arise during CMS review of our comments, the Office has provided contact information at the end of the comments document.

Sincerely,

Jeanne M. LaBrecque
Director of Health Policy and Medicaid

States of Indiana
Office of Medicaid Policy and Planning
Agency Comments Related to 42 CFR Part 447
Medicaid Program; Prescription Drugs; Proposed Rule
File Code: CMS-2238-P

I. "Background"

Agency Comments
None

II. "Provisions of the Proposed Regulations"

Definitions—Section 447.502; Page 77176

Dispensing Fee; Page 77176

Agency Comments
The definition of "dispensing fee" specifies that it is a "fee" that is incurred at the point of sale. Even though this facet of pharmacy reimbursement has historically and colloquially been referred to as a "fee", it more correctly is an administrative allowable paid to pharmacies for certain services they provide. The definition specifies, in part, that the dispensing fee is paying "*...for costs other than the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed*". This wording is problematical in a couple of aspects, the first being that it mentions only pharmacy "costs". CMS needs to advise States as to whether or not it is CMS's intent that some profit to the pharmacy be included in the dispensing fee. Obviously, drug component reimbursement (EAC) is to approximate the agency's best estimate of the pharmacy's actual acquisition cost of the drug, and the dispensing fee is, by the CMS definition, to cover certain "costs" that the pharmacy incurs in dispensing the prescription. This leaves the obvious and significant policy question as to whether or not CMS intends that pharmacies are entitled to "profit" (presumably, through the dispensing fee) and, if so, at what level of profitability. A literal interpretation of the EAC and dispensing fee definitions implies that pharmacies are reimbursed at cost for the drug and dispensing fee. CMS needs to establish clear and unambiguous policy in this regard, incorporate it into this rule, and communicate it to States. Conversely, if CMS's intent is that there is to be no profit to pharmacies for Medicaid dispensations, through the dispensing fee or otherwise, CMS should so-specify through this rule and advise States accordingly.

The second problematical aspect to the referenced wording is that it mentions a dispensing fee as being applicable "*each time a covered outpatient drug is dispensed.*" This wording is too prescriptive and would likely prove costly to the federal government and States. In addition, some States have policies such that pharmacies are NOT entitled to a dispensing fee each time they dispense, an example being both long term care and retail pharmacies that dispense to residents of nursing facilities. Some States have adopted fiscally prudent policies that, while ensuring and preserving recipient access to necessary drugs, limit the payment of dispensing fees in such circumstances to, e.g., one

dispensing fee per recipient per legend drug order ("prescription") per month. It is up to the pharmacies and the nursing facilities with which they contract to mutually determine how often the pharmacy dispenses to residents of the facility—daily if they so choose, or otherwise on an agreed-upon lesser frequency that meets the needs of the facility and its patients—and this rule should not inadvertently interfere with that relationship such that pharmacies could claim far more dispensing fees than to which they are currently entitled in such States. Basically, the provision as currently worded could significantly increase States' dispensing fee expenditures and do so at no benefit whatsoever to the States or beneficiaries.

The CMS definition States that the dispensing fee includes "*...only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy...*" . This definition is ambiguous, due to the "not limited to" and "reasonable cost" provisions. In order for States to properly administer the benefit, States will need greater specificity and clarity from CMS regarding CMS's intent pertaining to "pharmacy costs", and what CMS considers as "reasonable". Too, this definition seems to be unduly wordy, yet does not provide the clarity needed by States. The CMS definition specifies that pharmacy costs do NOT include "*administrative costs incurred by the States in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.*" That disclaimer seems unnecessary and confusing, since it should be inherently obvious that the referenced States costs are not those of pharmacy providers. In summary, CMS should craft a definition of "dispensing fee" that is brief, clear, fully descriptive as to what CMS considers as "pharmacy costs" and "reasonable", and provides States with the necessary policy direction regarding whether or not profit is to be included in the dispensing fee or elsewhere. CMS should be aware that one of the major "pushes" by organized pharmacy since the new FUL methodology was announced is for States to increase their dispensing fees to make up for the revenue that pharmacy providers will lose due to the deficiencies of the new FULs. Unless profitability is behind this "push", it does not make sense because the advent of the new FULs will in no way increase pharmacies' dispensing "costs"; rather, the new FULs would be removing some level of profitability that pharmacies currently enjoy, and the dispensing fee (which, according to CMS's definition, apparently reimburses only "costs") is the target that pharmacies have focused on as the means by which to make up the lost revenue. This leaves a policy disconnect that CMS should remedy via this rule.

CMS may want to consider defining the dispensing fee solely in terms of its adequacy in ensuring sufficient provider participation to maintain recipient access which is, of course, a requirement of existing Federal law. That is to say, if a pharmacy chooses to participate even in light of a dispensing fee that may not cover their "costs", there should be nothing binding on the States to preclude that from happening. "Cost to dispense" studies, some quite recent, have invariably shown a "cost to dispense" dollar figure that is a multiple of existing fee-for-service Medicaid dispensing fees. Yet, pharmacy participation in Medicaid remains substantial and far more than adequate, even in light of this fact. Moreover, pharmacies that service Medicaid populations in capitated managed care arrangements accept dispensing fees that are a fraction of the fee-for-service dispensing fee—in instances, one-half or less. In light of the fact that pharmacies are apparently more than willing to accept dispensing fees that are far below their purported "cost to dispense", and do so in such numbers that more than adequate beneficiary access has historically been easily maintained, it would be highly advisable for CMS to consider defining "dispensing fee" solely in terms of what States determine to be an adequate rate to ensure necessary access. Doing so would allow States to take full fiscal advantage of the intensely competitive forces at work in the pharmacy marketplace, and eliminate the need for CMS to try to come up with a holistic, all-inclusive definition that would have to address the complicated matter of provider "costs" and what constitutes "reasonable". It should also be noted that CMS has chosen to define dispensing fee in a similar fashion to how it is defined in the Medicare Part D program in 42 CFR 423.100. It is common knowledge that the Medicare prescription drug plans have dispensing fees that are a fraction of current Medicaid dispensing fees. This can be directly attributed to the competitive forces in the pharmacy marketplace that allow the prescription drug plans to contract with an adequate pharmacy provider network in order for beneficiaries to have uninterrupted access to necessary medications. Simply stated, let States do what they do best—manage their pharmacy benefits (and associated costs) by taking full advantage of the competitive forces of the marketplace, and ensuring that rates paid to providers are sufficient to enlist and maintain necessary access to services by beneficiaries. All this can be accomplished by adopting a simplistic and fundamentally clear and sound definition of "dispensing fee".

Innovator Multiple Source Drug; Page 77176

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

Multiple Source Drug; Page 77177

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition along with the other application types referenced under innovator multiple source drugs and single source drugs. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

CMS should also consider revising or creating separate definitions for this term. One component of the definition should define this term with respect to the establishment of the FUL since the FUL will be applied to a particular date of service on a pharmacy claim. The Office assumes that the new monthly FUL will apply to a particular date of service span that will be provided by CMS. A second component of the definition should be provided that is applicable to the rebate period.

Single Source Drugs; Page 77177

Agency Comments

CMS should consider adding products approved under Biologic License Applications (BLA's) to this definition. While many of these products, such as vaccines, are not subject to the national rebate agreement, there are several products, such as antihemophilic and coagulation factors, that have traditionally been subjected to the covered outpatient drug requirements and national rebate agreement. This would align with the definition of manufacturer where the term "biological product" is specifically mentioned.

