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BY HAND DELIVERY

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

SUBJECT: CMS-2238-P (Medicaid Program; Prescription Drugs)

Dear Administrator Norwalk,

Baxter Healthcare Corporation (Baxter) appreciates the opportunity to comment on the above-mentioned proposed rule published in the Federal Register on December 22, 2006 (the Proposed Rule).[1] Our comments address a number of topics included in the Proposed Rule, but those of primary importance to Baxter are as follows:

1. Regarding the retail pharmacy class of trade definition in the Proposed Rule, the Centers for Medicare and Medicaid Services (CMS) should:

   - Clarify that home healthcare providers are included in the definition because such entities provide pharmaceuticals to the general public;
   - Expressly permit manufacturers to treat hospital sales as sales for inpatient use in the absence of documentation regarding what portion of hospital sales are used in the outpatient setting;
   - Revise its guidance to clearly exclude rebates paid to State pharmaceutical assistance programs (SPAPs) from Average Manufacturers Price (AMP) and Best Price in order to treat them consistently with Medicaid rebates; and
   - Retain the provision including direct patient sales in the retail pharmacy class of trade.

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

2. CMS should clarify that administrative and service fees paid to group purchasing organizations are excluded from AMP and Best Price because such fees are not paid to purchasers.

3. CMS should provide further guidance and clarification as well as permit additional comment, before acting on the new definition of bundled sales.

4. CMS should clarify a number of issues related to the recalculation of base date AMP to ensure that the purpose of the provision is achieved when implemented.

5. CMS should clarify that manufacturer rebate liability for utilization where Medicaid is a secondary payer is limited to the proportion of the Medicaid allowable cost paid by the State.

6. CMS should encourage States to provide Medicare-mandated additional payments when reimbursing for hemophilia clotting factor and intravenous immune globulin.

For 75 years, Baxter has assisted healthcare professionals and their patients with the treatment of complex medical conditions, including hemophilia, immune disorders, cancer, infectious diseases, kidney disease, trauma, and other conditions. The company applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives.

The Deficit Reduction Act of 2005 (DRA) requires the Secretary to promulgate a regulation that "clarifies the requirements for, and manner in which, average manufacturer prices are determined."[2] In the Proposed Rule, CMS addresses not only AMP, but also Best Price and other aspects of the Medicaid drug rebate program. Baxter would like to thank you and the Secretary for your willingness to work with patients, providers, manufacturers, and suppliers of health care providers to bring clarity to the Medicaid program.

Baxter recognizes that the calculation of AMP and Best Price has a direct impact on rebate rates and federal upper limits (FULs), and ultimately patient access to necessary treatments. Given the importance the new regulation will have on the administration of the Medicaid program, Baxter believes it is imperative that CMS provide clear guidance to manufacturers, providers, States and all other interested parties. It is with this in mind that we address specific issues raised by the policies set forth in the Proposed Rule.

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[2] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c)(3)(B).

1. CMS Should Provide Additional Guidance with Respect to the Treatment of Different Entities in the Calculation of AMP and Best Price.

One of the most significant provisions of the Proposed Rule is its revised and more thorough definition of the retail pharmacy class of trade. CMS proposes to define 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."[3] Baxter appreciates CMS' effort to provide a comprehensive definition of retail pharmacy class of trade and requests that CMS provide still more clarity in relation to a number of specific entities.

A. CMS Should Clarify Whether Physicians Are Part of the Retail Pharmacy Class of Trade.

The Proposed Rule does not provide any guidance as to whether physicians are part of the retail pharmacy class of trade, nor has CMS discussed the retail status of physicians in any other previously issued guidance. In its May 2006 Report, Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005, the Office of the Inspector General noted that manufacturer groups had advised it of the "lack of guidance for classes of trade such as physicians, clinics, and patients."[4] The Proposed Rule addresses the treatment of clinics and patients, but is silent as to physician class of trade.[5] Baxter asks CMS to provide clear guidance on the retail or non-retail status of physicians in the Final Rule.

