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March 30, 2007

Carlos Simon, Director
Division of Regulations Development A
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Blvd
Mail Stop C4-26-05
Baltimore, MD 21244

Dear Mr. Simon:

This letter is in reference to the proposed rule regarding prescription drugs and biologicals under the Medicaid Program ("Proposed Rule") which the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* on December 22, 2006.[1] On February 20, 2007, Amgen, Inc., filed a public comment letter ("original comment letter") on this Proposed Rule ("Paper Copy #30", as referenced by CMS). As part of Amgen's original comment letter, we included an attachment ("Attachment B" in the original comment letter), that Amgen requested CMS exempt from disclosure under the Freedom of Information Act ("FOIA") because it contains confidential commercial and trade secret information.

Last week, Marge Watchorn of the Pharmacy Division of the Disabled and Elderly Health Programs Group in the Center for Medicaid and State Operations notified Amgen that CMS would not able to grant the aforementioned request, but that Amgen was welcome to redact confidential portions of our original comment letter and resubmit a revised letter to the Agency if done so in a timely fashion.

Via this correspondence, Amgen respectfully re-submits the enclosed letter with attachment ("revised comment letter"), which reflects the following revisions to our February 20th original submission:

- The redaction of the Attachment B contained in the original comment letter;
- The removal of the reference to Attachment B contained in footnote 27 on page 11 of the original comment letter; and
- A change of the word "Attachments" to "Attachment" on page 19 of the original comment letter.

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[1] 71 *Fed. Reg.* 77,174.

Amgen appreciates the opportunity to comment on the important issues raised in the Proposed Rule. Please contact Sarah Wells Kocsis at (202) 585-9713 or wellss@amgen.com if you have any questions or need further information about the enclosed revised comment letter.

Regards,

Joshua J. Ofman, MD, MSHS
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cc: Marge Watchorn, DEHPG, CMSO

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REDACTED VERSION

February 20, 2007

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

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

Dear Acting Administrator Norwalk:

Amgen is writing to comment on the proposed rule regarding prescription drugs and biologicals under the Medicaid Program (the "Proposed Rule"), which the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* on December 22, 2006.[1] As a science-based, patient-driven company committed to using science and innovation to dramatically improve people's lives, Amgen is vitally interested in improving access to innovative drugs and biologicals (collectively referred to in this letter as "drugs," following the agency's convention) for Medicaid program beneficiaries. For this reason, our comments address the following three areas:

- **Proposals related to the definition and treatment of "bundled sales."** For the reasons we discuss beginning on page 2, Amgen recommends that CMS not finalize the new proposed definition and instead clarify the applicability of the existing Medicaid drug rebate agreement definition.

- **Collection of Medicaid rebates on physician-administered drugs**. For the reasons we discuss beginning on page 8, Amgen recommends that CMS include in the final rule a clarification that Medicaid rebates may be collected only on the portion of the claim paid under Medicaid. Additionally, the agency should implement the statutory time limit for state submission of rebate claims.

- **Issues related to calculation of the average manufacturer price (AMP) and best price amounts**. For the reasons we discuss beginning on page 14, Amgen

[1] 71 *Fed. Reg.* 77,174.

makes a series of recommendations intended to improve the clarity of the agency's guidance to manufacturers.

Amgen recognizes the importance of ensuring adequate payment to retail pharmacies, providers, and suppliers for covered drugs so that Medicaid beneficiaries have access to critical treatments. CMS has historically placed a high value on access under the Medicaid program, a position that we applaud the agency for adopting. However, we are concerned that certain provisions of the Proposed Rule may have the unintended consequence of deterring appropriate access. For this reason, we submit the following comments for the agency's consideration as CMS prepares to publish a final rule.

PROPOSED DEFINITION OF "BUNDLED SALES"

(Comments regarding Definitions—Section 447.502)

The Proposed Rule includes a significantly revised and expanded definition of the term "bundled sale." This term is not defined by the Medicaid statute; however, it has been included as a defined term in the Medicaid Drug Rebate Agreement. The existing definition is as follows: " 'Bundled Sale' refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."[2]

In marked contrast, the new proposed definition of a "bundled sale" is "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types (that is, at the nine-digit National Drug Code (NDC) level) or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."[3] The new definition also states that for bundled sales, "the discounts are allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement. For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all the drugs in the bundle."[4]

There are important implications for CMS to evaluate regarding the proposed new definition of "bundled sale," given that it differs significantly from that term's definition in the Medicaid Drug Rebate Agreement.

Specifically, the proposed definition would:

- insert CMS in a significant and more intrusive way into the center of highly market-based and competitive contracting practices across the pharmaceutical and biotechnology industries without due regard to the fact that these competitive practices cause and give effect to price competition that is beneficial to the government and to consumers through lower drug prices;

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2 CMS Medicaid Drug Rebate Agreement, § I(e).

3 71 Fed. Reg. at 77195.

4 *Id.*

- expand the scope of "bundled sales" to include any "arrangement" and apply "regardless of physical packaging";

- apply for the first time to any price concessions that require the purchase of the same drug;

- specify that drugs are considered to be of different types whenever they have different NDC-9s;

- be triggered by any discount that is conditioned, not just on a purchase requirement, but also on a "performance requirement," including inclusion or tier placement on a formulary; and

- provide insufficient clarity for manufacturers regarding whether all discounts in a sale which includes both contingent and non-contingent price concessions are to be considered "bundled sales."

There is no reason to believe that the new proposed definition would improve the accuracy of the rebate calculations.

CMS does not identify any specific concerns about such sales in the preamble to the Proposed Rule or point to any harm resulting from current interpretations of the definition in the Medicaid Drug Rebate Agreement. Since there is no compelling policy rationale for the new proposed definition and there is no demonstrated problem with the current reporting procedure, the proposed change does not appear necessary or to serve a deliberate purpose. Further, CMS does not provide any specificity regarding the allocation methodology to be used or describe the end to be served through such allocation.

Given the insertion of CMS into the market-based arena of competitive contracting, the significance that this new definition could have on price reporting and reimbursement, and the vagueness inherent in definitional terms such as "arrangement," "performance condition," and "proportionately allocate," CMS should not finalize the new definition in this rulemaking. As it did with respect to a similar issue in the average sales price (ASP) context,[5] CMS should continue to allow manufacturers to make reasonable assumptions regarding applicability of the Medicaid Drug Rebate Agreement's "bundled sales" definition in their calculations of AMP and best price. In addition, CMS should clarify how the allocation methodology itself is applied, in instances in which allocation is necessary. Neither the proposed definition nor the existing one specifies, for example, how to determine the amount of the discount to be allocated or value the units sold, when a bundled sales arrangement includes both contingent and non-contingent discounts and rebates.

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[5] 71 Fed. Reg. at 69675.

There are important policy considerations that CMS should take into account in its treatment of "bundled sales."