Determination of Average Manufacturer Price—Section 447.504; Page 77177

Definition of Retail Pharmacy Class of Trade and Determination of AMP; Page 77178

Agency Comments

CMS states that "*States might use AMP to calculate pharmacy payment rates.*" The Office strongly recommends that CMS consider removing or revising this statement because AMP is not representative of pharmacy provider acquisition costs and would create additional problems over and above those forthcoming with the AMP derived FUL rates as proposed by CMS. The AMP does not take into account the markup that is applied within the distribution chain between the manufacturer and purchasing pharmacy. The Office strongly recommends that CMS consider other mechanisms to calculate

pharmacy payments rates. In terms of estimating pharmacy acquisition costs, the Office believes that there is no substitute for pharmacy provider acquisition costs surveys.

Upper Limits for Multiple Source Drugs—Section 447.514; Page 77186-77188

Agency Comments

Since CMS is ultimately accountable for the methodology, oversight, and administration of the FUL program, the Office has the following recommendations and suggestions for CMS:

- CMS should operate and staff an FUL call center. Many States utilize call centers to handle provider concerns relating to their SMAC programs. The CMS call center should be available during normal business hours, excluding holidays, via a toll-free number. This call center will triage and address concerns regarding FUL rates that have been established by CMS. These concerns would include, but not be limited to, drug shortages and lack of national availability at the FUL price. If CMS chooses not to establish a call center for this purpose, CMS, at a minimum, should designate a specific individual at each regional office to triage FUL related issues from pharmacy providers.
- CMS should establish a comprehensive quality assurance process for reviewing FUL rates prior to the rates being released to States. Incorrect FUL rates result in pharmacy claims being processed incorrectly. CMS should describe, in detail, the quality assurance process in the final rule. It is unreasonable and inappropriate for pharmacy providers to be reimbursed via the FUL rate if the FUL rate is not accurate. FUL rates that have not undergone a rigorous review for accuracy should not, in any circumstance, be released to States.
- CMS should allow reasonable timeframes for the implementation of new and revised FUL rates. The Office recommends a minimum of 30 calendar days. Particular attention should be focused on rate decreases since these rates are based on monthly AMPs submitted by manufacturers rather than pharmacy purchasing histories. There will most likely be an inherent lag time between the AMP derived FUL rates and what rates pharmacies actually purchase or have purchased the drug products that subject to the FUL rates. In addition, States need ample time to review the impact of the rates as it pertains to their Preferred Drug Lists. It is not uncommon for a State to designate a multi-source brand name drug as preferred when the supplemental rebate offered by a manufacturer results in the brand name drug being less expensive, in the aggregate, than the A-rated generic equivalent. The monthly release of FULs will require States to re-analyze the expenditures, in the aggregate, thus possible requiring States to cancel or amend supplemental rebate contracts with manufacturers. The Office requests that CMS address this issue in the final rule.
- The Office assumes that CMS will apply FUL rates to the full extent in terms of product depth and breadth of covered outpatient drugs as allowed by the

legislation. In the past, CMS has not assigned FULs to injectable covered outpatient drugs. The Office requests that CMS address this assumption in the final rule.

- Current CMS methodology states that "*If all formulations of a multiple source drug are not A-rated, there must be at least three A-rated versions of the drug listed in "Approved Drug Products with Therapeutic Equivalence Evaluations" for CMS to establish a FUL for the drug.*" A literal reading of the first part of this sentence entails a situation in which there are no A-rated products, and that is likely not what you intended to convey. Suggested corrective wording here would result in the following: "If not all formulations of a multiple source drug are A-rated, there must be at least three A-rated versions of the drug…(etc.)". This statement would make sense in the given context, and correct the currently existing methodology text.
- In general, the Office supports the use of the 9-digit NDC to calculate the AMP for the reasons specified in the proposed rule. However, the Office disagrees with the idea that the most economical package size is always the one with the lowest per unit cost. In particular, for pharmacies serving smaller populations, the package size with the lowest per unit cost may include many more units than is needed for the patient base. Purchase of this package size would lead to waste if that package size is ordered and units have to be later discarded due to product expiration. The expectation that the lowest per unit cost product is always the most economical for the pharmacy can lead to reimbursement that will not fully cover costs for pharmacies that prudently purchase quantities of drugs appropriate for their patient population. The Office requests that CMS should consider and make exceptions to utilizing only the 9-digit NDC for establishing certain FUL rates. CMS should strongly consider that package sizes for creams, ointments, eye drops and IV solutions are traditionally not consistent on a unit cost basis. These products, in the smaller package sizes, are typically more costly on a unit cost basis for providers to purchase as compared to the larger package sizes of identical drug products. Establishing the FUL utilizing the 9-digit NDC will result in reimbursement below pharmacy acquisition costs when the smaller package size is being dispensed. In these instances, it would be prudent for CMS to incorporate 11-digit NDC's into the FUL process or establish other mechanisms to ensure that pharmacy providers can purchase the smaller package size at or below the established FUL. It should be noted that prescribers dictate the package sizes that are dispensed when the prescription is written, not retail pharmacies. CMS states "We are proposing to use the currently reported 9-digit AMP for calculating the FUL." The Office would recommend that CMS revise this statement to read "We are proposing to use the AMP associated with the reported 9-digit NDC for calculating the FUL."
- Utilizing the February 2007 AMP rates, our analysis showed that over half of all FULs would reimburse below the average retail acquisition cost pharmacies incur to purchase these drugs. These results represent no change from the previous 2

iterations that were performed by the Office. The Office will provide the February analysis to CMS outside of the public comments due to concerns related to AMP confidentiality.

- We agree that safeguards are necessary to ensure that a drug is nationally available at the FUL price. However, based on our analysis of the Proposed Rule and the February 2007 AMP data supplied to all states, we strongly disagree that the proposed additional criteria (e.g., carve-out policy) will ensure that a sufficient supply of the drug will be available nationally at or near the FUL price for the following reasons:

The Proposed FULs are Extremely Poor Estimations of Pharmacy Acquisition Cost

1) Since 2002, the State of Indiana has been collecting drug acquisition cost data from Indiana retail pharmacies. Based on our extensive database of drug acquisition cost data which is currently updated on a monthly basis, we evaluated the retail pharmacies ingredient costs and the proposed FUL reimbursement for over 1,000 of these widely used drugs. Our analysis revealed a wide variance in underpayments and overpayments that will be made with the proposed FULs.
2) FUL Underpayment: We found that for **more than 51%** of drugs subject to a new FUL, the FUL reimbursement would be less than the average acquisition cost incurred by retail pharmacies to acquire the drugs from their suppliers. Among these drugs, many highly utilized drugs had FULs that were **less than 60%** of the average retail acquisition cost. In several cases, the FUL was **less than 10%** of the average retail acquisition cost. Underpayments on this scale would force pharmacies to reconsider participation in the Medicaid program or make States increase other payment to compensate for the insufficient ingredient cost reimbursement.
3) FUL Overpayment: On the other hand, for **nearly 49%** of drugs subject to a new FUL, the FUL reimbursement would be greater than the average retail acquisition cost. While this allows providers a margin for profit, in many cases, the profit margin can be much larger than intended if the State does not have a robust SMAC program in place. The range of overpayment extended as high as FULs that were **over 400%** of the average retail acquisition cost. The Office strongly recommends that, for this reason, CMS advise States not to discontinue their SMAC programs in lieu of the proposed FUL implementation.

Limited Supply of Drug at the FUL Price

1) Of the 1,454 drugs that meet the eligibility for an FUL, the supplier (5-digit NDCs) with the lowest AMP (after applying the proposed carve-out criterion) on average accounted for only 28% of recent claims made for the drug, which is a proxy for the current Medicaid market demand for the drug. That is to

say, the lowest cost supplier is currently distributing less than three out of ten units dispensed.