B. CMS Should Clarify That Home Healthcare Providers Are Included in the Retail Pharmacy Class of Trade.

The Proposed Rule also did not address the retail or non-retail status of home healthcare providers. Home healthcare providers typically are specialty pharmacies that provide for the home delivery and administration of product by health care professionals. As noted, the Proposed Rule defines the retail pharmacy class of trade as including any entity that purchases drugs and subsequently sells or provides those drugs to the general public.[6] Home healthcare providers purchase drugs

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[3] 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).
[4] Department of Health and Human Services, Office of the Inspector General, Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005 (A-06-06-00063) at 8 (May 2006).
[5] See 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. pts. 447.504(g)(7), (8)).
[6] Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).

that they dispense to their patients, who are members of the general public. In this regard, home healthcare entities are similar to outpatient clinics, which the Proposed Rule does specifically define as retail.[7] Baxter believes home healthcare providers, including home infusion providers, satisfy the retail pharmacy definition included in the Proposed Rule and urges CMS to specify this same conclusion in the Final Rule.

C. CMS Should Permit Manufacturers To Treat Hospital Sales As Sales for Inpatient Use in the Absence of Documentation Regarding What Portion of Hospital Sales Were Used in the Outpatient Setting.

The Proposed Rule specifically includes in the AMP calculation "[s]ales (direct and indirect) to hospitals, where the drug is used in the outpatient pharmacy" and specifically excludes "[s]ales to hospitals (direct and indirect), where the drug is used in the inpatient setting."[8] Baxter currently is generally unable to determine what proportion of its sales to a given hospital is used in the inpatient versus outpatient setting, and believes this is true for the industry as a whole. For this reason, Baxter asks CMS to clarify that all sales to a hospital may be treated as inpatient sales and excluded from AMP in the absence of information that identifies the amount of a hospital's purchases used in the outpatient setting.

D. CMS Should Revise the Proposed Rule To Exclude Rebates Paid to SPAPs from the AMP Calculation.

The Proposed Rule includes a provision clarifying the proper treatment of Release 68-qualified SPAP utilization and rebates in the AMP calculation. Specifically, the Proposed Rule directs the inclusion of SPAP sales and rebates in AMP.[9] Baxter believes SPAP rebates, instead, should be treated in the same manner as Medicaid rebates, which the Proposed Rule excludes from AMP.[10] SPAPs serve a similar function as Medicaid; they provide drug coverage to those state residents who do not meet Medicaid income qualifications using state funding. SPAPs also typically require participating manufacturers to pay the Medicaid rebate amount on program utilization. Given these similarities, Baxter asks CMS to revise its position and specify in the Final Rule that SPAP rebates, like Medicaid rebates, are to be excluded from AMP.

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[7] Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(g)(8)).
[8] Id. (proposed 42 C.F.R. pts. 447.504(g)(3), (h)(4)).
[9] See id. at 77,197 (proposed 42 C.F.R. pt. 447.504(g)(12)).
[10] See id. at 77,180.

E. Baxter Supports the Inclusion of Direct Patient Sales in the Retail Pharmacy Class of Trade.

In the Proposed Rule, CMS has included "sales directly to patients" in the AMP calculation.[11] Although direct patient sales are not addressed in the Medicaid rebate statute or Medicaid rebate agreement, Baxter agrees with CMS' position that when drugs are provided to patients through distributors, the distributor is acting as a wholesaler and the transaction is a sale to the retail pharmacy class of trade.[12] Baxter thus supports CMS' inclusion of direct patient sales in AMP and would urge the agency to retain this provision in the Final Rule.

F. CMS Should Clarify Whether HMOs That Act as Third-Party Payors are Excluded from the Retail Pharmacy Class of Trade.

The Proposed Rule specifically adopted the provisions of the Medicaid rebate statute and agreement that exclude sales to health maintenance organizations (HMOs) from the AMP calculation.[13] This categorical exemption of HMOs fails to distinguish between HMOs that purchase drugs for distribution to their members and HMOs that do not purchase drugs, but rather reimburse retail pharmacies for drugs dispensed to enrollees. The Proposed Rule appears to categorize as non-retail those HMOs that purchase and take possession of product because this type of HMO dispenses purchased product solely to its own enrollees through its own closed-door pharmacy, much in the way that hospitals purchase and dispense product to inpatients.[14] HMOs that do not purchase or take possession of product, on the other hand, function more like Medicaid, Medicare Part D, and SPAPs. These programs do not purchase drugs, but rather reimburse pharmacies that dispense drugs to their beneficiaries. Because the two types of HMOs function very differently, Baxter requests CMS to clarify whether utilization associated with HMOs that do not purchase and take possession of product also should be excluded from the calculation of AMP.

