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February 20, 2007

Hand Delivered

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

FEB 20 2007

Re: CMS-2238-P: Medicaid Program; Prescription Drugs

Purdue Pharma L.P. ("Purdue Pharma") is a privately held pharmaceutical company dedicated to finding, developing, and bringing to market new products that promote health and healing. We appreciate this opportunity to submit comments on the proposed rule implementing those provisions of the Deficit Reduction Act of 2005 ("DRA") relevant to the Medicaid Drug Rebate Program. 71 Fed. Reg. 77174 (Dec. 22, 2006).

We recognize that the proposed rule represents a serious and conscientious attempt by CMS to simplify and clarify the calculations of average manufacturer price ("AMP") and best price ("BP"). While we believe that in some areas CMS has succeeded in reducing the ambiguities surrounding many of the price reporting difficulties faced by manufacturers there still remains significant ambiguity in other areas of the proposed rule. Moreover, the proposed rule introduces several troubling positions that contradict long-standing CMS policy or are internally inconsistent with other aspects of the proposed rule. For that reason, we strongly suggest the proposed rule be modified and strengthened in the manner specified in these comments to further clarify the AMP and BP calculations and harmonize the regulations with the authorizing statutes and related regulations.

We set forth our specific concerns below.

I. PROSPECTIVE APPLICATION ONLY

As CMS recognized numerous times in the proposed rule, the Office of Inspector General ("OIG") and Government Accounting Office ("GAO") have separately concluded that CMS' historical guidance with respect to many aspects of the AMP and BP calculation has been ambiguous and confusing. The need for clarity in this area is beyond question and we appreciate CMS' attempts to offer such clarity in the proposed rule. Nonetheless, the proposed rule is wrought with ambiguity. Indeed, it is our understanding that some analysts are incorrectly interpreting certain ambiguities in the proposed rule as evidence that CMS intends for the Final

Rule to have retrospective effect. Such a result is contrary to Congressional intent, contrary to CMS' intent, and simply cannot stand. Simply put, the Final Rule must only be applied prospectively.

The convoluted retrospective interpretation offered by some analysts has been triggered by references in the proposed rule to certain guidance as "codifying" or "clarifying" an existing CMS position. Unfortunately, these terms might incorrectly suggest that manufacturers might be required to recalculate AMPs and BPs submitted prior to the issuance of the Final Rule. Such a result would be arbitrary and capricious for the reasons noted below. Thus, CMS should make clear in the Final Rule that all guidance has only prospective effect.

First, we are certain Congress and CMS agree that the Final Rule only has prospective effect since the Congressional Budget Office ("CBO") budgetary estimates of DRA costs only discuss budgetary impact beginning with the year 2006 and going forward and CMS' Regulatory Impact Analysis ("RIA") contained in the proposed rule only discusses the budgetary impact beginning with the year 2007 and going forward. The federal Administrative Procedure Act requires that CMS' Final Rule be consistent with the principle of logical outgrowth. A retrospectively-applied Final Rule would be a drastic divergence from the requirements of the proposed rule and therefore violate the APA. Furthermore, under Executive Order 12866 (as amended by Executive Order 13258), if CMS intended for the Final Rule to have retrospective effect, it should have provided a budgetary estimate for each of the prior years for which it intends the proposed rule to apply. Therefore, CMS is constrained from applying the proposed rule retrospectively by both the CBO estimate and its own RIA.

In any event, even if CMS could apply the proposed rule retrospectively, it would be arbitrary and capricious for CMS to do so. The unilateral manner in which CMS implemented its long-standing policies – *e.g.*, in releases for which manufacturers had no opportunity to comment – has been problematic and unfair in and of itself. To compound the lack of appropriate notice and comment period associated with manufacturer releases by issuing a contradictory rule with retrospective application raises serious due process concerns.

In addition, retrospective effect would be inequitable given that the Medicaid Rebate Agreement requires manufacturers to make "reasonable assumptions" in the absence of guidance from CMS. The lack of historical guidance on critical aspects of the AMP and BP calculation is irrefutable. The reasonable assumptions doctrine has eased the burdens associated with the wide gaps in guidance since the inception of the Medicaid drug rebate program. If CMS had intent to one day promulgate a rule that would have retrospective application, it should have provided manufacturers notice of such a possibility at the time it first directed manufacturers to make reasonable assumptions, as such a possibility would obviously influence a manufacturer's good-faith assumptions.

Furthermore, recalculations from prior years might require CMS to tender back to manufacturers a portion of prior rebate payments plus interest due on such amounts. This complication can be avoided if CMS makes clear that that Final Rule has prospective application only.

Finally, even if CMS were legally able to give the rule retrospective effect, recalculation may not be operationally feasible in light of significant systems limitations that we would expect most, if not all, manufacturers to face. Manufacturers may not have historical data on certain classes of trade or certain types of sales or price concessions because, at the time the data was gathered, CMS did not require manufacturers to maintain those figures separately. Moreover, even if manufacturers did maintain such data, the data may have been stored in what is now an obsolete drug price reporting system that prevents the manufacturer from extracting the data into its current drug price reporting system. The possibility of being forced to run two drug price reporting systems simultaneously – *e.g.*, an obsolete system for recalculation from prior years and the current system for new data – would be undeniably burdensome and costly. Given such operational limitations, retrospective application of the Final Rule would be impractical for many manufacturers because they will not be able to provide reasonably reliable recalculation figures. Indeed, others will not be able to provide any figures at all as CMS itself recognizes when it gives manufacturers the option to restate baseline AMP rather than requiring such recalculations in light of the fact that "some manufacturers may not have the data needed" to perform recalculations.[1]

For all these reasons, Purdue Pharma strenuously opposes retrospective application of the Final Rule. We therefore urge CMS to silence some analysts interpretation of the proposed rule by making clear in the Final Rule that CMS intends for the new regulations to apply prospectively only.

II. AUTHORIZED GENERICS

A. *Bona Fide Fees*

CMS has proposed defining "authorized generic drug" as any drug sold, licensed or marketed under an NDA and marketed, sold or distributed directly or indirectly under a different NDC number, trade name, trade mark or packaging than the listed drug.[2] We believe that the interconnection between the agency's guidance on bona fide fees and BP calculations for authorized generic drugs must be further clarified to avoid unnecessary confusion with respect to the determination of BP.

It is not uncommon for one manufacturer to use another entity (manufacturer, distributor or otherwise) for product distribution services and to pay the secondary entity an appropriate fee for the distribution and marketing services, regardless of the NDC the product may carry. Unfortunately, CMS' overly broad definition of "authorized generic drug" needs to be refined to clearly allow distribution, marketing or other fees to be paid to the secondary entity without impacting BP assessment where the title of the product remains with the manufacturer until sold to a downstream customer. In these circumstances, the mere possession of the product by the secondary entity which distributes it should not trigger an impact on BP. It is our view that such distribution fees are wholly appropriate where they satisfy the proposed definition of "bona fide service fees." Thus, we strongly urge CMS to clarify that the term "authorized generic drug" is strictly limited to only those products *for which the product's title passes* to an authorized

[1] 71 Fed. Reg. 77174, 77186 (Dec. 22, 2006).
[2] Proposed § 447.506(a).

generic entity and does not include fees paid by the manufacturer for bona fide services such as product distribution and marketing.

Significantly, failure to clarify the definition of "authorized generic" in this manner is inconsistent with Congressional intent. The statute (as amended by the DRA) defines "best price" as the lowest price available to non-excluded entities with respect to a single source, innovator multiple source, or authorized generic drug – not, significantly, with respect to the services paid for those drugs.[3] In other words, the statute does not contemplate the inclusion of bona fide fees paid by the owner and NDA holder of a drug to non-excluded entities for various services that the owner of the drug may desire for the manufacture, distribution, marketing and sales of the owner's drugs. Without our proposed clarification, the authorized generic regulations could unnecessarily complicate the issue of treatment of such bona fide fees incurred by the owner of the drug.

CMS appears to recognize that such a result is not appropriate or intended, although it fails to do so in an affirmative manner. Indeed, CMS has appropriately recognized in the proposed rule that "bona fide service fees" should not be taken into account for BP or AMP purposes. We applaud this policy, for not only is it consistent with Congress' intent in the DRA, but it is also consistent with the treatment of bona fide service fees under the Medicare Part B average sales price ("ASP") calculation. CMS' proposal is incomplete, however, as it currently stands because it does not make clear that bona fide fees paid by the owner of the drug to a secondary entity faces no risk of being treated as a sale price which must be included within the owner of the drug's BP. We strongly encourage CMS to clarify this gap in policy in its Final Rule.