2) Of the 1,454 drugs that meet FUL eligibility, there are ninety-three (93) drugs where there is only one 9-digit NDC with a reported AMP that is less than the FUL price. These include highly utilized drugs such as Glyburide, Heparin, Mirtazapine, Oxycodone, Prednisone, and Warfarin. For these 93 drugs, the suppliers (5-digit NDCs) account for an average of 44% of recent claims made for the drug. That is to say, the lowest cost supplier is currently distributing about four out of ten units dispensed.
3) Of the 1,454 drugs that meet FUL eligibility, there are two hundred and twenty four (224) drugs where less than 40% of the current suppliers (5-digit NDCs) have reported AMPs that are less than or near the projected FUL. These include highly utilized drugs such as Acyclovir, Ciprofloxacin, Fluoxetine, Gabapentin, Lisinopril, Metformin, Nitroglycerin, and Paroxetine. Also, for these 224 drugs, these low price suppliers account for, on average, 40% of recent Medicaid claims for the drugs.

Increase in Price of Lowest AMP Due to Effects of Supply and Demand and Time Lag Before FUL Reflects Price Changes

1) Initially, pharmacies will have a large incentive to purchase drugs from the supplier of the drug with the lowest AMP in order to maximize profits. In the short run; however, manufacturers will not be able to increase capacity the nearly fourfold (in the aggregate, see 1 above) necessary to meet the demand for their drug(s). When demand exceeds supply, the manufacturer with the lowest AMPs will increase its price to distributors who will increase their price to retailers. At that point, it is likely that no supplier will have the drug available at the FUL price due to the time lag inherent in reporting AMPs to CMS and CMS communicating new FUL prices.
2) As more pharmacies begin purchasing the drug with the lowest AMP, they will likely purchase these drugs in quantities necessary to meet all their client needs, including Medicare, commercial insurers and walk-ins. This will further reduce supply and cause the price of the lowest AMP to increase.

Regarding the exclusion criterion as proposed by CMS, we understand through discussions with CMS that it is meant to be applied only once for each FUL drug. In other words, if the lowest AMP is less than 30 percent of the second lowest AMP, and the second lowest AMP is less than 30 percent of the third lowest AMP, then the FUL would be established based on the second lowest AMP. Please confirm that you plan to apply the exclusion criteria only once. The Office also recommends that CMS utilize simple examples to illustrate the exclusion criterion as the present wording is confusing.

We applied the exclusion criterion in iterations of 40%, 50%, and 60% to the AMP data to gauge the impact of changing the carve-out percentage. We were discouraged to

discover that increasing the percentage had little impact on increasing the number of FUL drugs where the FUL rate exceeds the average retail acquisition cost of the drug. In summary, using the proposed 30% carve-out percentage resulted in only 49% of FUL drugs having a price greater than the average retail acquisition cost of the drug. Increasing the carve-out percentage to 60% resulted in a modest increase in the number of FUL drugs having a price greater than the average retail acquisition costs (58%).

Based on our analysis, the proposed carve-out approach is not adequate at any percentage to ensure access to drugs at or near the FUL. Therefore, we do not believe that adjusting the percent threshold for the carve-out policy addresses or corrects deficiencies with the AMP data or the proposed outlier approach. Based on our analysis of the data, we believe other safeguards beyond a carve-out approach, are necessary to ensure that a drug is nationally available at the FUL price.

Based on our analysis, we do not believe that the proposed approach for handling outlier AMPs is adequate to ensure that a drug is available nationally at the FUL price. With the stated goal to ensure that a drug is nationally available at the FUL price, we recommend CMS consideration of utilization data as a proxy for marketplace availability. Three suggested utilization data sources to explore are 1) claims data submitted by State Medicaid programs on a regular basis, 2) NDC-level utilization data collected for the Medicare Part D program, and 3) monthly purchase data submitted to CMS by 3 or 4 national drug wholesalers for all purchases made during the prior month.

In an example of using utilization data to ensure marketplace availability, we used State drug utilization data available from the CMS web site and defined the lowest AMP as the AMP where the cumulative claims for its NDC and those associated with lower AMPs was at least 80% of the current Medicaid drug claims (refer to Table 1 below for illustration). This resulted in slightly more than 80% of all FUL drugs having a price greater than the average retail acquisition cost of the drug. We believe this provides a reasonable balance between access to drugs and incentives to encourage pharmacies to acquire less costly generic drugs.

Table 1. Assuming all NDCs are within the same FUL group, are generic, A-rated, from rebating manufacturers and non-terminated

NDC	AMP	Diff %	Util*	Cumul. Util.**	Lowest AMP (30% carve out considered)	Lowest AMP (80% util.)
12345-6789-10	1.00	--	10%	100%		
98765-4321-01	0.5	-50%	50%	90%		Lowest (FUL:1.25)
56789-1234-11	0.25	-50%	25%	40%		
78910-2345-00	0.09	-36%	15%	15%	Lowest (FUL:0.225)	

* Utilization. May be utilization measured by claims data obtained from States, utilization data collected through Medicare Part D, or purchase history obtained from national drug wholesalers.
** The Cumulative Utilization increases from lowest AMP to highest since establishing the FUL based on the lowest AMP where at least 80% of utilization is at or below that AMP would result in a FUL that provides cost coverage for all NDCs at or below that AMP price.

FFP: Conditions Relating to Physician-Administered Drugs—Section 447.518; Page 77188

Agency Comments

The Office requests that CMS specifically clarify in the rule that claims for physician administered drugs must meet all covered outpatient drug requirements. Specifically, the NDC must be from a rebating manufacturer, not have a termination date prior to the date of service on the claim and the drug must not have a DESI value of 5 or 6.

The Office requests that CMS specify, in detail, the required file format for submission of claims for physician administered multiple source drugs using NDC numbers for those drugs with the highest dollar volume listed by the Secretary.

The Office requests that CMS require NDCs and NDC quantities on Medicare B claims involving covered outpatient drugs where the beneficiary is dual eligible. This is necessary for provision of services, coordination of benefits and to minimize paper billing of crossover claims to Medicaid where NDCs are not allowed or required by Medicare intermediaries. The paper billing of crossover claims is time consuming, resource intensive and fails to take advantage of the data interchange standards that are available to providers.

The Office requests that CMS provide State Medicaid programs and Medicare intermediaries with a comprehensive list of all HCPCS procedure codes pertinent to covered outpatient drugs. This list should be supplied on a quarterly basis to coincide

with the release of new HCPCS codes by CMS. This list will ensure consistency across all Medicaid programs as it pertains to the collection of NDC's for physician administered drugs. The Office recognizes the need for collection of NDC's based on wording from CMS in the proposed rule: *"We expect that States will require physicians to submit all claims using NDC numbers, as using multiple billing systems would be burdensome for physicians and States."*

The Office requests that CMS provide State Medicaid programs with a uniform remedy for the collection of NDCs and NDC quantities as it pertains to outpatient hospital claims that will be submitted on the UB-04 claim format. The UB-04 claim format does not accommodate these values and therefore would require each State to develop a non-standard mechanism to collect this information. In particular, this is problematic for providers who work across State lines with multiple State Medicaid programs.

The Office requests that CMS provide State Medicaid programs with a uniform remedy for processing HCPCS claims involving NDCs where the product has been compounded. The Office recommends that CMS only require the NDC and NDC quantity for the NDC that most closely ties the HCPCS narrative description since the various claim forms and electronic data standards do not allow for multiple NDCs to be transmitted for a single HCPCS code. The Office does not consider duplicate submission of a HCPCS coded claim reasonable or efficient for the purposes of collecting NDCs related to secondary ingredients involved in compound claims.