G. CMS Should Clarify That All Rebates, Discounts, and Other Price Concessions to Pharmacy Benefit Managers Are Included in AMP.

The Proposed Rule specifically includes in the calculation of AMP "[d]iscounts, rebates, or other price concessions to pharmacy benefit managers (PBMs) associated with sales for drugs provided to the retail

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[11] Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(g)(7)).
[12] Id. at 77,180.
[13] Id. at 77,179, 77,197 (proposed 42 C.F.R. pt. 447.504(h)(5)).
[14] See id. at 77,196.

pharmacy class of trade."[15] The preamble articulates this requirement as applying to "the amount received by the manufacturer for drugs distributed to the retail pharmacy class of trade."[16] The preamble also notes that manufacturers have no way of determining what portion of any discounts, rebates, or fees paid to PBM may be passed on by the PBM to its member health plans or network pharmacies.[17] Baxter believes that CMS intends the Proposed Rule to require the inclusion of all discounts, rebates, and other price concessions to PBMs in the AMP calculation, without regard to whether the PBM passes on any portion of those amounts to its plans/pharmacies or the amount that may be transferred. This is consistent with the text of the proposed regulation and also is the only approach that accounts for a manufacturer's inability to quantify any amounts passed on by the PBM. Baxter asks CMS to clarify that this is its requirement in the Final Rule.

H. CMS Should Clarify That Drug Prices Negotiated by a Qualified Retiree Plan on Behalf of Retirees and Retirees' Dependents are Excluded from Best Price.

Section 1860D-2(d)(1)(C) of the Social Security Act provides that "prices negotiated . . . by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to [covered Part D] drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price."[18] In accordance with this provision, the Proposed Rule clarifies that "[a]ny prices charged which are negotiated by . . . a qualified retiree prescription drug plan . . . with respect to [covered Part D] drugs on behalf of individuals entitled to benefits" are excluded from Best Price.[19] Baxter requests CMS to clarify that an "individual[] entitled to benefits" under a qualified retiree prescription drug plan includes not only the retiree, but also any dependents covered under the retiree's plan. Manufacturer rebate contracts for qualified retiree plan utilization do not distinguish between the retiree and his/her dependents. One price is negotiated that is applicable to all of the plan's enrollees because the drug utilization data submitted by the plan does not differentiate between the two groups. CMS should clarify that drug prices negotiated by a qualified retiree plan on behalf of retirees as well as their dependents are excluded from Best Price and thereby ensure the continued availability of significant discounts to this important population.

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[15] Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(g)(6)).
[16] Id. at 77,179.
[17] Id.
[18] Social Security Act §1860D-2(d)(1)(C), 42 U.S.C. § 1395w-102(d)(1)(C) (2006).
[19] 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(5)).

2. CMS Should Provide Additional Guidance With Respect to the Treatment of Certain Types of Transactions in the AMP and Best Price Calculations.

The Proposed Rule also provides significant additional guidance regarding the treatment of a number of different transaction types in the calculation of AMP and Best Price. Baxter appreciates this guidance and agrees with much of what CMS proposes. Baxter urges CMS to provide additional guidance to resolve any remaining confusion or uncertainty prior to the implementation of the Final Rule.

A. Baxter Supports Excluding Products Returned in Good Faith from the AMP Calculation and Asks CMS to Clarify the Standards for Determining When a Return Is Made in Good Faith.

The Proposed Rule makes a point of recognizing that the existing requirement to include returns in the AMP calculation has caused a number of technical and administrative problems for manufacturers.[20] Baxter therefore supports CMS' proposal to exclude returned goods from the AMP calculation when the return is made in good faith.[21] Baxter agrees with CMS that the effect of this proposal will be to generate a more accurate AMP for the relevant reporting periods, eliminate artificially low or negative AMPs, and lessen administrative burdens on manufacturers in calculating and reporting AMP.[22] Baxter also believes that additional clarification will help ensure that these goals are achieved.