There are also policy and practical reasons not to treat "bundled sales" as suggested in the preamble to the Proposed Rule.[6] Amgen's comments on this issue have been developed with the following principles in mind:

- **Multiproduct contracts are common, pro-competitive mechanisms for inducing and effectuating price competition.** Therefore, allocation or reallocation methodologies should be used judiciously and only where the per-unit market price (*e.g.,* the price at which purchasers actually acquire) cannot be determined by sales data alone.

- **Accurate AMP and best price calculations reflect a particular drug's price in the marketplace, and reallocation of discounts from one product to another could result in inaccurate AMP and best price calculations. Such distortions in the AMP and best price calculations could result in significant and troublesome unintended consequences, including impaired beneficiary access and inappropriate financial incentives.** This situation is a natural result since reallocations would likely cause AMPs for some drugs to be artificially high, while others would be artificially low, and perverse incentives could result in higher Medicaid payments, as buyers stocked only the "winners" and not the "losers." Therefore, AMP and best price calculations should reflect the drug's per-unit market price.

- **A new reallocation requirement could result in higher Medicaid costs for states and the federal government to the extent that AMP is used in the future to set pharmacy, provider, and supplier reimbursement rates.** Artificial manipulation of market prices by reimbursement mechanisms can lead to higher state and federal costs for the Medicaid program and impaired beneficiary access to important drugs and biologicals. Further, reallocation of discounts from one product to another may create a "phantom discount" that would dissociate transaction prices from AMP, potentially making AMP less useful as a payment methodology.

We discuss each of these issues in detail below.

Multiproduct contracts are common, pro-competitive mechanisms for price competition.

It is our understanding that so-called "bundled discounts," which provide buyers the opportunity to obtain larger discounts when purchasing multiple products that remain separately available, are common and provide recognized benefits to producers and consumers.[7] Bundled discounts, which are distinct from tying arrangements because

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6 71 Fed. Reg. at 77177, 77181.

7 *See* John Thorne, Discounted Bundling by Dominant Firms, 13 Geo. Mason L. Rev. 339 (2005)("Bundled discounts are in many ways akin to ordinary volume discounts, because in both cases the purchase of additional units leads to a lower overall price."); Michael A. Salinger, A

they do not require a consumer to purchase one product in order to purchase a second product in the bundle, often promote price competition and efficiency. The Supreme Court recognized that the discounting of a package of multiple products or services can benefit consumers and the market when it said, "[t]here is nothing inherently anticompetitive about packaged sales."[8] Specifically addressing this form of discount for items and services paid for by Medicare or Medicaid, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) said, "in certain circumstances, discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale. Such circumstances exist where the goods and services are reimbursed by the same federal health care program in the same manner, such as under a DRG payment."[9]

CMS should also be aware of the inherent dangers of being involved in intrusive and unnecessary micro-regulation of pharmaceutical and biotechnology companies' complex contracting practices. While the Medicaid Drug Rebate Agreement currently directs manufacturers to allocate certain discounts across all of the units of drugs in "bundled sales", a significant expansion or change in the definition of a "bundled sale" or a different allocation methodology could serve to have a chilling effect on common industry practices that serve to lower the cost of prescription medications to the federal and state governments, as well as to consumers. While CMS has not proposed to change the current allocation methodology, we anticipate that CMS may receive such a request from Johnson & Johnson (J&J), motivated by this company's desire to manipulate the AMP calculation to its commercial benefit. Later in this letter, we review in detail why CMS should not implement such changes.

Accurate AMP and best price calculations reflect a particular drug's price in the marketplace, and reallocation of discounts from one product to another could result in inaccurate AMP and best price calculations, with the potential for unintended consequences, including impaired beneficiary access and inappropriate financial incentives.

It is unnecessary to allocate price concessions among the products in a typical multiproduct contract in order to calculate an accurate AMP or best price. CMS has given informal guidance in the past suggesting that the bundled sales allocation methodology is intended to be used where multiple drugs are sold for a single price. This is a logical interpretation, since the purpose of the rebate calculation is to determine AMP and best price for each NDC of each drug. Indeed, the rebate agreement allocation methodology would be the most appropriate way to allocate a

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Graphical Analysis of Bundling, 68 J. Bus. 85 (1995) ("Bundling can . . . increase consumer surplus when it results in lower prices.").

8 Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 25 (1984); *see also,* Daniel Crane, Multiproduct Discounting: A Myth of Nonprice Predation, 72 U. Chi. L. Rev 27, 48 (2005) ("Packaged discounting is a common phenomenon among firms that have no predatory ambition. It is a business strategy that often makes perfectly good sense without any need for injury to a rival. In the short run it cannot harm competitors any more than an equivalent discount on a single product and, in the long run, it increases consumer welfare by lowering the price of goods and services even if no competitor exits the market.")

9 *See* 64 *Fed. Reg.* 63518, 63530.

fixed rebate amount, for example, among the various NDCs purchased. However, there is no policy rationale for reallocating discounts among the products in a multiproduct contract (or even among NDCs of a single drug), if the discounts and rebates are tracked by product (and NDC), resulting in an accurate picture of the total price concessions given on the specific product for which the AMP and best price are being calculated.

Furthermore, a requirement to reallocate discounts could create access issues for beneficiaries whose pharmacies, providers, and suppliers purchase only one or primarily one product or cannot access "bundled price concessions" for other reasons. Access problems would be created because the AMP on which the Medicaid payment rate may be based would not reflect an average price of that single drug because it would also include a reallocated discount given to other customers on the purchase of other products. As a result, an AMP-based reimbursement rate for the product could be lower than the price available to the purchaser, impairing access to the product. In other words, any attempt by CMS to require artificial reallocation of actual discounts could have troubling consequences.

A new reallocation requirement could result in higher Medicaid costs for states and the federal government to the extent that AMP is used in the future to set pharmacy, provider, and supplier reimbursement rates.

It is widely accepted that the use of market-based payment rates for Medicare Part B covered drugs has generally reduced payment rates and rates of increase in Medicare spending.[10] As CMS discussed in the preamble to the Proposed Rule, AMP likely will be used not only to determine rebate liability but also to calculate pharmacy payment rates.[11] Effective January 1, 2007, the federal upper payment limit for multiple source drugs is established at 250 percent of AMP for the least costly therapeutic equivalent.[12] While there is no statutory requirement that states use AMPs to set payment amounts for pharmacies, CMS clearly contemplates such use.[13]

As states consider moving to AMP as a possible Medicaid payment methodology, unnecessary application of a "bundled sale" definition could put that opportunity at risk, since the reallocation of discounts from one product to another may dissociate transaction prices from AMP, potentially making AMP less useful as a potential payment methodology. As noted earlier, since reallocations would likely cause AMPs for some drugs to be artificially high, while others would be artificially low, perverse incentives could result in higher Medicaid payments, as buyers stocked only the "winners" and not the "losers."

A related risk is that the complexity and market-distorting effects discussed above could lead manufacturers to discontinue use of multiproduct contracts. Government intervention in the competitive marketplace in such a manner could have a chilling effect

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10 *See, e.g.,* aforementioned statements by Robert A. Vito (HHS) and Mark Miller (MedPAC).