III. "Collection of Information Requirements"

Agency Comments
None

IV. "Response to Comments"

Agency Comments
None

V. "Regulatory Impact Analysis"

Requirements for Manufacturers; Page 77198

Agency Comments

The CMS text is as follows: "(a) *Quarterly reports. A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period."* Over the past several months, CMS has been "cleaning up" their MDR file, notifying States of NDCs for products that should not have been considered to be "covered outpatient drugs" but were, nonetheless, somehow included on CMS's MDR file. This erroneous inclusion and subsequent file clean-up has created confusion, as States have been reimbursing for these products and, apparently, invoicing manufacturers for rebates for the products. We anticipate that the initial inclusion of the NDCs/products on CMS's MDR file occurred because manufacturers erroneously identified the products as "covered outpatient drugs", but subsequently disputed rebate invoicings for the products and asked that CMS delete the products from CMS's MDR file. If that is the case, and in order to preclude future confusion such as caused by CMS's MDR file clean-up, we suggest that wording be added to this cite that clearly places the responsibility on manufacturers to ensure that they report to CMS ***only*** those products/NDCs that are truly "covered outpatient drugs". Further, that CMS be required to coordinate as necessary with FDA or other federal agencies to ensure that products that manufacturers report to CMS as being "covered outpatient drugs" actually are same. Finally, that if products that are reported to CMS by manufacturers as being "covered outpatient drugs" are subsequently determined to not be same, States are not to be held accountable for any expenditures for, or rebates collected for, the products in the interim.

Overall Impact; Page 77190

Agency Comments

It is not clear that the estimated savings accounts for savings already realized through State Maximum Allowable Cost (MAC) programs operated in most States. If this has not been taken into account then the State and Federal Savings is most likely grossly overstated. In many instances, a lower State MAC rate is already in place and pharmacies will continue to be reimbursed at the lower State MAC rate. These lower State MAC rates would negate some or most of the expected additional savings projected in the Proposed Rule. In addition, analysis of the February 2007 AMP rates shows that many FULs would reimburse pharmacies below their average retail acquisition cost for many drugs. States will receive tremendous pressure to increase their dispensing fees to compensate for deficiencies on the ingredient cost reimbursement, which would significantly diminish the projected savings or possibly end up costing the program more in the long term.

Alternatives Considered; Page 77194

Agency Comments

We are also concerned that a sufficient supply of drugs be available nationally at or near the FUL price and believe an exception is warranted. However, based on our analysis, we do not believe in any way, shape or form that the proposed carve-out policy will ensure that a sufficient supply of the drug will be available nationally at or near the FUL.

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States of Indiana
Office of Medicaid Policy and Planning
Agency Comments Related to 42 CFR Part 447
Medicaid Program; Prescription Drugs; Proposed Rule
File Code: CMS-2238-P

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

Organization : **Daiichi Sankyo, Inc.**

Category : **Drug Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2238-P-1269-Attach-1.PDF

1269

Daiichi-Sankyo

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February 20, 2007

VIA HAND DELIVERY AND ELECTRONIC DELIVERY
The Hon. Leslie Norwalk, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-2238-P, Proposed Rule – Medicaid Program, Prescription Drugs

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services ("**CMS**") proposed rule on Medicaid Program, Prescription Drugs, the "**Proposed Rule**".[1] Daiichi Sankyo, Inc. respectfully submits the following comments to the Proposed Rule regarding Medicaid average manufacturer price ("**AMP**") and Best Price ("**BP**") calculations. We appreciate the opportunity to submit these comments and are available to discuss them with you at your convenience.

We understand the challenges associated with providing clear guidance with respect to the highly complex issues surrounding the AMP and BP calculations. As a general matter, we are concerned that the Proposed Rule raises several questions that, if unanswered, may lead to inconsistencies in manufacturers' price reporting. We have set forth some of these issues below for your consideration. Where possible, we have attempted to organize our comments pursuant to the headings in the Proposed Rule.

I. DAIICHI SANKYO, INC. BACKGROUND

Daiichi Sankyo, Inc. is headquartered in Parsippany, New Jersey, and is the U.S. subsidiary of Daiichi Sankyo Co., Ltd., a global pharmaceutical company headquartered in Japan. The company's strategic focus is on cardiovascular diseases. Research and development of new therapies is also focused in the areas of glucose metabolic disorders, infectious diseases, cancer, immunology and bone and joint diseases. Daiichi Sankyo's portfolio of covered outpatient drugs currently includes Benicar® (olmesartan medoxomil) and BenicarHCT® (olmesartan medoxomil/hydrochlorothiazide), WelChol® (colesevelam HCl), Evoxac® (cevimeline HCl) and Floxin OTIC® (ofloxacin otic).

II. GENERAL COMMENTS

We respectfully request that CMS define what the terms "include" and "exclude" mean with respect to the dollars and units components of the AMP calculation generally. The Proposed Rule is not clear as to how to treat such terms for purposes of actually performing the AMP calculation. For example, if a discount is

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[1] 71 Fed Reg. 50,428 (Dec. 22, 2006), file code CMS-2238-P.

"included" in AMP, does CMS expect manufacturers to deduct the value of the discount from the numerator (dollars) of the AMP equation but keep associated units in the denominator (units)? Similarly, for an "excluded" sale, are the dollars to be subtracted out of the numerator and not reduced by any related discounts, and the associated units to be subtracted from the denominator? If so, in cases where the purchase price associated with an "excluded" sale is not known to the manufacturer (as is often the case with indirect sales), how should a manufacturer value such units – at wholesale acquisition cost ("**WAC**")? Alternatively, should "excluded" transactions be ignored (e.g., neither sales dollars, discounts or units deducted from the AMP calculation) in light of the difficulties in valuing the sales? Is there a difference in the treatment of transactions that are "not included" versus transactions that are "excluded"? In some cases the Proposed Rule references including "sales" to certain entities, in some cases it references including "sales and associated rebates, discounts and other price concessions": does CMS intend there to be a difference in the affect on sales dollars, discounts and units based on the terminology used? In this regard, we request that CMS include both of the following in the final rule: (i) a sample AMP calculation and (ii) a chart indicating for each of the various entities that may affect the AMP and BP calculation whether sales, discounts, and/or units are deducted from the gross ex-factory dollar and unit numbers for purpose of calculating AMP.

III. SPECIFIC COMMENTS

A. Section 447.502 (Definitions)

1. Bona Fide Service Fees

a. The Proposed Rule states that service and administrative fees are included in AMP. However, the Proposed Rule states that "bona fide" service fees are excluded from AMP, without reference to administrative fees. Can an administrative fee qualify as a "bona fide service fee" that would be excluded from AMP?

b. If an administrative fee is paid to a group purchasing organization in accordance with the group purchasing organization statutory exception and/or safe harbor to the federal healthcare anti-kickback statute (21 C.F.R. § 1001.952(j)), does it also need to fit the definition of "bona fide service fee" to be excluded from AMP?

c. When defining the term "bona fide service fees" for purposes of the average sales price ("**ASP**") final rule issued on December 1, 2006, CMS included extensive guidance in the preamble interpreting the various components of this term (*see* 71 Fed. Reg. 69623, 69666-70 (Dec. 1, 2006)). We respectfully request clarification as to whether CMS's guidance on this term issued in the ASP context is relevant to the analysis of service fees in the AMP and BP context. Specifically, we respectfully request CMS to clarify that, as is the case with ASP: "If a manufacturer has determined that a fee paid meets the other elements of the definition of 'bona fide service fee,' then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee paid is not passed on to a client or customer of any entity."

d. We respectfully request clarification that service and administrative fees, regardless of whether such fees are "bona fide" as defined by CMS, are not "included" in AMP unless paid to an entity included in AMP under Section 447.504(g) of the Proposed Rule. Also, if a service fee is determined not to be "bona fide", should manufacturers prorate the service fee to apportion it to AMP-included sales only? Because AMP-excluded sales are removed from gross sales, the discounts associated with such sales should be removed from the gross discount dollars before the discounts/rebates being included (dollars being removed) from AMP calculations. Otherwise, it would result in an artificially low AMP number and this AMP number would reflect sales to AMP-included entities and discounts for AMP-included and AMP-excluded entities.