Thus, for the reasons noted above, bona fide fees should be excluded from BP for arrangements which may otherwise fall into the scope of the proposed authorized generics provisions.[4] Accordingly, we respectfully request that CMS clarify that bona fide fees paid by one manufacturer to another entity for bona fide services related to the distribution, sales and/or marketing of a covered outpatient drug are excluded from BP.

B. *Manufacturer Certification*

We are particularly concerned about the proposed price reporting certification requirement, as applied to authorized generics. Should CMS choose to implement the certification requirement in the final regulations, it is absolutely critical to the success of the Final Rule that the agency also require the manufacturer and subsequent entities to submit pricing information only regarding their own sales so that CMS itself can calculate the primary manufacturer's AMP and BP.

CMS' proposal to have a manufacturer certify its AMP and BP calculations represents a thoughtful and well-intentioned approach to safeguarding the integrity of the Medicaid Drug Rebate Program. Nonetheless, this proposal is fundamentally flawed as applied to authorized generics. Indeed, as described in further detail below, the certification requirement poses

[3] 42 U.S.C. § 1396r-8(c)(1)(C)(i).
[4] Proposed § 447.505(d)(12).

significant operational and antitrust problems arising from the primary manufacturer's access to the secondary entity's pricing data for purposes of calculating AMP and BP. Accordingly, Purdue Pharma requests that, as it does in the ASP context, CMS collect pricing data separately from primary manufacturers and authorized generic entities and use that data to calculate the primary manufacturer's AMP and BP.

As CMS' proposal currently stands the primary manufacturer must include within its AMP and BP calculation the secondary entity's pricing information. Under proposed Section 447.510(e), the primary manufacturer's Chief Executive Officer ("CEO"), Chief Financial Officer ("CFO"), or delegated officer must then certify the calculations of AMP and BP, based in part on the secondary entity's information. This raises a significant operational problem because the primary manufacturer likely will not have access to the data and assumptions underlying the secondary entity's pricing information. Indeed, manufacturers treat their pricing data and assumptions as confidential, and section 1927(b)(3)(D) of the Social Security Act requires CMS to maintain this confidentiality.[5]

Furthermore, full disclosure of the secondary entity's pricing data and assumptions for certification purposes raises potential concerns under federal and state antitrust laws. Primary manufacturers and secondary entities of an authorized generic may be competitors within the marketplace, and the sharing of pricing data and related information between them may raise allegations of anticompetitive behavior.

Even if a primary manufacturer did have access to the secondary entity's data and putting aside, for sake of argument, the significant antitrust issues, the systems of the primary manufacturer and authorized generic entity may be incompatible with one another. It would, therefore, be difficult or impossible to transfer the data from the secondary entity to the primary manufacturer. Therefore, the primary manufacturer cannot meaningfully certify its AMP and BP calculations if those figures are based upon another entity's information which it cannot review or verify.

As mentioned above, this alternative approach is consistent with CMS' calculation of the Medicare Part B payment for multiple source drugs with respect to the CMS collection of data. CMS requires manufacturers to submit their ASP data and total number of units for each 11-digit NDC.[6] From this data, CMS calculates a volume-weighted average ASP for all multiple source drugs within the same billing and payment code.[7] We strongly encourage CMS to adopt a similar approach in calculating the primary manufacturer's AMP and determining its BP, by combining the primary manufacturer data with data collected from the authorized generic entity. The AMP approach would differ slightly in that ASP data is at the 11-digit NDC level and collected for all multiple source drugs in the same billing and payment code. We recommend that the primary manufacturer and the authorized generic entity each submit their AMP data (total net sales and total number of units) and BP data at the 9-digit NDC level to CMS. CMS

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[5] 42 U.S.C. § 1396r-8(b)(3)(D). In its final rule discussing ASP data, CMS has stated that it will maintain the confidentiality of pricing data and the reasonable assumptions submitted along with that data. 71 Fed. Reg. 69623, 69677 (Dec. 1, 2006).

[6] 42 U.S.C. § 1396r-8(b)(3)(A)(iii); 42 C.F.R. § 414.804.

[7] 42 U.S.C. § 1395w-3a(b)(3); 42 C.F.R. § 414.904.

could then calculate the AMP and BP for the primary manufacturer based on the weighted average of the combined data. We recommend the use of the 9-digit NDC due to the common use of 9-digit NDCs in the PBM, MCO, and HMO areas. Otherwise, manufacturers would have to make assumptions with that data with respect to 11-digit NDC utilization.

Thus, because the approach we suggest above is practical, consistent with CMS' ASP practices regarding the collection of data by CMS, and avoids federal and state antitrust issues, CMS should separately collect the pricing information from both manufacturers and authorized generic entities and independently determine the primary manufacturer's AMP and BP.

If CMS is unwilling to adopt this suggested approach, despite its clear advantages over CMS' current proposal, Purdue Pharma firmly contends that a primary manufacturer cannot be held accountable for the accuracy of drug price calculation where errors in the calculation arise from the data provided to it by the authorized generic entity. For the reasons explained above, primary manufacturers cannot necessarily verify or even review an authorized generic entity's data. If CMS insists on requiring primary manufacturers to perform the calculation, it should understand the fundamental flaws to its chosen approach and not hold primary manufacturers responsible for inaccuracies in pricing submissions that arise from blended pricing calculations.

III. DEFINING THE RETAIL PHARMACY CLASS OF TRADE

While we appreciate CMS' efforts to attempt to define "retail pharmacy class of trade" in a principled and consistent manner, we are deeply troubled by a number of missteps in CMS' approach. As discussed in further detail below, we respectfully insist that CMS correct its position on the following issues: PBM concessions, long-term care pharmacy sales, and Medicaid sales.

A. *PBM Concessions*

CMS has proposed including certain discounts, rebates and other price concessions within AMP when they are associated with sales for drugs provided to the retail pharmacy class of trade.[8] CMS has similarly proposed to include such concessions in the calculation of BP when these concessions adjust prices either directly or indirectly.[9] Purdue Pharma is deeply concerned that this proposal poses significant operational issues with respect to determining the amount of PBM concessions that may be impossible to overcome unless CMS affords manufacturers appropriate flexibility with respect to determining how to account for such concessions. We take this opportunity to offer specific suggestions to ease the otherwise tremendous operational burdens associated with the CMS' proposal, and strongly urge CMS to incorporate our suggestions into the Final Rule.

PBMs typically process utilization of rebates both within and outside of the retail pharmacy class of trade. Unfortunately, data that clearly assigns rebates paid to the PBM to either retail or non-retail non-mail order sales is often unavailable from PBMs. Even if the data is available, PBMs do not gather and report back to pharmaceutical manufacturers the level of

[8] 71 Fed. Reg. at 77197.
[9] 71 Fed. Reg. at 77197.

data that would be needed to account precisely for the effect of manufacturer rebates paid to PBMs for non-mail order sales in the AMP and BP calculation. Furthermore, Purdue knows of no commercially available source that would allow the PBMs to differentiate the pharmacies in their network, between retail and non-retail business. CMS should address this issue in the Final Rule by expressly permitting manufacturers, in the absence of clear data from a PBM, to make reasonable assumptions in determining the percentage of manufacturer rebates paid to PBMs for non-mail order sales that ultimately flow to the retail class of trade based on any of the following methods:

- Representations made by the PBM regarding its customer mix (e.g., retail versus non-retail);
- Reasonable sampling and extrapolation from representations of customer mix associated with other similarly-situated PBMs; or
- Other methods that lead to reasonable estimates.

The approaches above may permit manufacturers the flexibility they need to meet their price reporting obligations with respect to manufacturer rebates paid to PBMs for non-mail order sales in a manner consistent with applicable law and feasible business practices. At the same time, CMS will achieve its goal of monitoring the calculation methodologies chosen by manufacturers with respect to manufacturer rebates paid to PBMs for non-mail order sales.

However, if there is no data available or no representations actually made by PBMs on their customer mix, manufacturers should be able to include all of those rebates in their AMP.