11 71 Fed. Reg. at 77178.

12 DRA § 6001(a)(2) (codified as Social Security Act § 1927(e)(5)).

13 CMS stated in the preamble to the Proposed Rule its belief that "the Congress intended that States have drug pricing data based on actual prices," as compared to "previously available data that did not necessarily reflect actual manufacturer prices of sales to the retail class of trade." *See* 71 Fed. Reg. at 77178.

on competitive contracting practices that have been shown to have lowered prices to payers and consumers. Clearly, if CMS acts to impede price competition, costs to states and the federal government could rise.[14]

As mentioned previously, there does not appear to be a compelling policy rationale to change the definition and application of the term "bundled sale" for purposes of the AMP and best price calculation methodology, and there is risk of unintended consequences. However, we anticipate that CMS will receive comments regarding this Proposed Rule from J&J that claim that "bundled price concessions" on drugs alleged not to have clinical alternatives (so-called "dominant drugs"), should be reallocated using a methodology far more troubling than the one in this Proposed Rule. J&J submitted lengthy comments on this issue in a recent ASP rulemaking, and CMS should be aware of why J&J may suggest such a measure under this Proposed Rule. For this reason, we have outlined the key issues and relevant facts in this regard in Attachment A.

RECOMMENDATIONS ON "BUNDLED SALES"

For the reasons outlined above and in Attachment A, we provide the following recommendations for the agency's consideration.

- ***Recommendation 1: Apply the "bundled sale" definition only if a manufacturer cannot determine the average unit price without an allocation methodology.***

  Amgen recommends that CMS avoid entering into the center of market-based competitive contracting which lowers federal, state, and consumer drug expenditures and limit use of any bundled sales allocation methodology to those situations in which the price of a specific item cannot otherwise be determined. Bundled sales allocation methodologies should only be needed if, for example, multiple drugs or NDCs were sold for a single price or the discount and rebate data were not kept at the necessary level of detail.

- ***Recommendation 2: Clarify how discounts involved in a bundled sale are to be allocated proportionately, when such allocation is needed.***

  The existing and proposed allocation methodology allocates discounts across drugs in a bundled sale in proportion to the dollar value of the units of each drug sold under the bundled arrangement. Since an arrangement can include both contingent and non-contingent discounts, CMS should make clear that any allocation would apply to contingent discounts only and would be based on the sales of the products subject to the arrangement, in proportion to each product's sales volume as measured in dollars, inclusive of any non-contingent discounts.

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[14] As discussed in Attachment A, it is clear that the reason J&J brought a lawsuit seeking an injunction against Amgen's use of a particular multi-product contract is to relieve price pressure on its competing product. *See, e.g.,* statements by Bob Darretta, Vice Chairman and Chief Financial Officer, J&J (Third Quarter 2005 Earnings Webcast (October 18, 2005)), and Christine Poon, Vice Chairman and World Chair, Medicines and Nutritionals, J&J (Fourth Quarter 2005 Earnings Webcast (January 24, 2005)).

- ***Recommendation 3: Reject any suggested special reallocation methodology for discounts on so-called dominant drugs, as this special methodology is designed solely to benefit the commercial interests of a single company.***

  As outlined in Attachment A, J&J may ask CMS to implement for Medicaid rebate calculation purposes a different, special reallocation method for drugs without clinical alternatives (so-called "dominant drugs"). J&J already has recommended this in the ASP context. CMS has rejected J&J's "dominant drug" definition and a special allocation methodology for ASP purposes, saying:

  > *"Furthermore, we note that we received a comment suggesting that Medicare adopt a special policy concerning the treatment of bundled price concessions in the ASP calculation for bundling arrangements that include dominant drugs without significant clinical alternatives. We do not believe it would be feasible for the Medicare program to establish a definition of a dominant drug without significant clinical alternatives that would be precise enough to clearly delineate when a product was or was not dominant, especially given the potential for great variation in the structure of bundling arrangements and the characteristics of drugs included in those arrangements."*[15]

  We encourage CMS to maintain this position for ASP calculations and to reject any requests to implement such a methodology for Medicaid AMP and best price purposes.

COLLECTION OF MEDICAID REBATES ON PHYSICIAN-ADMINISTERED DRUGS

(Comments regarding Physician Administered Drugs—Section 447.520)

CMS should include in the final rule a clarification that Medicaid rebates may be collected only on the portion of the claim paid under Medicaid.

Amgen asks that CMS include in the final rule (and solicit comment on) a provision limiting manufacturer rebate liability for drugs to that proportion of the rebate amount that is equal to the proportion of the payment for the drug that is paid by the state Medicaid program. CMS has historically interpreted the Medicaid statute as requiring full Medicaid rebates whenever Medicaid pays any portion of the drug claim.[16] In other words, under CMS' guidance, manufacturers are required to pay the full Medicaid rebate even in instances in which another primary payer has paid almost all of the allowable charge. This interpretation has been included in program releases, but it has never been adopted through formal notice-and-comment rulemaking.

We ask that CMS take this opportunity to revise its current policy by including a provision in the final rule to make clear that, when Medicaid is the secondary payer, the rebate amount is limited to the proportion of the claim paid by Medicaid. As discussed in more detail below, this position is supported by the following:

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15 71 *Fed. Reg.* 69,675.

16 *See, e.g.,* Medicaid Rebate Program Release for State Medicaid Directors # 113, *available at* http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp (Mar. 12, 2002).

- the language of the Medicaid statute, which provides that the Medicaid rebate is to be considered a reduction in the amount expended by the state;

- the legislative history of the statute, which makes clear that the Medicaid rebate was intended to be a discount to provide the state with the best price at which the manufacturer sells the drug to any other purchaser; and

- a letter to CMS from Senator Grassley dated August 14, 2006, confirming that enactment of certain DRA amendments clarified that the Medicaid rebate is only available for the Medicaid portion of the total payment for a drug.

The plain text and legislative history of the Medicaid statute support the collection of rebates only in proportion to Medicaid payments.

The Medicaid statute provides that the rebates received by the State pursuant to a rebate agreement "shall be considered to be a reduction in the amount expended under the State plan."[17] This language supports the position that where the Medicaid agency has paid a portion of the drug claim, the amount of the rebate should be collected in proportion to the amount expended by the State. A State Medicaid program that receives the full Medicaid rebate payment when it has paid just a fraction of the drug's cost does not receive a "reduction in the amount [it] expended" but rather, a financial windfall.

This position is also consistent with the purpose of the Medicaid drug rebate program, which is to provide a discount to the State for drugs paid for by the State on behalf of Medicaid beneficiaries.[18] The notion that the rebate program was intended to secure for the Medicaid program the best price that a manufacturer gives its customers is repeated throughout the legislative history of the statute[19] and is reinforced by the description of the problems that the rebate program was intended to remedy. Noting that federal Medicaid payments for prescription drugs for fiscal year 1991 were projected to reach $2.8 billion, the House Report states:

> The Committee believes that Medicaid . . . should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy. The Committee bill would therefore establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser.[20]

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17 Social Security Act ("SSA") § 1927(b)(1)(B).