2. Bundled Sale

   a. "Bundling" is defined under the Proposed Rule to include an arrangement where an "other price concession is conditioned upon the purchase of the same drug or drugs of different types..." Does CMS mean to state that a bundle is where the discount on one drug is contingent upon the purchase of another drug (i.e., discount of drug X is contingent upon the purchase of drug Y)? While we do not believe it is the intention of CMS to consider different strengths of the same drug (e.g., same NDA, different NDCs) being offered to a customer as being a bundle, we believe that the definition requires clarification.

B. Section 447.504 (Determination of AMP)

1. (a) AMP means...

   a. As a general comment, while some wholesalers may send a manufacturer detailed reporting as to each entity to which they have sold the manufacturer's product, this is not necessarily a standard for all wholesalers and all manufacturers. As such, manufacturers in many cases rely on chargeback data to identify the retail pharmacy class of trade for AMP calculations. To the extent there is no chargeback associated with a sale, a manufacturer may have no way of knowing whether the end purchaser was "retail". We are seeking confirmation from CMS that this is acceptable.

2. (c) Customary Prompt Pay Discount means...

   a. We respectfully request clarification of the meaning of the word "routinely" when defining customary prompt pay discounts. If a manufacturer offers special or extended terms on a limited basis (e.g., during product launch) would such discounts be considered "routine" and, if, so, how should a manufacturer account for them with respect to AMP and Prompt Pay Discount reporting?

3. (e) Retail Pharmacy Class of Trade means...

   a. The Proposed Rule defines the "Retail Pharmacy Class of Trade" to include a pharmacy benefit manager (or "**PBM**"). We interpret the Proposed Rule to treat both PBM mail order business as well as other PBM business as retail pharmacy class of trade. If this interpretation is correct, it is logical that CMS should also treat non-staff model managed care organizations and employer group health plans as retail pharmacy class of trade. When a PBM is acting in a mail-order capacity as the rebate contracting agent of a plan, the financial incentives are analogous in many ways to a plan performing its own rebate contracting, and it seems incongruous to treat these two arrangements differently. We seek clarification in this regard.

4. (f) Wholesaler means...

   a. The definition of "wholesaler" appears to be inconsistent with CMS's list of sales included in the AMP calculation under the Proposed Rule. Because the AMP is to reflect the average price "from wholesalers for drugs distributed to the retail pharmacy class of trade" (emphasis added), CMS may need to adjust the definition of "wholesaler" to incorporate some of the entities listed under Proposed Rule § 447.504(g) such as individual patients (see §447.504(g)(7)). Alternatively, we respectfully suggest that CMS reconsider whether all of the sales enumerated under §447.504(g) are appropriately "included" in AMP based on the proposed definition of "wholesaler".

5. Sales, Rebates, Discounts, or other Price Concessions included in AMP

   a. We note that Proposed Rule § 447.504(4) states that nominal price sales to a "covered entity described in section 340B(a)(4) of the Public Health Service Act" are not included in AMP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children's hospitals in the definition of "covered entity" for purposes of the Best Price exclusion. However, the definition of "covered entity" under Public Health Service Act was not amended accordingly. Will prices to such children's hospitals (defined in 42 U.S.C. § 1396r-8(a)(5)(B) be eligible for the AMP exclusion?

   b. We respectfully request clarification as to CMS's position on PBM price concessions. In the preamble, CMS states: "We propose to include any rebates, discounts or other price adjustments provided by the manufacturer to the PBM that affect the net price recognized the manufacturer for drugs provided to entities in the retail pharmacy class of trade." Is it CMS's intent, based on its inclusion of PBMs in the definition of "retail pharmacy class of trade", that all rebates, discounts or other price adjustments to PBMs be included in (deducted from) AMP, unless specifically excluded? Alternatively, does the language "that affect the net price recognized by the manufacturer for drugs provided to entities in the retail pharmacy class of trade" place a burden on manufacturers to trace any non-mail order PBM discounts to the ultimate seller to identify whether such seller is an entity in the retail pharmacy class of trade? In the mail order context, chargeback data will generally allow manufacturers to attribute PBM discounts to the ultimate seller of the product. However, in non-mail order arrangements, where the PBM is not a purchaser, there can be difficulties in tracing and classifying such end sales. In many cases, such classification will be impossible. We respectfully request clarification as to CMS's expectations in this regard.

   c. We request that CMS add the wording "where identifiable and to the extent the data is available" when giving guidance on what items to include or exclude from AMP calculations (e.g., discounts given to an excluded class of trade that cannot be identified in a rebate submission from a PBM).

   d. Section 447.504(7) of the Proposed Rule "includes" direct sales to patients. See the discussion above under regarding the definition of "wholesaler." We note that "including" these sales and presumably, discounts, in the AMP calculation may potentially serve as a disincentive for manufacturers to offer patients assistance programs or other subsidies to patients. If the intent of the AMP calculations is to determine the net price by wholesalers to the retail class of trade, including sales and discounts directly to patients may improperly lower the AMP.

   e. Section 447.504(10) of the Proposed Rule "includes": "rebates, discounts, or other price concessions (other than rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations) associated with sales of drugs provided to the retail pharmacy class of trade." We respectfully request that CMS clarify the meaning of the term: "associated with".

   f. The Proposed Rule states that only manufacturer coupons redeemed directly by the patient can be excluded from AMP and BP:

      i. We note that manufacturer coupons and vouchers, directly or indirectly redeemed by the patient, serve to provide financial assistance to patients rather than the "retail pharmacy class of trade." We note that as an administrative matter, manufacturers do not always process patient coupons and vouchers directly. Two scenarios are common: (i) a patient will pay a co-pay for the

product at the pharmacy and then redeem a coupon to a third-party vendor under contract with the manufacturer, and the vendor (not the consumer) will then invoice the manufacturer for the value of the coupon; (ii) a patient will present with a coupon or voucher at the pharmacy, and the pharmacy will supply the drug to the patient out of its inventory, at a reduced cost to the patient according to the terms of the coupon, and the vendor (not the consumer) will then invoice the manufacturer for the reimbursement paid to the pharmacy (which may include a negotiated rate and a dispense fee). Is it CMS's intent that the value of coupons or vouchers redeemed by third party vendors are to be "included" in AMP and BP calculations? We respectfully request that they should not be, in light of the negligible impact such arrangements have at the "retail" pharmacy level versus the tremendous benefit to patients.

ii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance on how to value such transactions for purposes of the respective calculations. For privacy reasons, manufacturers often do not have full transparency into the dispensing of a coupon or voucher prescription (e.g., how many tablets are dispensed with a particular coupon). Similarly, even if the manufacturer were to have such transparency, other valuation issues should be addressed (e.g., if a single coupon were redeemed for an order of product that has to be filled over two prescriptions due to a pharmacy not having the full amount of medication to dispense at once – how should such coupon be allocated?).

iii. If CMS determines to include coupons and vouchers in AMP and BP, we respectfully request that CMS provide guidance regarding how a manufacturer may properly structure a Patient Assistance Program utilizing coupons (if the coupons are redeemed either at the pharmacy or through an agent of the manufacturer) and still keep its patient assistance program BP and AMP exempt.

iv. We respectfully request that CMS define "coupon" and clarify its position with respect to vouchers including the characteristics of a voucher program versus a coupon program.

g. Section 447.504(12) of the Proposed Rule "includes": "sales and associated rebates, discounts, or other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program (MA-PD), State Children's Health Insurance Program (SCHIP), State pharmaceutical assistance programs (SPAPs), and Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade (except for rebates under Section 1927 of the Act or as otherwise specified in the statute or regulations)." We respectfully request that CMS clarify the meaning of the term: "associated with sales of drugs provided to the retail pharmacy class of trade". If a manufacturer were to provide discount to a PBM in connection with its Medicare Part D mail order business, would that discount be "included" in AMP? We further request that CMS clarify the handling of a qualified retiree prescription drug plans for purposes of AMP.

h. We respectfully request that CMS clarify the meaning of the following statement in the preamble of the Proposed Rule: "Therefore, we would clarify that rebates paid to the States under the Medicaid Drug Rebate Program should be excluded from AMP calculations but that the price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included." This will also effect SCHIP XIX. How are rebates paid to states Medicaid agencies under either the CMS Rebate Agreement or a CMS-approved supplemental rebate agreement (and the associated units) to be

treated for purposes of AMP? Are manufacturers expected to perform some level of diligence to "trace" Medicaid sales to the retail pharmacy class of trade.