The Proposed Rule limits the returns that can be excluded from AMP to those returns made in "good faith." According to the preamble discussion, CMS considers goods to be returned in good faith when they are "being returned pursuant to manufacturer policies which are not designed to manipulate or artificially inflate or deflate AMP."[23] Baxter requests that CMS clarify that the "good faith" to be evaluated is that of the manufacturer in accepting the return and not that of the purchaser, as there is no basis for a manufacturer to evaluate the bona fides of the returning entity. Baxter also requests CMS to adopt a standard that deems a return to be made in good faith whenever submitted and accepted in accordance with a manufacturer's written return policy. Such a standard will provide a clear guideline for determining those transactions that can be excluded from the AMP calculation.

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[20] See id. at 77,181.
[21] Id. at 77,181, 77,197 (proposed 42 C.F.R. pt. 447.504(h)(13)).
[22] See id. at 77,181.
[23] Id.

Baxter also requests that CMS provide additional guidance specifying that the new rule requiring the exclusion of returns applies whether a return results in a refund or the provision of replacement product. In either case, the original sale would remain in the AMP calculation and the corrective action, in cash or in kind, would be excluded.

B. CMS Should Adopt the ASP Preamble Guidance on the Bona Fide Service Fee Definition and Clarify That Fees Paid to Non-Purchasing Entities Are Excluded from AMP and Best Price.

The Proposed Rule includes a new standard for the treatment of administrative and service fees in the calculation of AMP and Best Price.[24] Under previous CMS guidance, administrative and service fees were included in AMP only to the extent that they affected the price realized by an "entity included in the calculation of AMP."[25] Under the Proposed Rule, however, administrative and service fees would be included in AMP unless they satisfy the definition of a bona fide service fee, and under that definition, such fees may be subject to inclusion even if paid to an entity that does not take title to the drug purchased.[26] Baxter makes two comments with regard to this issue. First, Baxter requests that CMS expressly adopt the preamble discussion of the proposed bona fide service fee definition contained in the 2007 Physician Fee Schedule ("PFS") Final Rule, which first adopted this definition in relation to the calculation of Average Sales Price (ASP). Baxter also asks CMS to clarify that fees paid to non-purchasing entities, including group purchasing organizations (GPOs), remain excluded from AMP and Best Price.

The definition of bona fide service fee that CMS proposes to adopt for use in the calculation of AMP and Best Price is the same definition CMS previously adopted for use in the ASP calculation in the 2007 PFS Final Rule.[27] The preamble to the 2007 PFS Final Rule provides important guidance as to how CMS interprets this term and intends it to be applied.[28] Baxter requests that CMS clarify that manufacturers can rely on the preamble language when applying this definition in relation to the calculation of AMP and Best Price as well.

Baxter's other comment relates to the treatment of fees paid to non-purchasing entities, such as GPOs. The bona fide service fee definition, as adopted for the ASP calculation and as proposed for AMP and Best Price, specifies that this definition applies even to fees paid to an entity

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[24] Id. at 77,180, 77,183.
[25] Id. at 77,180.
[26] Id. at 77,197-98 (proposed 42 C.F.R. pts. 447.504(i), .505(e)(1)).
[27] Id. at 77,180; 71 Fed. Reg. 69,623 (Dec. 1, 2006).
[28] 71 Fed. Reg. at 69,668.

that does not take title to product.[29] CMS specifically declined to address the treatment of GPO administrative fees in its discussion of this definition in the 2007 PFS Final Rule, noting that the issue needed further review and urging manufacturers to make reasonable assumptions regarding such fees in the interim.[30] Baxter continues to urge CMS, as it did in its comments to that rule, to explicitly exclude GPO administrative fees from the AMP and Best Price calculations.

It is Baxter's position that administrative fees paid to a GPO do not constitute a price concession because they are not paid to a purchaser and so should not be included in calculations that measure price. GPOs generally are non-purchasing entities and do not take title to drugs. Any fees distributed by the GPO to its members are in accordance with contractual terms established between the GPO and its members and do not represent a discount, particularly as provider members make their own purchases from manufacturers based on the contract terms previously negotiated by the GPO. Manufacturers have no way of tracking these fees as they do not have visibility to how those earned fees are being discharged by the entity. For these reasons, Baxter urges CMS to clarify in the Final Rule that administrative fees paid to GPOs are excluded from AMP and Best Price and need not be evaluated under the bona fide service fee definition.