18 *See, e.g.,* 136 Cong. Rec. S12954-01 (Sept. 12, 1990) ("[The Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act] mandates that . . . a prescription drug manufacturer must provide the Medicaid Program the same substantial discounts it is now giving to other purchasers of that medication.").

19 *See, e.g.*, H.R. Rep. No. 101-881, at 96 (1990), as reprinted in 1990 U.S.C.C.A.N. 2017, 2108. ("Specifically, the [Budget] Summit agreement assumed that for single source drugs manufacturers would be limited to charging Medicaid the best price given any bulk purchaser, subject to a minimum discount of 10 percent, with savings returned to Medicaid through a quarterly rebate.").

20 *Id.*; *see also* 136 Cong. Rec. S12954-01 (describing the rebate calculation under the Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act as designed "to guarantee that Medicaid continues to receive the best discounts in the market").

Requiring manufacturers to pay the full Medicaid rebate regardless of the level of Medicaid reimbursement does not ensure that Medicaid receives "the benefit of the best price for which a manufacturer sells a prescription drug," but instead grants a windfall to State agencies that, in some cases, are seeking rebates several hundred times greater than the amount reimbursed by Medicaid.[21]

Senator Grassley recently confirmed that the Medicaid rebate is available only for the Medicaid portion of the payment for the drug.

The aforementioned letter to CMS Administrator McClellan from Senator Charles Grassley, who was Chairman of the Senate Finance Committee during the enactment of the Deficit Reduction Act of 2005 ("DRA"),[22] further clarifies that rebates are to be limited to the portion of the claim paid by Medicaid where Medicaid is the secondary payer. Congress specified in section 6002 of the DRA that States must collect and submit utilization data and coding to secure Medicaid rebates "for drugs administered for which payment is made under this title."[23] Senator Grassley explained in the letter that the "language in Section 6002 makes clear that the Medicaid rebate is only available for the Medicaid portion of the payment."[24] In other words, where Medicaid is a secondary payer for a single source, physician-administered drug, it is not entitled to collect the full Medicaid rebate; rather, it is entitled to only the portion of the rebate for which payment by Medicaid was actually made.

Specifically, Senator Grassley stated that "Federal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program."[25] Senator Grassley also requested that CMS issue guidance "stating that the rebates due for physician-administered drugs furnished to dual-eligibles and Qualified Medicare Beneficiaries is limited to that portion of the Medicaid allowable payment that the State

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21 This is similar to the outcome that Senator Pryor, one of the sponsors of the Medicaid drug rebate provision, cautioned against in his assessment of one manufacturer's proposed rebate plan. The proposed plan provided for a flat rebate of $1.36 for each Medicaid prescription, regardless of the price of the drug. Senator Pryor explained that if a stock bottle of 1000 generic tablets cost $3.00, and could be used to fill 10 Medicaid prescriptions of 100 tablets each, the generic manufacturer would be required to rebate $13.60 on a product sold for $3.00, or, "in other words, the generic industry would be paying the Medicaid program $4 for every $1 of sales!" 136 Cong. Rec. S12954-01, S12960. He described this result as "grossly unfair to generic manufacturers who will be forced to overwhelmingly and disproportionately bear the burden of cost containment under this approach." *Id.* This "grossly unfair" outcome is precisely what is occurring now under current policy that manufacturers must pay the full rebate amount regardless of the level of Medicaid reimbursement.

22 Letter from Chairman Charles E. Grassley to Administrator Mark B. McClellan, Aug. 14, 2006. Sen. Grassley is now the ranking Republican on that Committee.

23 DRA § 6002, Pub. L. No. 109-171 (adding SSA § 1927(a)(7)). This language was added to the DRA in the Energy and Commerce Committee Chairman's amendment in the nature of a substitute. Prior to the Chairman's amendment, the Energy and Commerce "Committee Print" Section 3102 read "for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section."

24 Letter from Chairman Charles E. Grassley to Administrator Mark B. McClellan, Aug. 14, 2006.

25 *Id.*

actually pays as a copayment or deductible on the claim paid by Medicare as primary payor."[26]

In December 2006, Acting Administrator Norwalk sent a letter to Senator Grassley pointing to the requirement under section 1927(b)(1)(A) of the SSA that manufacturers pay a statutorily established rebate on drugs for which a payment is made by the State. As is discussed below, requiring proration of Medicaid rebates would not change the rebate calculation under section 1927(c) of the SSA. Rebates would still be calculated according to the statutory formula.

Nothing in the Medicaid statute prohibits limiting the rebate amount to the proportional amount paid by the State.

Limiting the Medicaid rebates to the proportional amount paid by Medicaid would not change the rebate calculation under section 1927(c) of the Act. Rebates would still be calculated according to the statutory formula. This amount would then be collected proportionally based on the ratio of the State's actual payment amount to the total amount reimbursed for the drug. Thus, the terms of the Medicaid statute would be met if CMS were to limit the amount of a manufacturer's rebate for a drug by the proportional amount paid for the drug by the State.

Fairness and common sense also support the collection of rebates only in proportion to Medicaid payments.

As is discussed above, the Medicaid rebate program was intended to make sure that Medicaid did not pay the undiscounted price for prescription drugs. Indeed, it requires manufacturers of innovator drugs to give rebates to Medicaid based on the best price given to commercial customers. The rebate is calculated by comparing that best price to AMP, the average price from the manufacturer to the retail pharmacy class of trade. If the states reimbursed pharmacists at AMP, the state would be getting the same price as the commercial customer receiving the best price.

Many of the Medicaid beneficiaries for whom claims are submitted for physician-administered drugs are also eligible for Medicare, which is the primary payer. Unlike the typical Medicaid pharmacy benefit, Medicare Part B has a 20 percent coinsurance for most services, including drugs. For the Medicare and Medicaid dual-eligibles, Medicaid pays the coinsurance, usually up to an amount that would make the total payment no more than the Medicaid allowable for the drug or service. This means that the payment made by Medicaid can be as little as a penny or as much as 20 percent of the product's Medicare allowable, which is based on 106 percent of ASP.

In the hypothetical example in Chart A, a drug has an AMP of $600, a best price of $350, and an ASP of $470. As you can see, the resulting rebate amount does not result in Medicaid paying the same price as the commercial customer receiving the best price. Instead of a discount, this transaction results in a windfall profit of $150 each time such a claim is received.