6. (h) Sales, Rebates, Discounts, or other Price Concessions excluded from AMP

   a. We respectfully request confirmation that clearly identifiable indirect sales to "excluded" entities should be excluded from AMP calculations (e.g., sales identified through chargeback data). Similarly, please confirm that indirect sales to excluded entities, if not identifiable as such by the data available to a manufacturer, are not required to be "excluded".

   b. We respectfully request that CMS clarify whether the references to health maintenance organizations ("**HMOs**") and managed care organizations ("**MCOs**") under section 447.504(h)(5) of the Proposed Rule are limited to so-called "staff-model" HMOs and MCOs that purchase pharmaceuticals for dispensing to their members, or whether they include so-called "IPA-model" HMOs and MCOs that arrange for pharmacy discounts but do not actually purchase drugs.

   c. We respectfully request clarification as to the appropriate AMP treatment of direct and clearly identifiable indirect sales and discounts to entities that dispense to only their own patients (e.g., to physicians, home health care, clinics, long term care, prisons, ambulatory care centers, surgi-centers, and other outpatient health care centers).

   d. We respectfully request clarification as to the appropriate AMP treatment of discounts and administrative fees paid to group purchasing organizations.

   e. We support CMS's determination to exclude returned goods from the AMP calculation. However, we respectfully request additional clarification regarding what it means that goods were "returned in good faith." Assuming that a manufacturer has no evidence to the contrary, may a manufacturer assume that goods are returned in good faith? Alternatively, we request that CMS delete the "good faith" requirement, as this issue is in the purview of the returners and not the manufacturer.

   f. We request clarification on whether a manufacturer may treat all chargeback reversals as returns if data is not available to the manufacturer to indicate otherwise.

7. (i) Further Clarification of AMP Calculation

   a. We understand that the requirement that a manufacturer must adjust the AMP if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized is not new. However, we suggest that CMS consider implementing a tolerance level for quarterly AMP variation, within which an AMP restatement (positive or negative) would not be permitted, in order to reduce the burden on states, CMS and manufacturers.

   b. When calculating quarterly AMP, would CMS consider allowing manufacturers the option of calculating a weighted quarterly AMP based upon the monthly AMPs that were submitted for the quarter? In this regard, we would respectfully request that manufacturers choosing this option not be required to restate AMPs. This would eliminate restating of quarterly AMPs as monthly AMPs are generally not allowed to be restated. This would also reduce the administrative burden on the states, CMS and manufacturers in connection with the restatement of quarterly AMPs.

C. 447.505 (Determination of Best Price)

1. CMS states for Best Price reporting "that the best price includes the lowest price available to any entity..." We respectfully request that CMS clarify that the intent of this provision is that the BP represents the best price *achieved* and consider conforming the proposed regulation to this intent.

2. When referencing "Tricare" after depot throughout the Proposed Rule is CMS stating that all Tricare discounts (mail and retail) are to be excluded from AMP and best price? Further, if CMS is asserting that Tricare's retail discount program (TrXX) is viewed as a depot, we respectfully request that CMS clarify that CMS is interpreting only the Medicaid Drug Rebate Statute and not the Veterans Health Care Act.

3. With regard to a manufacturer's patient assistance program ("**PAP**"), would reduced charges to recipients be included in best price? The Proposed Rule indicates that only "goods provided free of charge under a manufacturers' patient assistance program" would be exempt. We respectfully request that CMS exclude all prices under manufacturer PAPs from BP determinations.

4. The determination of what constitutes a "state pharmaceutical assistance program" ("**SPAP**") has been subject to varying guidance from CMS over the years. We are familiar with the several CMS Manufacturer Releases in this regard. We respectfully request that this issue be resolved through the regulatory process. One suggestion would be that manufacturers be allowed to rely on the most current SPAP list published by CMS, and that any deletions from that list apply only prospectively from the first date a manufacturer is able to terminate its contract with that program.

5. See also comments above under AMP discussion.

D. Section 447.506 (Authorized Generic Drugs)

1. The Proposed Rule indicates that, with respect to authorized generics, the original manufacturer must include the authorized generics' manufacturer's data in the calculation of AMP and Best Price. In light of the potentially anticompetitive ramifications of such data sharing, we respectfully request that CMS address an appropriate mechanism to exchange such information within applicable regulatory parameters, including those of the Federal Trade Commission.

2. We request that CMS clarify how manufacturers should handle situations where pricing data is not available from the secondary manufacturer.

3. We request that CMS clarify how manufacturers should account for any transfer pricing of the product when sold from the NDA-holder to the authorized generic manufacturer.

4. We request that CMS clarify that "authorized generic drugs" do not include situations where a drug product is purchased from a branded manufacturer and being marketed under two labeler codes solely during the term while the original product holder sells out its inventory.

E. Section 447.508 (Exclusion from Best Price of Certain Sales at Nominal Price)

1. We note that Proposed Rule § 447.508(a) states that nominal price sales to a "covered entity described in section 340B(a)(4) of the PHSA" are excluded from BP. Under the Deficit Reduction Act of 2005 (Pub. L. 109-171 (Feb. 8, 2006), the Medicaid Drug Rebate Statute at 42 U.S.C. 1396r-8(a)(5)(B) was amended to include certain children's hospitals in the definition of "covered

entity" for purposes of the Best Price exclusion. However, the definition of "covered entity" under Public Health Service Act was not amended accordingly.

2. Separately, 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I) (and Section 447.505(d)(1) of the Proposed Rule) excludes any price to a "covered entity described in subsection (a)(5)(B) of this section (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title)."

3. Will nominal prices to children's hospitals defined in 42 U.S.C. § 1396r-8(a)(5)(B) be eligible for the BP exclusion? Will such prices be separately reportable under Section 447.510(4) of the proposed rule?

F. Section 447.510 (Requirements for Manufacturers)

1. (a) Quarterly Reports

   a. Can CMS clarify how manufacturers will be required to report the Customary Prompt Payment discount to the agency from an operational perspective? For example:

      - When reporting customary prompt payment discounts, should manufacturers recognize these at the time of the sale of the product to the customer?

      - Do manufacturers report customary prompt payment discounts at the 9 digit NDC, the 11 digit NDC or at the labeler code level?

2. (c) Base Date AMP Report

   a. Due to the intense amount of resources that may be required to restate Base Date AMPs, we respectfully request that CMS offer additional time to complete this process beyond the first full quarter after the final rule has been published. We recommend that manufacturers be given 12 months to accomplish this. It may be difficult and, in some cases impossible, for manufacturers to recalculate Base Date AMPs, due to factors such as the passage of time and product sales and acquisitions. As an alternative to recalculating Base Date AMP, we respectfully request that CMS consider allowing manufacturers to calculate AMP under their current (pre-final AMP rule) methodology, then calculate AMP under the methodology established in compliance with the final AMP rule, when issued. The manufacturer could then use the ratio from that difference and apply it to their original Baseline AMP.