Importantly, a reasonable assumption approach is clearly aligned with CMS' approach in the Medicare Part B context. Indeed, with respect to ASP reporting, CMS has recognized that allowing manufacturers to make reasonable assumptions is an appropriate way to handle ambiguous and often complex calculations.[10] By permitting manufacturers to adopt reasonable assumptions with respect to rebates paid to a PBM for non-mail order sales when such data is not available from the PBM itself, CMS will take an appropriate step toward harmonizing the determination of the Medicaid drug price calculations and the Medicare Part B drug price calculation.

B. *Long-Term Care Pharmacies*

In a 1997 manufacturer release, CMS indicated in no uncertain terms that nursing home pharmacy sales are included in the AMP calculation.[11] Under the proposed rule, however, CMS reverses its long-standing policy by excluding sales to nursing home pharmacies from the AMP calculation.[12]

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[10] With respect to the ASP certification requirement, CMS has recognized that the "complexities of each calculation can differ across manufacturers" and that "manufacturers' reasonable assumptions remain an important aspect of ASP reporting. 71 Fed. Reg. 69623, 69676 (Dec. 1, 2006).

[11] Medicaid Drug Rebate Program Manufacturer Release No. #29

[12] Proposed § 447.504(h)(6).

If CMS maintains this position, which appears to be due to the non-retail nature of the sales, Purdue believes that sales to hospice pharmacies and other closed-provider home health pharmacies, including sales by a retail pharmacy as a result of a network pharmacy arrangement (closed provider pharmacy) with one of these sub-classes of trade, should be treated the same as sales to LTC pharmacies with respect to the AMP and BP calculations. Hospice and other home health care are types of long-term care, and therefore their treatment for purposes of AMP and BP calculations should be the same.

C. *Medicaid Sales*

CMS proposes in Section 447.504 of the proposed rule to include within the AMP calculation sales under the Medicaid program that are associated with sales of drugs provided to the retail pharmacy class of trade, but to exclude from the AMP calculation rebates associated with such Medicaid sales.[13] This approach will lead to an erroneous AMP calculation. If CMS determines to include Medicaid sales in the AMP calculation, it needs to include both the Medicaid units and the prices for those sales, net of the applicable Medicaid rebates. It should not include just the units without including the applicable Medicaid rebates. Inclusion of Medicaid units in the AMP calculation without including the applicable Medicaid rebates may arrive at a number, but the number will have no relationship to average manufacturer price.

By definition, AMP is calculated by dividing the transaction price, less applicable concessions, by total number of units. Including Medicaid transactions in the denominator portion of the calculation without including applicable Medicaid rebates necessarily will skew the calculation and make the resulting AMP number inaccurate. Therefore, we urge CMS to require the same treatment of Medicaid sales as it does with other sales included in the AMP calculation: if the units are included in the denominator, applicable rebates must be included in the numerator.

D. *Prices to Federal Programs*

CMS proposes to exclude from AMP the prices provided to a series of government programs. We endorse CMS' position, as it properly excludes such purchases on the basis that they are outside the retail pharmacy class of trade.

IV. OTHER CRITICAL ISSUES

A. *Administrative Fees and Service Fees*

Consistent with its approach in the Medicare Part B context, CMS has proposed to exclude bona fide administrative and service fees from AMP and BP, provided that the fees represent the fair market value for bona fide services actually performed on the manufacturer's behalf.[14] With respect to Medicare Part B, CMS refrained from mandating the specific method(s) manufacturers must use to determine fair market value for ASP, stating, "We believe

[13] Proposed § 477.504(g)(12).
[14] Proposed § 447.504(h)(11).

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."[15] Purdue Pharma respectfully requests that CMS adopt the same policy for bona fide service fees in the AMP and BP contexts and permit manufacturers to determine the most appropriate method for determining fair market value for such fees.

Fair market value will necessarily be fact-specific and depend upon a number of different elements, including the uniqueness of the manufacturer's needs, the services the contracting entity will perform, the number of market participants that can adequately perform the needed services, and the agreed-upon mechanism for establishing a payment resulting from good-faith, arm's length negotiations. Moreover, CMS' concept or definition of fair market value should not prohibit manufacturers from structuring their service fee arrangements consistent with accepted market practices, *e.g.*, by determining the amount payable as a flat-fee, a percentage of the drugs' purchase price or wholesale acquisition cost ("WAC"), or some combination of these methods. Furthermore, manufacturers should be able to rely upon the fair market value assessments of reputable, independent third parties, such as the "Big 4" public accountancy firms. Indeed, CMS should refrain from defining fair market value in any manner that would limit flexibility of good-faith, arm's length negotiations for bona fide services.

In sum, manufacturers are best situated to determine the appropriate method for determining fair market value for bona fide fees given their individual needs. Therefore, CMS should confirm that manufacturers may self-determine fair market value consistent with the manner described above. This approach will preserve the flexibility in the market and harmonize the requirements for the AMP and BP calculations with the ASP calculation.

B. *Customary Prompt Pay Discounts*

Purdue Pharma thanks CMS for allowing manufacturers the option to recalculate base date AMP by excluding customary prompt pay discounts, in accordance with the DRA's revised definition of AMP. Consistent with CMS' proposed definition of customary prompt pay discount, we believe that the term properly refers to the discount "routinely offered by the manufacturer to *a* wholesaler"—*i.e.*, the discount offered to an *individual* wholesaler.[16] Accordingly, we understand the term "customary prompt pay discount" to refer to the discount offered an individual wholesaler at the time of payment, and not to a historical figure approximating the typical discount offered to all wholesalers at some indeterminate point in the past.

C. *Bundled Price Concessions*

CMS proposes that manufacturers adjust their AMP and BP for any bundled sale, defining the term, in part, as "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

[15] 71 Fed. Reg. 69624, 69669 (Dec. 1, 2006).
[16] Proposed § 447.504(c) (emphasis added).

drugs of different types."[17] Purdue Pharma finds this definition troubling, particularly given the reference to "same drug."

We can conceive of only one instance where sales of the same drug properly should be considered bundled—where the manufacturer provides a discount or free drugs if the purchaser agrees to buy a certain amount of the same drug (e.g., "buy 9, get 1 free" or "buy 9, get the 10th at half price"). Such sales essentially represent volume discounts, and the discount properly should be apportioned among the drugs provided by the manufacturer. Indeed, the Medicaid rebate statute mandates such a result, requiring "free goods that are contingent on any purchase requirement" and volume discounts to be included in BP.[18]

We understand CMS' proposed "bundled sale" definition to apply to sales of the same drug only where the manufacturer provides free or discounted goods contingent on a purchase requirement. Understood in this manner, the bundled sale provision represents a codification of the Medicaid rebate statute. We ask CMS to confirm our understanding in its Final Rule.

D. *Returned Goods*

We support CMS' proposal to exclude returned goods from the calculation of AMP pursuant to manufacturer policies that are not designed to manipulate or artificially inflate or deflate AMP.[19] We believe that manufacturers should be able to design freely their return policies and exclude such returns from AMP, provided the policies do not represent a covert means of manipulating AMP. As we understand it, CMS' proposal permits manufacturers the operational freedom to define and accept returned goods, while eliminating administrative burdens, preserving the integrity of the Medicaid drug rebate program, and harmonizing the AMP calculation with that of ASP. Thus, we ask that CMS finalize its proposed rule on returned goods.

E. *Survey of Retail Prices*

Notwithstanding Section 6001(e) of the DRA, which amends the Social Security Act to provide for a survey of retail prices and State performance rankings effective January 1, 2007, CMS fails to address the provision of the survey and rankings in the proposed rule.

We are disturbed by CMS' decision to defer until a later date implementation of this important requirement given that the DRA requires that, beginning January 1, 2007, (i) the States must receive information on retail survey prices on "at least a monthly basis," and (ii) the Secretary of the Department of Health and Human Services must provide an annual report, based on a monthly survey of national retail sales price data, that compares the survey prices to AMP and BP.[20] Given that Congress has provided the Secretary the flexibility to contract with a vendor to gather the relevant survey information and that the Secretary had over ten months to locate such a vendor before Section 6001(e) took effect, we are disappointed by the fact that the

[17] Proposed § 447.502 (emphasis added).
[18] 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(I).
[19] *Id.* at 77181. *See* Proposed § 447.504(h)(13)
[20] 42 U.S.C. § 1396r-8(f) (as amended by the DRA).

January monthly survey has not been released. We strongly urge CMS to take whatever steps that it can to ensure that DRA Section 6001(e) is implemented as quickly as possible.