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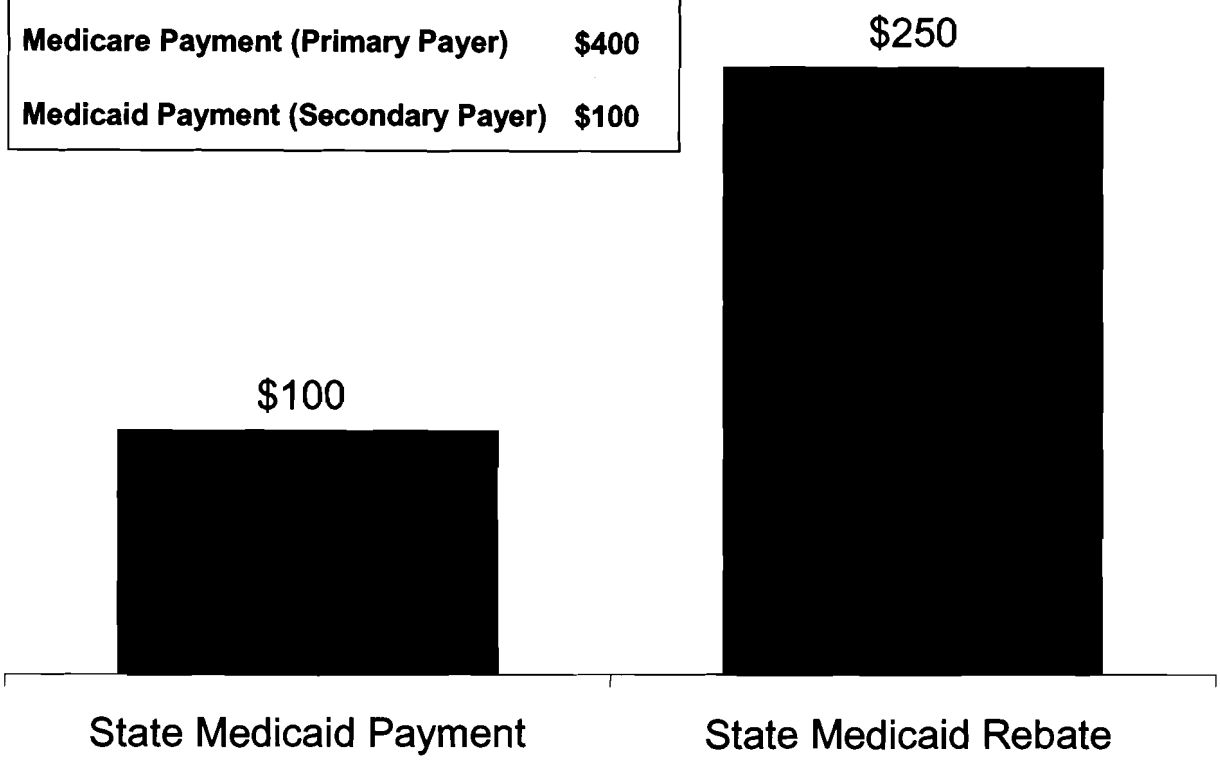
26 *Id.*

Chart A: Example of Overpayment to States for Medicaid Secondary Payer Claims

Drug Allowable at ASP+6%	**$500**
Medicare Payment (Primary Payer)	**$400**
Medicaid Payment (Secondary Payer)	**$100**



This scenario cannot be what was intended by the Congress, and Senator Grassley has confirmed that it was not what was intended. Therefore, CMS should conform its interpretation to legislative intent and end the unfair and inappropriate windfall rebates at this time.

CMS Form R-144 enables states and manufacturers to calculate rebates in proportion to Medicaid payments.

With the recent changes to the state invoice form, CMS Form R-144, CMS has the tools to require collection of the Medicaid rebate in proportion to the payment by the state.[27] Specifically, the new form includes two new columns: the Medicaid Amount Reimbursed column and the Non-Medicaid Amount Reimbursed column. This information will permit states and manufacturers to determine the portion of the Medicaid rebate due to the states by the manufacturers. In situations in which the Medicaid program is not the primary payer, the state would invoice only that proportion of the unit rebate amount equal to the ratio of: (a) the state's actual payment amount, to (b) the total amount reimbursed for the drug. By including on this revised form a column for the Medicaid Amount Reimbursed, states and manufacturers could easily determine the correct, proportional rebate amount due.

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[27] *See,* Medicaid Rebate Program Release for State Medicaid Directors # 143, *available at* http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp (Aug. 23, 2006).

CMS should implement the statutory time limit for state submission of rebate claims.

Although CMS has insisted that it must follow a narrow interpretation of the Medicaid statute (notably, one that does not take into account Senator Grassley's letter) with respect to payment of the full rebate amount on Medicaid secondary payer claims, it has simply ignored the statute with respect to the time limit on the period during which state Medicaid agencies may submit utilization data and seek payment of rebate claims. The Medicaid drug rebate statute requires that state agencies report on covered outpatient drugs paid during the period "not later than 60 days after the end of each rebate period."[28] There is no exception to this deadline and the statute does not provide for extensions. CMS stated in the preamble to its September 19, 1995 proposed rule (the "1995 Proposed Rule") that although the statute requires states to meet the 60-day requirement, CMS did not believe that the statute limited manufacturers' liability for rebates if states were unable to report utilization data by the deadline.[29] CMS did not provide any explanation or statutory support for this policy, nor has it adopted the policy through formal notice-and-comment rulemaking.

CMS's current policy contradicts the express reporting deadline of 60 days set forth in the Medicaid drug rebate statute. Amgen requests that CMS include a provision in the final rule that, consistent with the statute, limits the manufacturer's Medicaid rebate obligation to only those claims that meet the state's reporting requirement. The requirement should be to report within 60 days after the end of the rebate period. Alternatively, Amgen would not object to a reasonable longer period, not to exceed one year, as discussed below. As the time limit currently exists in the statute, it should become effective upon publication of the final rule and prohibit states from submitting any further rebate claims for quarters that precede the specified period.

CMS has recognized the need to establish a maximum timeframe during which the manufacturer is bound to pay Medicaid rebates and included in the 1995 Proposed Rule a provision that would require states to submit rebate period utilization data within one year after the rebate period ends.[30] CMS believed that a maximum timeframe of one year was equitable because it parallels the maximum timeframe of one year for pharmacies to submit claims and up to one year for states to pay claims under other Medicaid provisions. CMS also believed that a one-year timeframe would meet the needs of both states and manufacturers, because a state "would not lose rebates on those drugs for which it cannot compile the data within 60 days, and a manufacturer would not be held liable for rebates for an extensive period of time due to a state's failure to report utilization data within 60 days."[31]

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28 SSA § 1927(b)(2)(A).

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

30 1995 Proposed Rule, 60 Fed. Reg. at 48,486. Proposed section 447.530(c)(3) provided that:
(3) If a State does not submit its rebate period utilization data to the manufacturer within 1 year after the rebate period ends—
(i) a manufacturer is not required to pay a rebate on those drugs; and
(ii) a State may be considered out of compliance with section 1927 of the Act for failure to collect rebates.