3. (d) Monthly AMP

   a. With respect to price concessions to the retail class of trade, is it acceptable for manufacturers to run monthly reports, and include these sales and discounts in the AMP calculations, based upon the "post" date of chargebacks, which indicates when a chargeback has been "paid"? This would be using the "cash" methodology.

   b. We respectfully request that CMS clarify how a manufacturer may "estimate" their monthly AMP. With respect to using an "estimation" or "smoothing" methodology, we recommend that manufacturers should be permitted to use a four-quarter rolling average of rebates to sales, and apply that percentage to monthly sales. Using a four quarter rolling average for smoothing is operationally more feasible than a 12-month rolling average because rebates and other price concessions are typically invoiced by customers and paid by manufacturer on a quarterly basis. We also request that CMS clarify that manufacturers should be allowed to estimate excluded sales for the month, using a four-quarter rolling average based upon gross

sales units divided by excludable AMP units for determining the ratio of non-eligible AMP sales.

c. The Proposed Rule requests comment on the issue of estimating the lagged discounts associated with quarterly AMPs in addition to monthly AMPs. We note that in some cases, it may be appropriate for a manufacturer to use the estimation methodology for the monthly calculations and the cash methodology for the quarterly submissions, as, on a quarterly basis, the lagged concessions may be significantly reduced. We note that this may vary from manufacturer to manufacturer, and thus it would make sense for CMS to permit manufacturers to use either cash or estimation for quarterly AMPs, provided the determination as to which method is to be used is consistent.

d. Regardless of CMS's determination as to timeframe for estimation, we request that CMS clarify whether the current reporting period is included in the estimation (e.g., does the current month data count as one of the twelve months in a twelve-month rolling average?).

e. We respectfully request that CMS clarify how a manufacturer should treat a negative monthly AMP.

f. We respectfully request that CMS clarify what it considers to be "lagged price concessions".

g. CMS Manufacturer Release # 76 (Dec. 15, 2006) states: "Adjustments, such as those resulting from sales data, received after the reporting period ends, should be reflected in the next monthly AMP submission." We respectfully request that CMS confirm whether this is CMS's position under the Proposed Rule as well. If so, we note that the addition of data attributable to a previous month's transactions into a later month's AMP could artificially inflate or deflate the later month's AMP.

4. (e) Certification of Pricing Reports

a. The requirement in the Proposed Rule that the CEO, CFO or delegated direct report of CEO or CFO certify the AMP and BP submissions seems unnecessary and burdensome to manufacturers. We note that there are already a number of significant legal disincentives to a manufacturer in connection with reporting inaccurate numbers, including civil monetary penalties and various state and federal prohibitions against false claims. As a practical matter, in may be difficult to obtain a signature from such senior executives on a routine basis every month, due to travel schedules. Moreover, such individuals are not necessarily in the best position organizationally to verify the accuracy of the reporting to CMS. Therefore, we respectfully request that CMS reconsider requiring such certification.

b. In the event that CMS keeps the certification requirement, we note that the references in the Proposed Rule to the CEO, CFO or delegated direct report of CEO or CFO may not fit the organizational structure of all manufacturers. The titles "CEO" and "CFO" are organization-specific, and we note that Daiichi Sankyo, Inc. has neither (rather, we have a President and a Vice President of Finance). We recommend that CMS clarify that the certification may come from an individual with within the organization with authority and accountability equivalent to an individual holding such a title.

G. Other Comments

1. We note that there is a strong potential for duplicate discounting by manufacturers in connection with physician-administered drugs that are paid as primary under Medicare and secondary under Medicaid. In some cases, this could result in a manufacturer being required to rebate more than

100% of the WAC of a product on a single claim. We respectfully request that CMS use this rulemaking as an opportunity to clarify that when a state Medicaid program pays on a drug claim in the capacity of a secondary payor, such Medicaid program should not be entitled to a full rebate on the associated unit. We do not believe that it was the intent of the Medicaid Drug Rebate Statute to permit states to claim rebates that are disproportionate to the reimbursement payments made by the states on the drugs.

2. How should manufacturers handle the Health Resources and Services Administration Office of Pharmacy Affairs' ("**OPA's**") request for a separate AMP calculation (reduced by prompt pay discounts)? How would the OPA AMP number be reported to CMS (if OPA's request stands) so that CMS can use this AMP for their reporting obligations to OPA? This requirement may be burdensome for both manufacturers and for CMS.

3. What is the process for manufactures to dispute a monthly AMP published on the CMS website if they believe it to be incorrect?

4. Will manufacturers be permitted or required to restate their AMP back through 1Q2007 after the AMP rules become final? We respectfully request that CMS clarify that any final rule applies prospectively only. In this regard, we further request that CMS permit manufacturers at least six months from the publication of the final rule to be in compliance with any requirements that are not statutory requirements under the Deficit Reduction Act of 2005.

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Please feel free to contact us if you have any questions or require further information in this regard.

Sincerely,

Daiichi Sankyo, Inc.

By: Edward J. McAdam Sr.

Edward J. McAdam Sr.
Director Contract Administration
973-630-2682

Submitter : Mark Kinney **Date:** 02/20/2007

Organization : Independnet Pharmacy Cooperative

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment. Sending a second time since I did not receive a confirmation of receipt.

CMS-2238-P-1270-Attach-1.RTF

#1270

February 19, 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

Re: Prescription Drugs

Dear Acting Administrator Norwalk:

Thank you for the opportunity to comment on the proposed regulations governing the definition of retail class of trade and determination of AMP. The Independent Pharmacy Cooperative (IPC) represents the interests of pharmacist owners, managers, and employees of more than 3200 independent community pharmacies across the country.

The Reason for Ensuring that AMP be an Accurate Reflection of Retail Pharmacy Acquisition Cost

The Average Manufacturers Price (AMP) and the resulting Federal Upper Limit (FUL) impacts not only government Medicaid programs, but now has the far reaching effect of substantially impacting the entire private marketplace as well. Therefore it is essential that the FUL represents an accurate determination of pharmacy's actual acquisition cost. Former CMS administrator McClellan already backed away from posting incorrect AMP data, stating, "They just aren't the right numbers to use…We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a reference point for setting pharmacy reimbursement."

1. Rationale Against CMS Redefining Average Manufacturer Price to Lowest Manufacturer Price

In light of a recent Government Accountability Office (GAO) report (*GAO-07-239 Medicaid Federal Upper Limits, December 22, 2006, hereinafter "GAO report")*, it appears that CMS' initial determination at a proper FUL, based on its newly proposed definition of AMP, falls significantly short of an accurate mark. In that report, dated December 22, 2006 the GAO issued a strong rebuttal to CMS's contention that retail pharmacy could mitigate the effects of AMP-based FULs as a reimbursement measure.

The GAO report found that on average, FUL, defined as a ceiling of 250% of the proposed lowest AMP for the drug, was still on average 36% below the acquisition cost to pharmacies. CMS notes that rebates were not included in the GAO analysis. However, where independent pharmacies do receive rebates, the amount would not off set this significant short fall.

Most importantly, the issue of generic drug availability makes the CMS defined Lowest Manufacturers Price unworkable. As smaller generic manufacturers seek to capture market share (many from outside the United States, i.e., India) they would be willing to enter the market with a discounted price of 20-30% in an effort to force pharmacies to buy their product. **The problem is manufacturing capacity**. These small generic manufacturers, (and the larger manufacturers as well) do not have the capacity to provide more than just a percentage of the Medicaid population's utilization. This effectively would require many pharmacies to acquire the product at a cost that is significantly higher than the LMP. To mitigate this outcome is the reason the statute defines manufacturer's price as the average. We would ask CMS to apply the plain meaning of the statute and utilize Average Manufacturer Price in their calculation.

It is also foreseeable that this process will stimulate more frequent generic conversions. The multiplicity of dosage shapes and sizes used for a single patient may contribute to a higher potential for medication misadventures, reduced patient confidence and compliance.