F. *Definition of "Dispensing Fee"*

CMS proposes to define the term "dispensing fee," in relevant part, as including "any reasonable [pharmacy] costs" associated with "ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient," including, but not limited to, verifying Medicaid eligibility, performing drug utilization review and preferred drug list review activities, and performing various tasks and expenses associated with physically providing the drug product to the beneficiary.[21] This portion of the definition of "dispensing fee" makes clear through its reference "includ[ing], but not limited to" that it does not intend to exhaustively list the services for which pharmacies can be compensated by state agencies as part of the dispensing fee. For example, based on the proposed definition, a dispensing fee might include payment for inventory management data related to Medicaid beneficiaries, patient/customer counseling, stocking inventory or other services. We urge CMS to review current documentation on dispensing costs to assure that the pharmacies are adequately compensated for serving the Medicaid population, without seeking funds from elsewhere.

By making clear that the services listed in the definition are merely illustrative, CMS appropriately allows for the inclusion of other pharmacy costs in the dispensing fee aside from those listed in the proposed rule so long as the costs as "associated with ensuring that possession of the appropriate covered outpatient drugs is transferred to a Medicaid recipient." If CMS has another or additional interpretation of the definition of "dispensing fee," we respectfully request that CMS explain its position prior to issuing a Final Rule.

IV. MANUFACTURER REPORTING REQUIREMENTS

A. *"Adequate Documentation"*

CMS proposes to include in AMP all sales to wholesalers except for those sales that can be identified with "adequate documentation" as being subsequently sold to any excluded entity.[22] Because CMS did not specify in the proposed rule what might constitute adequate documentation, we presume that manufacturers may make reasonable assumptions in determining whether they have satisfied the adequate documentation requirement. In the event that CMS does provide further clarification as to what it means by "adequate documentation," we insist that CMS provide an opportunity for manufacturers to comment on its proposal prior to issuing a Final Rule.

[21] Proposed § 447.502.
[22] Proposed § 447.504(g)(1).

B. *Reporting Issues*

CMS proposes to interpret Section 6001(b)(1) of the DRA as requiring manufacturers to report AMP on a monthly basis, and AMP, BP, and customary prompt pay discounts on a quarterly basis.[23] We endorse this interpretation.

C. *Restatement of Baseline AMP*

In light of the amended statutory definition of AMP, CMS proposes to permit, but not require, manufacturers to recalculate their base date AMPs.[24] CMS recognizes that some manufacturers may not have data available to recalculate base date AMP or may find the administrative costs of such recalculations outweigh the financial benefits.

We applaud CMS for its recognition of the difficulties related to such recalculations, and appreciate the agency's flexibility. Consistent with CMS' approach, we assume that CMS will permit a manufacturer to estimate its recalculated base date AMP by relying on reasonable assumptions where partial data, reasonable extrapolation, or other accepted methods of estimation are available.

D. *Implementation Period*

The proposed rule does not specify the time frame within which manufacturers will be required to be in compliance with the Final Rule, once issued, except for the restatement of baseline AMP. We find the absence of an implementation period troubling. The changes in the proposed rule, if finalized, will require manufacturers to implement a new drug price reporting system and train personnel on these systems. It is our understanding that the industry leader in drug price reporting software will hold off any work on new software with the required capabilities until after the Final Rule is issued.

Therefore, we respectfully request CMS to provide manufacturers at least six months to implement the Final Rule, once issued. An implementation period of this duration will greatly assist manufacturers in the challenging task of revising their systems (pending the release of new software by software vendors with expertise in this complex area) and retraining personnel on the requirements of the Final Rule and the new software system. Furthermore, to the extent the end of the implementation period does not fall at the beginning of the first month of a new quarter, the implementation period should be extending to the next whole calendar quarter.

E. *Collection of Information*

CMS asserts that it will take manufacturers a mere 31 hours per quarter to comply with the requirements of the proposed rule, if finalized. This is a gross underestimation. We are not sure at this time how long it will take for Purdue Pharma to revise its systems, train its drug price reporting and other relevant personnel on the requirements related to the proposed rule, and submit the new information required under the proposed rule, but we are certain it will take

[23] 71 Fed. Reg. at 77185.
[24] 71 Fed. Reg. at 77185.

substantially beyond 31 hours per quarter. We find it troubling that CMS views the burdens on manufacturers associated with the new regulations to be so minimal. In and of itself, performing AMP calculations four times per quarter instead of one time per quarter and the training and revision of systems will be burdensome on an ongoing and sustained basis, with respect to personnel, IT time and other resources.

V. CONCLUSION

Purdue Pharma appreciates the opportunity to comment on the foregoing issues and looks forward to working with CMS to further clarify and revise the AMP and BP calculations and price reporting requirements in accordance with its comments herein.

Respectfully submitted,

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February 14, 2007

Centers for Medicare and Medicaid Services
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7500 Security Blvd
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Subject: Medicaid Program: Prescription Drugs; AMP Regulation
CMS 2238-P RIN 0938-AO20

The Iowa Pharmacy Association (IPA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

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

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§447.504 Determination of AMP

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

Defining Retail Pharmacy Class of Trade

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

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

Mail order pharmacy and PBMs sales, just as LTC pharmacies, should be excluded because these are not traditional retail pharmacies. According to the GAO's own definition of retail pharmacy in its December 22, 2006 report entitled: *"Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs,"* the GAO defines retail pharmacies as "licensed non-wholesale pharmacies that are open to the public." The "open to the public" distinction is not meet by mail order pharmacies as they are not open to the public and require unique contractual relationships for service. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts, fundamentally making them different classes of trade. Given that retail pharmacies do not benefit from these rebates and discounts, the resulting AMP would be lower than the acquisition cost paid by retail pharmacies for medications.

The proposed regulation correctly assumes that LTC pharmacies do not dispense to the general public, and therefore, all price concessions received by LTC pharmacies should not be included in the definition of AMP. The proposed regulation, however, incorrectly makes an assumption that mail order pharmacies' and PBMs' discounts, rebates, and price concessions should be included in the definition of AMP because mail order and PBM pharmacies dispense to the general public. Again, the definition of "general public" must be analyzed in this assumption. Study data demonstrate that the overwhelming majority of Medicaid recipients do

not receive their medications from mail order pharmacies or PBMs; Medicaid recipients obtain their medications from their community retail pharmacy unless state were to mandate mail order pharmacy. Most states bill for and receive rebates (or other price concessions) directly from the drug companies for their Medicaid programs. Proposing to include "all price concessions" given by drug manufacturers to mail order pharmacies and PBMs as part of AMP will artificially lower AMP because, as a matter of course, these pharmacies provide a fraction of the prescriptions to this part of the "general public." For further discussion on the distinctions of mail order and PBM pharmacies from community retail pharmacies we address the unique contractual arrangements in detail later in these comments.

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

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

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

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

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

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions

that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

Market Manipulation

[1] Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.
[2] GAO-07-239R, Medicaid Federal Upper Limits, Government Accountability Office December 22, 2006.

Under the proposed regulation the manufacturer is required to report on both a monthly and quarterly basis. The quarterly reporting requirement matches the 'rebate period' and should accurately reflect any and all discounts the manufacturer choose to employ. The monthly reporting requirement states that the "manufacturer may estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period".[3] The proposed regulation states that the allowable timeframe for revisions to the quarterly report is to be a period of three (3) years from the quarter in which the data was due.

As the entities engaged in the profession of pharmacy become more vertically integrated the potential for misuse of this dual reporting mechanism increases. Potentially, a manufacturer with a vertically integrated market position could use the 'rebate period' based reporting to manipulate AMP. Additionally, the ability to estimate and apply discounts to the monthly AMP can also allow for market manipulation. The accounting involved in this dual time-frame reporting allows a manufacturer with a vertically integrated position to shift costs and revenues, in the form of discounts employed, to enhance their financial position or, worse yet, manipulate the market through a manipulation of reported AMP. Furthermore, this ability would exist for a period of three (3) years, the allowable time for revisions. This undue flexibility, afforded to find a market price, allows for market manipulation, a potential loss of price transparency and places a significant accounting burden upon the manufacturer.