31 *Id.*

The 1995 Proposed Rule was never finalized, but the issues CMS highlighted in the preamble remain. CMS stated that it considered "any time period longer than one year after the rebate period ended to be extensive since this period could ultimately translate into a manufacturer being responsible for rebates more than three years after the drug is dispensed."[32] This is because pharmacies have up to one year to bill the state agency and the states can take as long as a year to pay the pharmacy claim. The 1995 proposal would comport with general business principles, because, as CMS noted, the Internal Revenue Service generally requires that records be maintained for three years and because manufacturers may not be able to substantiate rebate claims more than three years after a drug is dispensed. Although manufacturers are now required to maintain Medicaid records for ten years,[33] because states have an apparently limitless timeframe in which to submit rebate claims or revise claims for prior years, disputes may still arise for which no records exist.

For all of these reasons, Amgen strongly urges CMS to impose a time limit on state submission of rebate claims and implement that time limit immediately upon publication of the final rule to prevent continued state submission of untimely rebate claims.

REVIEW OF RECOMMENDATIONS ON THE COLLECTION OF MEDICAID REBATES ON PHYSICIAN-ADMINISTERED DRUGS

For the reasons noted above, Amgen makes the following two recommendations:

- ***Recommendation 1:*** Include a clarification, consistent with Congressional intent, that Medicaid rebates may be collected only on the portion of the claim paid under Medicaid.

- ***Recommendation 2:*** Implement the statutory 60-day time limit for state submission of rebate claims or, at a minimum, a time limit of one year, as previously proposed by CMS.

ISSUES RELATED TO CALCULATION OF AMP AND BEST PRICE AMOUNTS

(Comments regarding Determination of Average Manufacturer Price and Best Price and Requirements for Manufacturers—Sections 447.504, 447.505, and 447.510)

CMS should clarify whether physician offices, dialysis centers, and home healthcare pharmacies are included in the retail class of trade.

CMS is proposing to define the retail pharmacy class of trade as "any independent pharmacy, chain pharmacy, mail order pharmacy, pharmacy benefit manager (PBM), or other outlet that purchases, or arranges for the purchase of, drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public."[34] Amgen is pleased that CMS has provided this guidance and believes that it will promote uniformity in the calculation of AMP. We request, however, that CMS provide specific guidance as to this definition's application to

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32 *Id.*

33 69 Fed. Reg. 68,815.

34 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. § 447.504(e)).

physician offices, dialysis centers, and home healthcare pharmacies. The Proposed Rule provides that sales to outpatient clinics and sales to hospitals when the drug is used in the outpatient pharmacy are included in AMP,[35] but does not specifically address physician offices, dialysis centers, or home healthcare pharmacies. These entities purchase a significant quantity of drugs from manufacturers, both directly and indirectly, and Amgen believes that specifying the retail or non-retail status of these entities in the final rule would provide valuable guidance to the industry.

CMS should clarify that manufacturers have discretion to restate baseline AMP on a product-by-product basis.

In the preamble to the Proposed Rule, CMS states that it is proposing to allow manufacturers "the option to decide whether they will recalculate and submit to CMS a base date AMP based on the new definition of AMP or submit their existing base date AMP."[36] Amgen supports CMS' decision to allow manufacturers to exercise discretion in making this decision, because, as CMS states, "some manufacturers may not have the data needed to recalculate base date AMP."[37] Amgen notes, however, that there may be other, additional, factors that also could affect a manufacturer's decision to restate base date AMP. Additional factors include the administrative burden of performing these recalculations, particularly given that the recalculations would have to occur during the same period that the manufacturer is implementing the final rule.

Amgen requests that CMS clarify that a manufacturer has complete discretion in making the recalculation decision and that that decision need not be based solely on data availability. Amgen requests further that CMS clarify in the final rule that manufacturers will have the option to decide on a product-by-product basis whether to restate baseline AMP. Amgen also asks CMS to provide confirmation that where a manufacturer decides to restate AMP for a given product, the recalculation should be performed in accordance with the manufacturer's current methodology for calculating AMP, inclusive of any changes required by the Proposed Rule once it is made final, and that the manufacturer may make reasonable assumptions consistent with the general requirements and intent of the Act, federal regulations, and its customary business practices.

CMS should clarify that service fees paid to non-purchasers are not included in the calculation of AMP and best price.

CMS is proposing that all administrative and service fees paid by the manufacturer be included in the calculation of AMP and best price unless the fee satisfies the Proposed Rule's definition of *bona fide* service fees. The proposed definition of *bona fide* service fees is the same definition recently adopted by CMS for purposes of the ASP calculation, and includes fees paid by the manufacturer to an entity "whether or not the entity takes title to the drug."[38] CMS declined to make a specific proposal with respect to the ASP calculation regarding the treatment of fees paid to entities that may be non-purchasers, specifically pharmacy benefit managers (PBMs) and group purchasing

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35 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. § 447.504(g).
36 71 Fed. Reg. at 77,185.
37 *Id.*
38 71 Fed. Reg. at 77,195.

organizations (GPOs).[39] Amgen urges CMS to clarify in its final rule that fees paid to non-purchasers, in particular GPOs, are not relevant for purposes of Medicaid price reporting. Inclusion of GPO fees in the calculation of AMP would distort the AMP calculation by likely lowering AMP figures, and thus pharmacy payment rates, potentially resulting in barriers to access for Medicaid beneficiaries as well as lowering Medicaid rebates.

Amgen believes that fees paid to GPOs should not be considered price concessions on drugs not purchased by GPOs. GPOs typically are entities that negotiate contracts with manufacturers on behalf of healthcare providers (*i.e.,* hospitals, nursing homes and physician clinics). GPOs generally do not purchase products. Instead, they negotiate discounted pricing on behalf of their members, who are purchasers. Inclusion of GPO fees in the calculation of AMP likely would lower AMP figures, and thus reimbursement rates.[40] If CMS nevertheless decides that GPO administrative fees are to be considered for inclusion in the AMP calculation, Amgen urges CMS to adopt the safe harbor to the federal anti-kickback statute as the test for evaluating whether or not those fees need to be included in the AMP calculation.[41] Through the existing safe harbor for GPO administrative fees, the OIG has identified conditions which, if satisfied, represent an acceptable and non-abusive arrangement that fosters business competition and economy.[42] No additional criteria should need to be met in order to exclude GPO fees from the AMP calculation.

CMS should allow manufacturers discretion in selecting methodologies for determining fair market value and in identifying the types of services that can qualify as bona fide services.

In the preamble to the Proposed Rule, CMS invited comment on an appropriate definition for "fair market value" for purposes of the proposed definition of *bona fide* service fees.[43] In the ASP final rule, CMS stated its belief that "manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value of drug distribution services for which they contract," and thus decided not to mandate a specific method for manufacturers to use to determine whether a fee represents fair market value.[44] Amgen recommends that CMS allow manufacturers the same discretion in selecting a methodology to determine whether a fee represents fair market value for purposes of excluding the fee from the AMP calculation. In the event CMS decides to specify a definition for fair market value of *bona fide* service fees in its final rule, Amgen requests that CMS clarify that manufacturers may rely on any

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39 Medicare Program; Revisions to Payment Policies; Final Rule, 71 Fed. Reg. 69,623, 69,669 (Dec. 1, 2006).

