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

Organization : THE MEDICINE SHOPPE PHARMACY

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

2/20/2007

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

Ms. Norwalk,

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

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

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

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

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

Sincerely,

KEVIN EVETTS
920 ESTATE DRIVE
MEMPHIS TENNESSEE 38119

THE MEDICINE SHOPPE PHARMACY

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

Organization : McKesson Corporation

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

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

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

1260

McKesson Corporation
One Post Street
San Francisco, CA 94104

Ann Richardson Berkey
Senior Vice President
Public Affairs

[redacted]

McKESSON

February 20, 2007

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

Re: CMS-2238-P

Dear Ms. Norwalk:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Provisions of the Proposed Regulations

Definitions – Section 447.502

Bona Fide Service Fee

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

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

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

Dispensing Fee

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

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

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

National Drug Code

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

Determination of Average Manufacturer Price – Section 447.504

Mail Order

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

PBM Rebates, Discounts and Other Price Concessions

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

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

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

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

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

Retail Pharmacy Class of Trade

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

Customary Prompt Pay Discounts

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

Definition of Wholesaler

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

Outpatient Hospital Sales

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

Manufacturer Coupons

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

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

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

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

Determination of Best Price – Section 447.505

Customary Prompt Pay Discounts

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

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

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

PBM Rebates, Discounts and Other Price Concessions

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

Administrative, Service and Distribution Fees

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

Manufacturer Coupons

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

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

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clarification, we expect that manufacturers will be reluctant to continue these kinds of electronic programs. A major benefit of these programs is the coordination of both the physician and the pharmacist in the patient's care. Unlike traditional samples given out at the physician's office, electronic sampling and discount programs allow a pharmacist to provide drug utilization review for potential harmful interactions, therapeutic duplication, and adverse reactions. As a result, these programs promote enhanced patient safety and provide a direct benefit to the consumer.

Requirements for Manufacturers – Section 447.510

Monthly AMP Calculation Methodology

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

Posting of AMP Data

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

Upper Limits for Multiple Source Drugs – Section 447.514

FULs Representative of the Most Commonly Purchased Package Size

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

National Drug Code

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

Eliminating Outliers from FUL Calculations

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

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

Weighted Average AMP:

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

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

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

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

Market Share-Based AMP: Example 1

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

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

Market Share-Based AMP: Example 2

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

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

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

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

Retail Survey Price

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

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

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

Conclusion

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

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

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

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

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

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

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

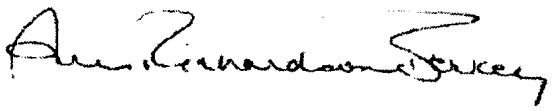
6. ***Confirm the definition of Retail Survey Price (RSP) as stated in the Deficit Reduction Act (DRA) of 2005*** and encourage states to use RSP as an alternative methodology that reflects the average consumer purchase price at retail pharmacy; and

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

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

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

Sincerely,



Ann Richardson Berkey

ATTACHMENT

List of Wholesaler Services As Compiled by HDMA

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

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

1. Logistic Support Services

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

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

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

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

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

2. Order Processing Services

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

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

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

3. Financial Management Services

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

[1] Industry Overview: IMS National Sales Perspective™

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

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

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

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

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

Additional Background Information:

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

4. Inventory Management

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

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

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

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

5. Data Management and Reporting Services

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

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

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

Additional Background Information:

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

6. Sales and Marketing Services

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

#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 ful y understand and appreciate the rising costs of prescription medication as we, unlike m ny of our payers, are required to pay for the medication we buy promptly. Prescripti n 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
Fax: 518-563-5946
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 : Miss. JAGINA HOWARD **Date:** 02/20/2007

Organization : PROFESSIONAL PHARMACY AT MT. VIEW, INC.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I THINK THIS IS DETRAMENTAL TO THE PROFESSION OF PHARMACY. THIS DOES NOT TAKE INTO ACCOUNT THE TRUE COST OF FILLING PRESCRIPTIONS AT THE PHARMACY. IT DOES NOT INCLUDE THE PHARMACIST'S LEGAL OBLIGATION TO COUNCIL PATIENTS OR CALL INSURANCE COMPANIES. I THINK REMOVING PBM AND MAIL ORDER FROM RETAIL CLASS OF TRADE CREATES CONSISTENCY IN THE REGULATION AND CONFORMS DEFINITION WITH MARKET REALITY. IMPLEMENTING A TRIGGER MECHANISM ADDRESSES SEVERE PRICE FLUCUATIONS AND MITIGATES RISK OF PRICING LAG. USING AN 11-DIGIT NDC REPRESENTS THE MOST COMMON PACKAGE SIZE DISPENSED AT RETAIL PHARMACIES. I ALSO SUPPORT MORE EXTENSIVE COMMENTS THAT ARE BEING FILED BY THE SOUTH CAROLINA PHARMACY ASSOCIATION REGARDING THIS PROPOSED REGULATION.

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

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

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[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