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

The inherent market volatility, associated with pharmaceutical manufacturing, occasionally results in dramatic shifts in price structure. The proposed regulation is noticeably silent in offering any mechanism to account for this fact. Severe price shifts and the significant issues associated with pricing lag can be effectively addressed with the implementation of trigger

[3] §447.510(d)(2)

mechanisms. CMS should identify a reasonable and appropriate percentage shift in real time price that would trigger a review and recommendation by the Office of the Inspector General (IG). It is recommended that CMS clearly define the stakeholders empowered to alert CMS of significant price shifts. Once alerted the IG would research and then recommended an updated AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

In its simplest form the trigger mechanism could accomplish the following: (i) limit the affects of price posting lag; (ii) mitigate potential market manipulation; (iii) mitigate a possible disincentive to fill generics by the retail pharmacies; (iv) limit incorrect public data; and (v) provide CMS with the most up-to-date calculation of AMP. The ability to adjust the posted AMP, between reporting periods, will mitigate pricing lag by efficiently correcting any significant material shifts in pricing. A price that does not materially change from one reporting period to the next will be unaffected by any structural lag. However, a material shift in price during a reporting period is amplified by the structural lag inherent in the proposed regulation. An adequate trigger mechanism can address, and mitigate, the issues surrounding pricing lag. The ability for appropriate stakeholders to trigger a review of severe price fluctuations by the IG will act as a damper to market manipulation. The long standing intent of Congress and CMS to maximize generic utilization can be protected through a proper trigger mechanism. When a severe price fluctuation causes a generic drug's acquisition cost to rise above the FUL reimbursement rate there is a market disincentive to increase the drug's utilization. The trigger mechanisms ability to efficiently adjust the reported AMP will remove this disincentive by keeping the FUL in line with a near real time posting of the generic's AMP. Clearly the ability of CMS to efficiently respond to and adjust market fluctuations will severely limit incorrect public data and allow CMS the ability to have to most up-to-date AMP data.

Record Keeping

The proposed regulation states in §447.510(f)(1) that "[a] manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period". This time requirement is unduly burdensome and a substantial departure from the Internal Revenue Services' seven (7) year standard for audit record keeping. We recommend that CMS adjust the record keeping requirement in the proposed regulation to be consistent with the widely accepted seven (7) year standard.

Additional Comments

Use of the 11-Digit NDC Rather Than the 9-Digit NDC

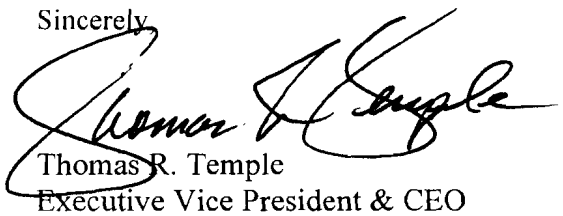
CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to

have AMP calculated at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

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

We appreciate your consideration of these comments and ask that you please contact us with any questions. Thank you.

Sincerely,



Thomas R. Temple
Executive Vice President & CEO

cc: Senator Chuck Grassley
Senator Tom Harkin
Representative Leonard Boswell
Representative Bruce Braley
Representative Tom Latham
Representative Dave Loebsack
Representative Steve King

PARD

SAMUEL D. BROG
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EXECUTIVE DIRECTOR

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ESTABLISHED 1898

February 16, 2007

Ms. Leslie V. Norwalk, Esq.
Center for Medicare and Medicaid Services
Attention: CMS 2238-P Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

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

Dear Ms. Norwalk, Esq.:

***AVERAGE MANUFACTURER PRICES* as defined in the Social Security Act 1927.**

The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacture for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

***BEST PRICE* as defined in the Social Security Act 1927.**

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States. (With some Governmental exclusion).

The above two definitions were for the sole purpose of setting the stage for Drug Manufacturers rebates back to the states and in turn the states forwarding 54% of the total to CMS.

Since 1990, when OBRA 90 was written there was *never* any intent to utilize the *AMP* as a means of reimbursement to pharmacies in the Medicaid Program.

Why would CMS even consider such a payment method? Every wholesaler in the United States of America can show CMS the actual invoice amount the pharmacy pays for the drugs. AMP will cause many Independent Pharmacies to close their doors especially when in a high volume Medicaid area. If the Medicaid volume is not the factor than the pharmacy will refuse to fill the prescription and create an *Access Problem for the poor in locating a pharmacy that is willing to loose money in the process.*

This is a true story in 1997 when CMS granted a waiver for the states to participate in Managed Care the 5 County Southeastern region of Pennsylvania including Philadelphia, the Pharmacy Benefits Manager of the four (4) HMO's set the reimbursement below the pharmacy cost. In Philadelphia approx. 225 pharmacies had to close.

Can you imagine what this AMP reimbursement will do across the United States! Does CMS wish to close all Independent Pharmacies or create a *Access Problem* for the Medicaid recipients?

The Government Accountability Office (GAO) an investigative arm of Congress found that under the CMS proposed AMP/FUL formula the reimbursement would be 36% below Pharmacy *acquisition costs for Medicaid Prescriptions.*

The GAO found that the impact of AMP/FUL, will be devastating on small Independent Pharmacies.

Sincerely,

Sam D. Brog

Sam D. Brog, R. Ph.
Executive Director/PARD

CC: Rep. Allison Y. Schwartz
Sen. Arlen Specter
Sen. Robert P. Casey, Jr.

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

Robert L Pelot
831 Manatee Ave East
Bradenton, Fl 34208
941-748-8130

February 15, 2007

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-2238-P
Mail Stop: C4-26-05
Baltimore, MD 21244-8015

Dear Ms. Leslie V Norwalk, ESQ

RE: Deficit Reduction Act of 2005 as to Pharmacy Acquisition cost and AMP.

To identify myself I will tell you I am a 4th generation pharmacy owner in Manatee County, Florida. My daughter will be the 5th generation. Thank you very much for the opportunity to speak to you on this subject.

My colleges and other organizations could probably speak much more eloquently than myself. I only want to add something else to the mix. For years the insurance companies, State and Federal Medicaid organizations have nickel and dimed retail pharmacies to death. Now with this new pending ruling we will be dollared to death. One must only look at the total picture and ask some questions.

1. *Why is it that so many independent pharmacies are closing? Even the chains derive a big supporting profit from the front end or non pharmacy related business. Independents cannot compete with these terms.*

2. *Why are the PBM's selling for a record BILLION of dollars? They don't produce anything, they don't sell anything but yet they make much more profit then the pharmacies that sell and consult with their patients. I can only speak for myself. We deliver, consult with the patients, go to their homes and give advise and give many services, yet each third party prescription that goes thru the PBM's are rewarded with many dollars profit, whereby the pharmacy is rewarded much smaller.*

3. *Why are drugs that go to Canada, Mexico, and other countries cheaper?*

What is a closed shop Pharmacy?

A) Hospital pharmacy, do they compete with retail pharmacy?
B) A mail order pharmacy, do they compete with retail Pharmacy?
C) ACLF and nursing home pharmacy's, do they compete with retail pharmacy?

The answer is yes, but why are they rewarded with lower cost of goods. How do these prices compare with other countries prices? Should we not look into this?

Thank you for your time

Robert L Pelot RPH/Owner

Mrs. Beckie Bates
604 Country Club Drive
Marshall, Texas 75672
(903)938-9247

February 16, 2007

Dear CMS,

In making your final decisions regarding the definition of AMP, please take some time to consider some of the issues stated in the next few pages. To this point, the AMP has been defined without seeking any input from one of the major entities it will impact, community pharmacy.

The rule regarding AMP, as currently written, will effectively put my two pharmacies out of business. It is not a fair reimbursement. As a result, it will force me to either stop accepting Medicaid, which forces me to give up over half of my patient base. Or, I can choose to continue accepting Medicaid and fill each prescription at a financial loss. Either choice is a devastating one for my businesses.

So, if AMP is accepted as currently defined, two East Texas pharmacies will close their doors, not to mention the countless number of other pharmacies across the nation. These community pharmacies provide valuable services to numerous indigent patients who rely on these services. I ask you, is putting thousands of pharmacies nationwide out of business a wise healthcare decision? Please be careful in your deliberations over this issue. Seek wise counsel from ALL parties involved, not just the PBMs.

Sincerely,

Beckie Bates

Beckie Bates, R.Ph.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.— pg. 31-33

Inclusion in Best Price of PBM rebates, discounts and other price concessions— pg. 53

Treatment of Manufacturer coupons with regard to Best Price— pg. 55
Inclusion of Direct-to-Patient Sales with regard to AMP— pg. 41

AMP Must Differ From Best Price

If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.

CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: *These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.*

The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs receive manufacturer rebates off of the market price of those drugs. *Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.*

For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a ***contrasting measure*** to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. *In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.*

How PBM price concessions should be reported to CMS.— pg. 33

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper and grossly negligent. Specifically, *to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate.*

CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, *the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.*

PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, ***the PBM is allowed, again through lack of regulation; to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.***

Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.— pg. 70

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are ***NOT*** accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that *the published pricing data will be at least 60 days behind the market place pricing.* Invoice pricing to community pharmacy, however, *continues to change **daily**.* In order to accurately realize market costs and reimburse retail pharmacy accordingly, *AMP data must be reported weekly.*

Use of the 11-digit NDC to calculate AMP— pg 80

AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy

We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.
Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. *Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.*
Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would **NOT** adequately cover pharmacy acquisition cost.

The 11-digit NDC must be used when calculating the FUL.

Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.— pg. 110

CMS discusses impact on pharmacy:

** On independents: potential "significant impact on small, independent pharmacies."—pg. 101

** On all retail: $800 million reduction in revenue in 2007; $2 billion annually by 2011 ("a small fraction of pharmacy revenues").—pg. 108

** "We are unable to estimate quantitatively effects on 'small' pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries."—pg. 110

Impact on small pharmacies demonstrated by GAO findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees. The impact on independent pharmacies also cannot be mitigated by an increase in stateset dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely
that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study. Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

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

CMS Must Employ a Complete Definition on Cost to Dispense

The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments. Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.

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

The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing. *All calculations must be independently verifiable with a substantial level of transparency to have accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.*

Final Comments:

The rule, as currently written, would amount to gross negligence on the part of CMS if it ignores the OIG findings and input from all retail pharmacy organizations. By choosing to listen to the highly erroneous and self-serving input from PBM's, (which is readily apparent in

the rule as submitted), CMS would be ignoring the one group (Independent Pharmacy) that truly makes the medicaid plan work on the patient level. For example: Most independent pharmacies deliver, chains and discount pharmacies do not. Many independent pharmacies are at the clinics near where patients live. Many communities only have access to small community pharmacies that rely on Medicaid for their business.

As a pharmacy business owner of two stores, I can assure you this will put many small businesses and their employees out of business, and will most definitely cause the ***surviving pharmacies to no longer accept medicaid patients***. I, for one, will no longer accept Medicaid beginning on July 1st if the Final Rule defining AMP is not changed. You **can** choose to do what is right and just, if you have the morals and ethics to do so!

TAS Drug
500 West Church Street
Cherryville, North Carolina 28021
Phone: (704) 435-5082 E-mail: TASDrug@aol.com

February 15, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Post Office Box 8015
Baltimore, Maryland 21244-8015

Dear Ms. Norwalk:

I am a pharmacist for TAS Drug, an independent pharmacy serving approximately 1,800 of your entity's beneficiaries in a rural area of North Carolina's western piedmont. I am writing to request that the finalization of the above referenced legislation be delayed until more detailed information is made available.

Federal Register Vol. 71, No. 246, 12/22/2006 page 77176 Section 447.502 "Definitions"

AMP appears to provide reimbursement of acquisition costs only, without consideration of costs of doing business (dispensing costs, labor, packaging, rent, utilities ...). TAS Drug, as well as, all other community pharmacies, could not even break even if we were to provide our products at "cost". A minimum level of dispensing fee should be included as an alternative to the definition only position.

Federal Register Vol. 71, No. 246, 12/22/2006 page 77178-77179 Section 447.504 "Definition of Retail Pharmacy Class of Trade and Determination of AMP"

Regarding inclusion of mail order pharmacy prices in the definition of retail pharmacy class of trade for purpose of inclusion in the determination of AMP: TAS Drug, as well as, other independent pharmacies does not purchase pharmaceuticals at the same cost as mail order pharmacies and chain pharmacies. This is due in part to our inability to negotiate collectively with manufacturers, and our having to acquire products through wholesaler/distributors (who in turn must impose additional margins for the distribution of the products). The disparity between acquisition costs of mail order/chain pharmacy and independent pharmacy (such as TAS Drug) are very significant. Unfortunately, CMS's inadequate provision of data regarding AMP's to the retail pharmacy industry makes it difficult to respond definitively to this matter, therefore a final rule should be delayed until the CMS can provide more detailed/accurate information to allow a legitimate, valid evaluation of the AMP data.

I do not understand why PBM's rebates, discounts, etc. would be included in AMP calculations. TAS Drug has never received a share of any PBM's rebates. To the contrary, PBM's impose service fees to TAS Drug for the ability to provide service to the patients.

Federal Register Vol. 71, No. 246, 12/22/2006 page77187-77188 Section 447.514 "Upper Limits for Multiple Source Drugs"

Regarding the request for comment on 11 digits v. 9 digits NDC calculation of AMP:
A number of large bulk size products typically available to direct purchasers at discounted rates are not available for purchase by TAS Drug and other independent pharmacies. The 11 digit NDC should be utilized for FUL calculation to compensate for this disparity. Once again, independent pharmacies should not be asked to provide products and services below their acquisition costs.

Federal Register Vol. 71, No. 246, 12/22/2006 page 77190-77194 Section 447.514 "Impact Analysis"

The statement "we believe that these legislatively mandated section 6001 savings will potentially have a significant impact on some small, independent pharmacies" should be changed to read "...will have a **catastrophic** impact on **most** independent pharmacies" if your entity's proposed changes are ruled on as-is.

Another possible development from the rule changes as-proposed, would be the refusal of pharmacies to accept the reimbursement offered, leaving significant gaps in providers for your entity's beneficiaries.

In summary:

1. A minimum level of dispensing fee based on national annual independent analysis should be included in addition to the FULs for reimbursement determination.
2. Inadequate provision of hard data by CMS of AMP's to the retail industry hampers our ability to provided definitively accurate commentary on the matter. Therefore, the final rule should be postponed until adequate information is provided to allow for statistically significant evaluation.
3. If mail order is included in the definition of retail pharmacy class of trade, a significant additional increase should be provided to those entities that provide the more desirable mode of delivery of products and services, namely community pharmacies.
4. PBM's rebates, discounts, etc., should not be included in AMP calculations.
5. The 11 digit NDC should be utilized for FUL calculation.

In closing, CMS should provide additional information to the industry related to the actual AMP and established FUL prior to implementation of a final rule. This will enable us to make a more educated commentary to help CMS and the legislature meet the intent of the legislation.

Thank you for your time.

Sincerely,

Lacey M Malcolm

Lacey M. Malcolm, Pharm.D.

273

Center Drug
201D Island Ford Road
Maiden, North Carolina 28650
Phone: (828) 428-0668

February 15, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Post Office Box 8015
Baltimore, Maryland 21244-8015

Dear Ms. Norwalk:

I represent Center Drug, an independent pharmacy serving approximately 1,900 of your entity's beneficiaries in a rural area of North Carolina's western piedmont. I am writing to request that the finalization of the above referenced legislation be delayed until more detailed information is made available.

Federal Register Vol. 71, No. 246, 12/22/2006 page 77176 Section 447.502 "Definitions"

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I do not understand why PBM's rebates, discounts, etc. would be included in AMP calculations. Center Drug has never received a share of any PBM's rebates. To the contrary, PBM's impose service fees to Center Drug for the ability to provide service to the patients.

Federal Register Vol. 71, No. 246, 12/22/2006 page77187-77188 Section 447.514 "Upper Limits for Multiple Source Drugs"

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Federal Register Vol. 71, No. 246, 12/22/2006 page 77190-77194 Section 447.514 "Impact Analysis"

The statement "we believe that these legislatively mandated section 6001 savings will potentially have a significant impact on some small, independent pharmacies" should be changed to read "...will have a **catastrophic** impact on **most** independent pharmacies" if your entity's proposed changes are ruled on as-is.

Another possible development from the rule changes as-proposed, would be the refusal of pharmacies to accept the reimbursement offered, leaving significant gaps in providers for your entity's beneficiaries.

In summary:

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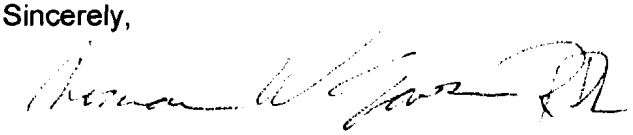
In closing, CMS should provide additional information to the industry related to the actual AMP and established FUL prior to implementation of a final rule. This will enable us to make a more educated commentary to help CMS and the legislature meet the intent of the legislation.