40 GPOs perform various services in exchange for the administrative fees paid by manufacturers. Those services include notifying their members of the manufacturer's product offerings and the discounted pricing available on those products, monitoring member compliance with the terms of the GPO contract (*e.g.*, own-use requirements), distributing prescribing information in response to product inquiries from members, and facilitating product recalls and investigations of diversion or counterfeit product.

41 *See* 42 C.F.R. § 1001.952(j).

42 54 Fed. Reg. 3088.

43 71 Fed. Reg. at 77,180.

44 71 Fed. Reg. at 69,669.

generally recognized and accepted methodology for determining the fair market value of such services.

In the ASP final rule, CMS declined to establish a list of "bona fide services" to avoid inadvertently limiting the scope of what could be considered a bona fide service.[45] Amgen urges CMS to adopt the same approach for purposes of the AMP calculation.

Amgen supports the exclusion of returns from the AMP calculation.

Amgen is pleased that CMS has proposed to exclude returned goods from the AMP calculation when the goods are returned in good faith.[46] Amgen supports the consistent treatment of returned goods for purposes of the AMP and ASP calculations and strongly urges CMS to finalize this proposal. Amgen further requests, however, that CMS clarify in its final rule that the "good faith" standard applies to the good faith acceptance of the return by the manufacturer, because manufacturers are typically not in a position to determine the good faith of the returning entity. Amgen also seeks clarification that a return that is consistent with the manufacturer's published return policy can be considered to be made "in good faith." This straightforward approach will further CMS' goal of lessening the administrative burden associated with the treatment of returned goods for purposes of AMP calculations.

CMS should permit manufacturers to smooth monthly and quarterly AMP calculations using the smoothing methodology adopted in the ASP final rule.

The preamble to the Proposed Rule invites comments on allowing the use of a 12-month rolling average estimate of lagged discounts for monthly and quarterly AMP reporting.[47] Amgen urges CMS to adopt for the monthly AMP calculation the same estimation methodology for lagged discounts that CMS has adopted for purposes of the ASP calculation.[48] Amgen also urges CMS to permit the use of this methodology in the quarterly calculation of AMP, so that quarterly AMP figures also would not need to be restated. The application of this methodology in the context of AMP reporting would require manufacturers to develop a 12-month rolling average ratio of AMP-eligible price concessions to AMP-eligible sales and then apply that ratio to the total AMP-eligible sales in the reporting period.

Amgen believes that building upon the smoothing methodology that CMS developed for purposes of ASP will reduce administrative and implementation burdens on both manufacturers and the agency. The ASP smoothing methodology has already been subject to review and comment by industry, and manufacturers of Medicare Part B drugs already have developed smoothing formulas that are consistent with the ASP final rule. Using the same approach for both ASP and AMP reporting would reduce confusion among manufacturers, lower the risk of error in AMP calculations, and minimize the volatility of AMP data. This is particularly important now that states may be using AMP to calculate pharmacy reimbursement rates. The ASP final rule did not mandate the use of a particular methodology for estimating lagged ineligible sales (*i.e.*,

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45 71 Fed. Reg. at 69,668.
46 71 Fed. Reg. at 77,181.
47 71 Fed. Reg. at 77,186
48 ASP final rule, 71 Fed. Reg. at 69,787 (amending 42 C.F.R. § 414.804(a)).

those ineligible sales identified through lagged price concessions).[49] Accordingly, Amgen further requests that CMS clarify that manufacturers may use their current smoothing methodology for ASP-exempt lagged sales to estimate ineligible lagged sales for purposes of AMP.

CMS should make clear that the Proposed Rule is prospective only and should provide manufacturers with four quarters to implement the final rule.

CMS has set forth in the Proposed Rule a number of important changes and clarifications to its current policies on AMP and best price. Implementing these changes will require manufacturers to upgrade and conform their existing systems, capture and track data elements they may not currently receive, and train personnel. Accordingly, Amgen requests that CMS provide manufacturers a one-year period to bring their Medicaid price reporting systems and operations into compliance with the requirements of the final rule. Additionally, Amgen requests that CMS make clear that the changes in the Proposed Rule are to be implemented on a prospective basis only. The Proposed Rule represents a departure from existing CMS policy in respect to a number of significant topics and therefore the final rule should be clearly identified as applicable and binding as to future calculations alone.

REVIEW OF RECOMMENDATIONS ON ISSUES RELATED TO CALCULATION OF AMP AND BEST PRICE AMOUNTS

For the reasons noted above, Amgen makes the following recommendations:

- ***Recommendation 1:*** Clarify whether physician offices, dialysis centers, and home healthcare pharmacies are included in the retail class of trade.

- ***Recommendation 2:*** Clarify that manufacturers have discretion to restate baseline AMP on a product-by-product basis.

- ***Recommendation 3:*** Clarify that service fees paid to non-purchasers are not included in the calculation of AMP and best price.

- ***Recommendation 4:*** Allow manufacturers discretion in selecting methodologies for determining fair market value and in identifying the types of services that can qualify as *bona fide* services.

- ***Recommendation 5:*** Finalize the exclusion of returns from the AMP calculation.

- ***Recommendation 6:*** Permit manufacturers to smooth monthly and quarterly AMP calculations using the smoothing methodology adopted in the ASP final rule.

- ***Recommendation 7:*** Make clear that the Proposed Rule is prospective only and provide manufacturers with four quarters to implement the final rule.

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[49] 71 Fed. Reg. at 69,671.

Amgen appreciates the opportunity to comment on the important issues raised in the Proposed Rule and we look forward to working with you to ensure that Medicaid beneficiaries have continued access to critical treatments. Toward that end, Amgen would welcome the opportunity to meet with the Center for Medicaid and State Operations staff to review Amgen concerns and specific recommendations outlined in this letter. Sarah Wells Kocsis from our Global Government Affairs office will follow-up with Deirdre Duzor to request and arrange a meeting. In the meantime, if you have questions or need further information about Amgen's comments, please contact Sarah Wells Kocsis at (202) 585-9713 or wellss@amgen.com.

Regards,

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Vice President
Global Coverage and Reimbursement
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David Beier
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Attachment

cc: Dennis Smith, Director, Centers for Medicaid and State Operations (CMSO)
Bill Lasowski, Deputy Director, CMSO
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Deirdre Duzor, Director, Pharmacy Division, DEHPG, CMSO
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REDACTED VERSION

ATTACHMENT A

SETTING THE RECORD STRAIGHT ABOUT AMGEN'S CONTRACTS AND ALLEGATIONS BY J&J

FEBRUARY 20, 2007

SETTING THE RECORD STRAIGHT ABOUT AMGEN'S CONTRACTS AND ALLEGATIONS BY J&J

BACKGROUND

Amgen markets Aranesp® (darbepoetin alfa), Neulasta® (pegfilgrastim) and NEUPOGEN® (filgrastim). These products are administered incident to a physician's service and are generally covered by Medicare under Part B and by Medicaid programs and commercial payers under medical service benefits, rather than under pharmacy benefits. Amgen offers price reduction incentives to customers in the oncology office setting under the Amgen Portfolio Contract (APC), which is a multiproduct contract that (1) offers separate discounts and rebates for each Amgen oncology product regardless of purchase volume and (2) enables providers to receive additional discounts and rebates if they choose to purchase products across the Amgen portfolio of related oncology support products.