2. Retail Pharmacy Class of Trade Definition

IPC requests that CMS change its proposed definition of "retail pharmacy class of trade", proposed 42 CFR Sec. 447.504(e) at p. 130 as follows:

(e) Retail pharmacy class of trade means any independent pharmacy, independent pharmacy franchise, independent chains, independent compounding pharmacy, and traditional chain pharmacy – including each traditional chain pharmacy location, mass merchant pharmacy and supermarket pharmacy. This definition currently encompasses over 55,000 retail pharmacy locations.

In passing the DRA, Congress also gave CMS the authority to create a workable definition of AMP.

IPC requests that CMS adjust its proposed definition of AMP, 44 CFR Sec. 447.504 (a) as follows:

(a) AMP means, with respect to a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the federal Food, Drug, and Cosmetic Act) for a calendar month, the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade. AMP shall be determined without regard to customary prompt pay discounts extended to wholesalers. AMP shall be calculated to include retail pharmacy sales only (chain and independent); volume discounts related to retail pharmacies; AMPs for authorized generics; charge-backs to the extent paid to retail pharmacies; contingent free goods; and only adjustments that reduce the actual price paid by retail pharmacy.

IPC recommends that the following elements, which retail community pharmacy does not receive, be excluded from the calculation of AMP:

- Discounts, rebates and price concessions to PBMs/Mail Order
- State supplemental, state only and SPAP prices
- FFS/depot
- Non-contingent free goods
- Price adjustments that do not affect the actual price paid by retail pharmacy

3. The Rational Against Inclusion of PBM Price Concessions and Mail Order Rebates in the Definition of "Retail Class of Trade"

The Omnibus Reconciliation Act of 1990 through amended Section 1927 of the Social Security Act (the Act), created the Medicaid Drug Rebate Program. The rebate legislation became effective on January 1, 1991. **CMS has indicated that the program affords state Medicaid programs the opportunity to pay for drugs at discounted prices similar to those offered by pharmaceutical manufacturers to other large purchasers**. The rebate agreement attaches to sole-source drugs (new, under patent with no generic equivalents); and innovator multiple-source drugs (drugs that have new-drug FDA approval for which generic equivalents exist). **The rebate also includes non-innovator multiple-source generic drugs at 11%**. The purpose of the rebate for both brand name and generic medications is, and has been since its inception in 1991, to ensure that the government is buying in the marketplace like other large private purchasers. The proposed rule would result in the government "double dipping" by realizing the cost benefit on the front-end reimbursement to pharmacies and the back-end manufacturer rebate.

The PBM/mail order pharmacy business model today is so closely interrelated that the ability to distinguish between price concessions, discounts, rebates and fees of the two entities would likely be impossible.

Mail order pharmacies are frequently owned and/or operated in the HMO and "closed model" systems that are not available to the general public.

In addition, due to the transient nature of the Medicaid population, the mail order pharmacy model has not been found to drive savings and therefore has not been adopted by almost the entirety of state Medicaid programs. Since mail order pharmacies do not service this population, they should not be included in the definition of "retail class of trade".

IPC would recommend that PBM/Mail Order price concessions, discounts, rebates and fees not be included in the "retail class of trade" definition.

4. CMS is Setting an Unrealistic Threshold for Outlier Prices in the FUL Calculation

CMS proposes to set the FUL based on the lowest AMP, as long as that AMP is not more than 70 percent below the second lowest AMP for that drug.

It is particularly harmful to set an outlier exclusion at an AMP that is so much less (70%) than the next lowest AMP. A reasonable outlier exclusion would be no more than 20%.

5. According to the CBO, CMS's Costs Savings Assume that States will Increase Dispensing Fees. If the States do not do so, then Pharmacy Reimbursements will be so Inadequate that Most Pharmacies will not be able to Participate in the Medicaid Program.

From *Congressional Budget Office Cost Estimate, January 27, 2006, S. 1932 Deficit Reduction Act of 2005 Conference agreement, as amended and passed by the Senate on December 21, 2005*:

Based on administrative data on AMPs and prescription drug spending by Medicaid, CBO estimates that those provisions would reduce Medicaid spending by $3.6 billion over the 2006-2010 period and $11.8 billion over the 2006-2015 period. **Those savings reflect CBO's expectation that states will raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid.** The estimate also accounts for lower rebates from drug manufacturers resulting from increased use of cheaper generic drugs.

CBO does not reveal to what degree it "expects" states to raise dispensing fees when it calculates its numbers. A study recently completed by one of the four largest world-wide accounting firms, Grant Thornton, has found that the average cost to dispense in the nation was $10.50. As the current average dispensing fee among the states is only $4.50, states will be highly challenged to provide an adequate reimbursement to pharmacies, consistent with the documented cost.

6. Definition of "Dispensing Fee" needs to be Inclusive of the True Costs to Pharmacists/Pharmacies to Dispense Medicaid Drugs.

An adequate Dispensing Fee definition includes the true costs of: 1) valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling: communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and 2) other real costs such as rent, utilities and mortgage payments. Perhaps most importantly, pharmacies provide important health, safety and counseling services 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 outcome for the patient.

IPC accordingly recommends that the dispensing fee definition section of the final rule be written as follows:

42 CFR Sec. 447.502 Definitions.

Dispensing fee means the fee which:

Includes pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient. Pharmacy costs include, but are not limited to any reasonable costs associated with:

Staffing costs: (a) salaries for pharmacists and technicians, and compensation to other employees such as managers and cashiers; (b) Licensure/continuing education for pharmacists and technicians.

Store operations and overhead: (a) rent or mortgage; (b) Cleaning, repairs, and security; (c) Utilities; (d) Computer systems, software ,and maintenance; (e) Marketing and advertising; (f) Accounting, legal and professional fees; (g) Insurance, taxes, and licenses; (h) Interest paid on pharmacy-related debt; (i) Depreciation; (j) Complying with federal and state regulations; and (k) Corporate overhead.

Preparing and dispensing prescriptions: (a) prescription dispensing materials (packages, labels, pill counters, etc.); (b) compounding the Rx when necessary; (c) special packaging (unit dose, blister packs, bingo cards) and special supplies (syringes, inhalers).

Assuring appropriate use of medication: (a) drug use review; (b) consumer/patient counseling; (c) consulting with prescribers, (d) disease management, and (e) education/training.

Adjustment for medical inflation.

A reasonable profit margin to ensure business viability.

7. IPC Supports the use of NDC 11-Digit Codes for Reimbursement Purposes

CMS states that the National Drug Code (NDC) would be defined as it is used by the FDA and based on the definition used in the national rebate agreement. For the purpose of this subpart, it would mean the 11-digit code maintained by the FDA that indicates the labeler, product, and package size, unless otherwise specified in the regulation as being without respect to package size (9-digit numerical code) (p. 19). Identifying package size for reimbursement purposes should lead to a more accurate measurement of acquisition costs – i.e. the cost to pharmacy to purchase the medications.

Pharmacies already maximize product buying decisions. For example, an independent pharmacy would like to buy drugs in 1000-count package sizes in order to take advantage of the economies of scale that exist with the larger package size. However, that medication may be used infrequently. A pharmacist that bought the 1000-count size for such a medication might have to destroy significant amounts of unsold medications. In these situations, switching to an 11-digit NDC would fairly reflect the efficient purchasing of pharmacies.

8. IPC Advocates "Smoothing" of AMP Data

There are frequent, sudden changes in drug prices that are not accurately captured by the currently contemplated reporting period. Indeed, prices change on a daily basis, reflecting market place availability and the number of manufacturers supplying the product in question.

Under monthly pricing, 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. Invoicing to community pharmacy, however, continues to change daily.

Since frequent changes in drug prices and corresponding changes in AMP could negatively impact community pharmacists. Purchase prices could turn out to be significantly higher than reimbursements that are received after purchase and filling of the prescription. To lessen this unfair outcome, "smoothing" of AMP data is necessary because failure to average out AMP pricing could result in significant fluctuations from month to month. IPC recommends that CMS develop a "smoothing" process for AMP.

Respectfully,

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