Thank you for your time.

Sincerely,



Thomas W. Eason, R.Ph.
President

Center Drug
201D Island Ford Road
Maiden, North Carolina 28650
Phone: (828) 428-0668

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February 15, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Post Office Box 8015
Baltimore, Maryland 21244-8015

Dear Ms. Norwalk:

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Thank you for your time.

Sincerely,

Robert Stamey, R.Ph.

TAS Drug
500 West Church Street
Cherryville, North Carolina 28021
Phone: (704) 435-5082

February 15, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Post Office Box 8015
Baltimore, Maryland 21244-8015

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Thank you for your time.

Sincerely,

Antony D. Eason, R.Ph.
TAS Drug

28

February 9, 2006

D & L Pharmacy
P.O. Box 222
13456 Choctaw Ave.
Gilbertown, AL 36908

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.

I own and operate D & L Pharmacy, a small town independant pharmacy in Gilbertown, Alabama. We have seven employees who provide care to about five thousand patients in this area. Our patients are from Gilbertown, 36908; Silas, 36919; Toxey, 36921; Needham, 36915; and Melvin, 36913.

We at D & L Pharmacy and all our customers are counting on you to be our voice in this matter. We need you to communicate our pharmacys' concerns about the problems with the Medicaid prescription reimbursement proposal (CMS-2238-P) that is trying to be passed.

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.

We are the main providers to the Medicaid patients in our area. Most of these patients cannot afford to go to another pharmacy farther away. They do all their shopping here in this town. We even have some who have to walk to get their needed supplies as they cannot afford to own a car. If D & L Pharmacy cannot fill their prescriptions then most of them will stop taking their medicine.

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,

Dougals P. Calvin R.Ph.

Mercy General Hospital
CHW

4001 J Street
Sacramento, CA 95819-9990
(916) 453-4545 Telephone

February 20, 2007

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

Re: (CMS-2238-P) Medicaid Program: Prescription Drugs, Proposed Rule, (Vo. 71, N0. 246), December 22, 2006

Dear Ms. Norwalk:

Mercy General Hospital is pleased to provide comments on the proposed rule implementing the Medicaid prescription drug program provisions of the *Deficit Reduction Act of 2005* (DRA). Our comments address CMS' interpretation of Section 6002 of the DRA and the new requirement that all outpatient settings, including hospitals, report physician-administered drugs using the National Drug Code (NDC).

Our comments focus on the following areas:

- the legal premise upon which CMS has based its interpretation of Section 6002,
- the significant administrative burden – and the associated costs – these new reporting requirements impose on hospitals, and
- the potential impact to safety-net hospitals if they are no longer able to participate in the 340B drug program.

Conditions Relating to Physician-Administered Drugs – Section 447.420

Section 6002 of the DRA added a new requirement to the Medicaid statute specifically to enhance the ability of state Medicaid (Medi-Cal in California) programs to secure rebates from drug manufacturers under the Medicaid drug rebate law. This section ties Medicaid rebate payments for covered outpatient drugs that are physician administered, as determined by the Secretary, to "the collection and submission of such utilization and coding data (such as J-codes and NDC numbers) ....as necessary to identify the manufacturer of the drug." The data collection requirement extends to both single and multiple source drugs.

However, in the proposed rule, CMS does not define "outpatient drugs that are physician administered" as the statute clearly states that the Secretary must do. Instead, the rule's preamble indicates that CMS intends to interpret Section 6002 to require submission of the NDC numbers for outpatient drugs furnished as part of a physician's service to Medicaid beneficiaries in hospital outpatient clinics and departments – not solely in physicians' offices. CMS' proposal to apply Section 6002 so broadly is incorrect. It is not supported by the statute's plain language, is inconsistent with congressional intent, and would nullify the *Social Security Act of 1965*

exemption of hospital outpatient clinics and departments from Medicaid rebate program obligations.

Section 6002 requires only the collection of utilization and coding data for drugs that are subject to a rebate requirement under Medicaid statute provisions that predate the DRA. Under Section 6002, state Medicaid programs are expressly directed to provide for the submission and collection of drug utilization and coding data "as necessary to identify [manufacturers of drugs] in order to secure rebates" under the Medicaid rebate law. For outpatient drugs that are not subject to a rebate payment requirement – like those dispensed in hospital outpatient clinics and departments – the collection of NDC information with respect to that drug plainly is not necessary to securing a rebate, and the law does not require submission or collection of NDC data on the drug.

The statutory language, in fact, does not directly compel states to collect only NDC information on drugs subject to the rebate requirement. While reporting of the NDC numbers is preferred after January 1, 2007, the statute clearly authorizes the Secretary to allow for an alternative coding system. The statute states that the purpose of the data collection is "as necessary to identify" the manufacturer of the drug in order to collect Medicaid manufacturer rebates. The statute mentions J-codes and NDC numbers as examples of the type of "utilization and coding data" that could be collected. To the extent that J-codes can be used to identify a drug for Medicaid rebate purposes, use of J-codes to identify drugs is consistent with statutory compliance.

Section 6002 does not affect the existing rebate exemption for drugs administered to patients in hospital outpatient clinics and departments

Nothing in Section 6002 casts doubt on the continuing existence of the Medicaid statute's pre-existing exemption from drug rebate requirements for outpatient drugs established by Section 1927(j) of the *Social Security Act*. Section 6002's language is entirely silent as to any legislative intent to repeal or amend this pre-existing exemption, which expressly identifies outpatient drugs dispensed through hospital outpatient clinics and departments as not subject to the Medicaid drug rebate requirements.

The DRA Conference Report explicitly states that hospital outpatient clinic and managed care drugs described in Section 1927(j) are exempt from rebate requirements, and that the Section 6002 data collection requirements are intended to pertain only to physician-administered drugs for which there is no statutory exemption from rebate requirements (See H.R. Rept. No. 109-362 accompanying S.1932, December 19, 2005) Although the conference report does not directly cite Section 1927(j) *per se*, it expressly acknowledges the existence of exemptions from rebate requirements for outpatient prescription drugs using terms that unmistakably mirror the descriptions of managed care drugs in Section 1927(j)(1) and hospital drugs in Section 1927(j)(2).

It is clear that the physician-administered drug provision enacted by Section 6002 can only be read to impose a data collection requirement with respect to drugs that are not within the Section 1927(j) (2) exemption. Because the subsection (j) remains unchanged in the Medicaid rebate law, CMS cannot ignore the statutory exemption. The agency must continue to give subsection (j) the same meaning it had prior to the enactment of the DRA as the agency applies Section 6002. In doing so, CMS is compelled to draw meaning from Section 1927(j) (2) in a concrete way by referring to drugs dispensed or administered in an actual hospital setting.

Section 1927(j)(2) specifically exempts from the rebate requirements outpatient drugs that are administered in a "hospital ... that dispenses covered outpatient drugs using formulary systems, and bills [the Medicaid State Plan in the relevant state] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan)." This section cannot plausibly be construed as a reference to hospitals participating in the 340B federal drug discount program because the 340B program did not exist at the time Section 1927(j) was enacted.

On the other hand, drugs administered by medical professionals to patients on an outpatient basis in hospital clinics and departments generally have not been subject to Medicaid rebate collections, and fall squarely within the (j)(2) exemption, as properly construed. Drugs administered in the hospital outpatient clinic setting are dispensed almost always within a formulary system – thus meeting the first statutory criterion for inclusion in the (j)(2) exemption. Covered outpatient drugs administered in hospital clinic settings also are billed to Medicaid in a manner that meets the description of the second (j)(2) criterion, namely that the hospital "bills the [Medicaid State Plan] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the state plan)." Most, if not all, drugs administered to Medicaid-eligible patients in hospital outpatient clinics and departments fall within the (j)(2) exemption from rebates, and accordingly must be excluded from the physician-administered drugs to which Section 6002 applies.

Administrative and Financial Burden for California Hospitals

California is moving forward with implementing this new NDC reporting requirement with planned implementation January 1, 2008. Mercy General Hospital is concerned because these instructions fail to recognize the significant difficulty, burden and cost imposed upon California's hospitals in order to meet these new billing requirements. Hospital patient accounting systems are not designed to handle the routine reporting of a drug manufacturer's NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS) to report a particular drug or biologic rendered to a patient.