Based on the clinical attributes of our products and our willingness to inject price competition into the marketplace, Amgen has had success in overcoming the historical monopolization of the non-dialysis segment of the market for red blood cell growth factor that J&J previously enjoyed with its competitor product, Procrit® (Epoetin alfa).

In response to the lower prices and lower Procrit® market share that has followed from the introduction of Aranesp® into the marketplace, J&J has entered into litigation with Amgen claiming that our APC is an illegal contract. We are aware that J&J has urged Congress and CMS to enter into this commercial dispute on behalf of J&J to use regulation to enhance J&J's market position and to enable it to avoid direct price competition. In the process, J&J has disseminated misinformation about Amgen's contracts and the litigation.

An important fact is that Amgen provides its best discounts to its best customers.

These discounts lead to lower costs to Medicaid, other payers, and—importantly—patients. However, J&J appears to be attempting to avoid true price competition in the marketplace. For example, J&J senior executives have stated publicly this intent, as evidenced in the following statements to investors:

- Third Quarter 2005 Earnings Webcast (October 18, 2005), Statement by Bob Darretta Vice Chairman and Chief Financial Officer, J&J

  "We're pleased about the [Procrit®] price stability....The latest competitive tactic though is very difficult to handicap should we be unsuccessful in getting the injunction to which we believe we are entitled, because it will reinject tremendous price pressure...."

- Fourth Quarter 2005 Earnings Webcast (January 24, 2005), Statement by Christine Poon, Vice Chairman and World Chair, Medicines and Nutritionals, J&J

  "On Procrit I think you know that in a third of the marketplace at the oncology clinics that we are in litigation now with Amgen regarding what we believe is an illegal bundling of Neulasta and Aranesp...for that piece of the business its going to be tough going; a lot of pressure on pricing."

While there is no reason for CMS to enter into this legal and commercial dispute between two manufacturers, Amgen feels compelled to set the record straight on several issues in response to the misinformation disseminated about Amgen's multiproduct contracts by J&J in comments to CMS and MedPAC .

Here are the facts:

- The J&J proposal is based on allegations in a lawsuit pending in federal court. Amgen vigorously denies the allegations in that lawsuit, including the allegation that its contracts give discounts on drugs for which there is no clinical alternative in lieu of discounts on a drug (Aranesp®) with which J&J's product Procrit® (Epoetin alfa) competes. The federal court will determine whether Amgen's portfolio contract is good for competition and for consumers.

- Importantly, the federal court did not grant J&J a preliminary injunction. Amgen is confident that Amgen will obtain a ruling that our contracts are legal under the antitrust laws.

- In addition to Aranesp®, the other drugs in the contract at issue are NEUPOGEN® and Neulasta®, both of which are available for sale individually.

  - Amgen's multiproduct contract offers price concessions, including a discount and a rebate, to Neulasta® and NEUPOGEN® customers without regard to the amount of Aranesp® they purchase, including if they purchase no Aranesp® at all.

  - J&J has alleged in comments to CMS that there are no clinical alternatives to Neulasta®. This statement is simply not true. Both Amgen's NEUPOGEN® and Berlex's Leukine® (sargramostim), represent clinical alternatives across many indications, when used appropriately. While NEUPOGEN® may also be acquired under Amgen's portfolio contract, it is available for separate purchase by pharmacies, suppliers, and providers. Amgen does not market Leukine®, and pharmacies, suppliers, and providers clearly can acquire it separately.

  - Numerous policies published by the agency's Medicare Part B carriers acknowledge this fact in their Local Coverage Determinations (LCDs).

These policies specifically demonstrate the availability of Medicare coverage for these three products across many of the same International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes.[1]

- J&J has alleged that discounts on a product without a clinical alternative are intended to be an incentive to induce sales of other drugs and so should be completely reallocated based on this intent.

    - J&J may suggest that CMS should **infer** that discounts on drugs with no clinical alternatives were intended solely to benefit other drugs in the bundle. In fact, such inference is without any basis, but there is no such intent with respect to Amgen's multiproduct contracts, and this intent should **not** and cannot be inferred.

    - There are many reasons for discounting across a family of products, including (1) brand loyalty considerations, (2) the practice of giving the best discounts to the best customers, (3) the clinical attributes and practice patterns related to such products, and (4) other appropriate marketing considerations.

    - In fact, if CMS were to acquiesce to J&J's likely request and require reallocation of all discounts from certain types of drugs to others (including in cases where per-unit market prices are already available), even more significant unintended consequences of the sort described above would be the unavoidable result. Such intervention would create a chilling effect on contracting and restrict competitive practices unnecessarily and in a manner that would stifle free-market competition that leads to lower prices. As discussed above, the true market prices of these drugs would not be reflected in their AMPs or best prices and the distortion would make AMP an unattractive candidate for use by states to pay for drugs under Medicaid.

- J&J has told Congress and may be telling CMS that it should reallocate discounts because customers who do not choose to access additional discounts in a multiproduct contract could receive a discounted price on one product that is below the reimbursement set for a drug, creating an access barrier.

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[1] *See, e.g.*, CMS Medicare Coverage Database: Noridian Administrative Services, Local Coverage Determination (LCD) for Filgrastim (NEUPOGEN), Sargramostim (Leukine), and Pegfilgrastim (Neulasta) [L14920]; AdminaStar Federal, LCD for Granulocyte Colony-Stimulating Factors [L15352]; TrailBlazer Health, LCD for Colony Stimulating Factors [L18411]; Wisconsin Physicians Service Insurance Corporation, LCD for Human Granulocyte/Macrophage Colony Stimulating Factors [L19956]; Palmetto GBA, LCD for White Cell Colony Stimulating Factors [L6332]. Amgen continues to believe that these products all have clinical differences and that physicians should be able to choose which products to use for their patients. The CMS Medicare Coverage Database is available at http://www.cms.hhs.gov/mcd/search.asp.

- This alleged access barrier is rhetorical rather than real. While there is no reason for CMS to insert itself into this legal dispute, we think it appropriate to clarify that all Procrit® users have access to white blood cell growth factor (WBCGF) drugs.

- Importantly, Amgen's multiproduct contract offers price concessions, including a discount and a rebate, to Neulasta® and NEUPOGEN® customers without regard to the amount of Aranesp® they purchase, including if they purchase no Aranesp® at all.

- The fact that Procrit® users also have access to Neulasta® is evident just from looking at how much Neulasta® is purchased by customers who choose to purchase more Procrit® than Aranesp®. Of the Procrit® prescribers who also use either of Amgen's WBCGF drugs, the vast majority of them purchase Neulasta®; therefore, allegations of an access barrier are without merit.