It should be noted that the language in the DRA conference report specifically indicates that the state Medicaid programs must "provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered." The DRA further states that the "reporting would include J–codes and NDCs." As such, Mercy General Hospital believes that state Medicaid agencies must provide for the collection process and bear the cost for hospitals to meet these new NDC reporting requirements. State Medicaid

programs should pay hospitals to handle the system changes and new work routines required to collect and submit this coding information. California estimates rebates will net the state Medicaid program approximately $50 million. Hospitals will clearly be required to invest this much and more to ensure compliance with this onerous rule.

Preliminary estimates, which focus on rudimentary changes to hospital systems, indicate that it will take roughly 500 to 1,500 work hours to design, build and test a short-term work around. Early estimates are that California hospitals could be required to spend $1 million and more to make the necessary system and staffing changes to put these reporting requirements in place. It is worth noting that California's Medicaid expenditures per beneficiary are either the lowest in the nation or among the lowest (depending on which data source cited). Requiring such an expensive, onerous requirement with no hope of recovering any of the associated costs will force hospitals to cut costs in other areas. This could result in reduced hospitals services and compromised access to care for all Californians.

When a drug needs to be replenished, the pharmacy goes to the primary manufacturer; however, often the primary manufacturer cannot supply or meet the hospital's need. In such instances, the hospital pharmacy seeks a secondary drug from another manufacturer with a different NDC. Therefore, the hospital pharmacy record keeping systems will need the ability to include multiple secondary sources for similar drugs. These changes also require massive system modifications and additional work routines.

During the past several years many hospitals have introduced new automated drug dispensing systems in an effort to reduce medication errors. Many of these systems also would require costly modifications. For example, these drug dispensing systems have bins for each specific drug based on ingredient and dosage – not on manufacturer NDC. There also is a human cost since hospitals that are interested in acquiring such systems to reduce medication errors would have to postpone their acquisition until the vendors make all of the system modifications. And, patient safety could be compromised in other ways as hospitals transition to using and reporting NDCs.

This proposed rule applies to Medicaid only. This eliminates efficiencies and administrative simplification – and increases costs – that comes with submitting standard claims using standard coding systems. The bottom line is this proposed requirement requires a costly upgrade without tangible benefit for Medi-Cal patients.

340B Prescription Discount Program for Safety-Net Hospitals

California's safety-net hospitals are concerned about the potential impact on the "340B Program." Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to provide discounts on covered outpatient drugs purchased by specified entities – including safety-net hospitals. Hospitals participating in the 340B Program are entitled to receive 340B discounts on all covered outpatient drugs. One condition of participation is that a

drug purchased under Section 340B shall not be subject to both a 340B discount and a Medicaid rebate. To avoid these duplicate discounts, 340B hospitals bill Medi-Cal at acquisition cost (plus dispensing fee) for 340B drugs, and Medi-Cal, in turn does not collect manufacturer rebates on the drugs acquired at the discounted 340B prices.

If Medi-Cal collected rebates on drugs administered to Medi-Cal patients in hospital outpatient settings, this would result in manufacturers providing duplicate discounts on many of those drugs because manufacturers already will have provided the 340B discounts to participating hospitals.

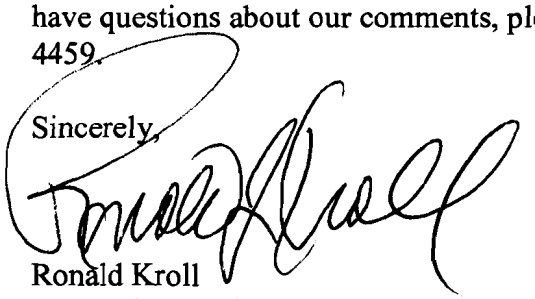
If Medi-Cal were to pursue rebates as planned – which ultimately would entail the 340B hospitals essentially passing their 340B savings on to California instead of using them to stretch their own indigent-care resources – it likely would drive many 340B providers out of the program. Ultimately this would increase Medi-Cal net drug costs by depriving Medi-Cal of the savings it now derives from these hospitals' participation in the 340B Program. The fiscal impact on these facilities would be significant and coming at a time when more than half of the state's hospitals are operating in the red and facing burdensome unfunded mandates, such as seismic retrofitting.

Mercy General Hospital is pleased the California's Department of Health Services has identified a possible work-around solution to allow hospitals to continue participation in the 340B Program. However, this proposed solution has not been implemented and it remains to be seen whether it will receive the approvals, etc. necessary to ensure hospitals can continue participation in this important program.

Conclusion

We urge CMS to revise its interpretation of Section 6002 of the DRA and not require the reporting of physician-administered drugs to hospital outpatient or clinic settings. We are happy to work with you to ensure the appropriate implementation of Section 6002 of the DRA. If you have questions about our comments, please contact me at Ronald.Kroll@chw.edu or 916-453-4459.

Sincerely,



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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.

* * * *

[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
Vice President
Global Coverage and Reimbursement
and Global Health Economics

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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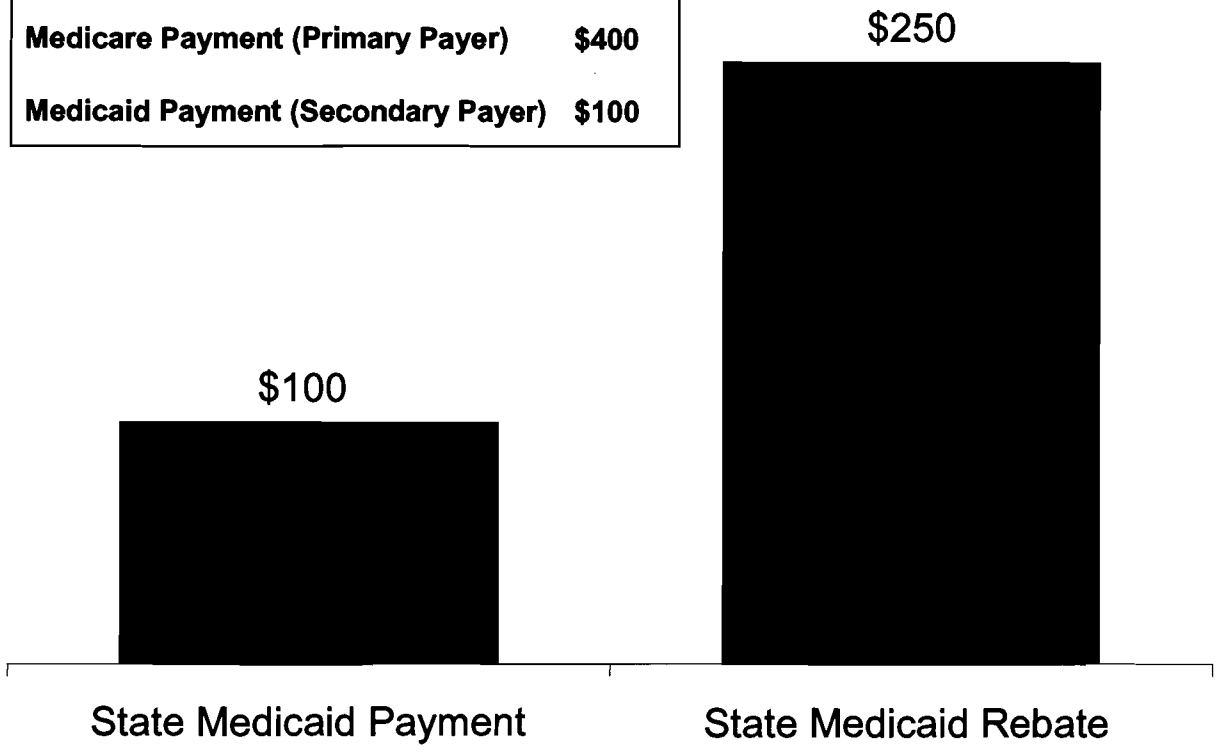
26 *Id.*

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,

Joshua J. Ofman, MD, MSHS
Vice President
Global Coverage and Reimbursement
and Global Health Economics

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
Larry Reed, DEHPG, CMSO
Kimberly Howell, DEHPG, CMSO
Marge Watchorn, DEHPG, CMSO
Christina Lyon, DEHPG, CMSO

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.