C. CMS Should Provide Additional Guidance on the Proper Treatment of Patient Coupons and Manufacturer Patient Assistance Programs Before Finalizing Those Provisions.

CMS included guidance on the treatment of patient coupons and patient assistance programs in the Proposed Rule. For patient coupons, CMS has proposed including all coupons in AMP and Best Price unless the coupon is redeemed directly to the manufacturer by the consumer.[31] Baxter believes that additional guidance is necessary to implement this provision, including an explanation of what arrangements CMS considers to be patient coupons and directions regarding how such arrangements should be incorporated in AMP and Best Price. In the provisions regarding Best Price, CMS has excluded free goods provided under a manufacturer sponsored patient assistance program (PAP).[32] Baxter asks CMS to clarify how such programs will be treated if they are effectuated through use of coupons. Baxter also encourages CMS to confirm that PAPs continue to remain excluded from both Best Price and AMP.

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[29] 71 Fed. Reg. at 77,195 (proposed 42 C.F.R. pt. 447.502).
[30] 71 Fed. Reg. at 69,669.
[31] 71 Fed. Reg. at 77,181, 77,183.
[32] Id. at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(9)).

The Proposed Rule specifically excludes coupons redeemed directly to the manufacturer from AMP and Best Price,[33] but is silent as why and how other coupon types are to be accounted for in those calculations. In the preamble to the Proposed Rule, CMS directed that coupons redeemed by an entity other than the consumer (e.g., a retail pharmacy) should be included in AMP and Best Price because such coupons ultimately affect the price paid by the retail pharmacy, while coupons redeemed by the consumer directly to the manufacturer do not.[34] Baxter disagrees with the necessary assumption underlying this requirement: that a pharmacy's redemption of a coupon to and reimbursement by the manufacturer necessarily and in all cases affects the price realized by the redeeming pharmacy. To the contrary, Baxter's experience is that manufacturer reimbursement to redeeming pharmacies is limited to the pharmacy's out-of-pocket expense (actual or estimated) plus a fair market value fee for the services involved in accepting and processing the coupon.

CMS' discussion of coupons in the Proposed Rule also is too limited and does not account for the variety of coupon arrangements that exist. The Proposed Rule does not consider those Patient Assistance Programs that provide for free goods to qualified patients through patient coupons that can be redeemed at a pharmacy. The Proposed Rule exempts patient assistance programs from Best Price calculation, but the coupon provision also could be interpreted to require the inclusion of such a program in that calculation. Given the variety of potential coupon arrangements, the lack of prior guidance, and the crucial role patient coupons play in ensuring patient access to needed therapies, Baxter urges CMS to refrain from finalizing this provision until such specifics are provided and stakeholders have a meaningful opportunity to comment.

D. CMS Should Provide Further Guidance and Permit Additional Comment Before Acting on the New Definition of Bundled Sale.

The Proposed Rule includes a new definition of "bundled sale" that appears to be significantly broader than the existing definition of that term in the rebate agreement.[35] CMS provided no guidance on the purpose or meaning of the changes to the definition, nor any directions regarding how to implement the definition's requirement to reallocate discounts involved in such arrangements. The text of the Proposed Rule does not even

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[33] Id. at 77,197-98 (proposed 42 C.F.R. pts. 447.504(h)(9), .505(d)(8)).

[34] Id. at 77,183. CMS has provided the rationale for including coupons redeemed by an entity other than the consumer in the Best Price context. Baxter assumes that this rationale extends to the inclusion in the AMP calculation as well.

[35] Id. at 77,195 (proposed 42 C.F.R. pt. 447.502); 56 Fed. Reg. 7049, 7050 (Feb. 21, 199) (Medicaid Rebate Agreement at I(e)).

address bundled sales in its discussion of AMP and Best Price. Finalizing the Proposed Rule without further clarification will result in difficult and unknown administrative burdens to manufacturers. Most importantly, the Proposed Rule does not specify that this revised definition, if finalized, necessarily must be applied on a prospective basis only. For all of these reasons, Baxter strongly urges CMS to refrain from finalizing this new definition until it provides additional guidance so that manufacturers and other stakeholders can have a meaningful opportunity to review and comment on the new approach.

E. CMS Should Provide Additional Guidance Regarding the Proposed Definition of Customary Prompt Pay Discounts and Reporting Requirements.

Section 6002 of the DRA requires manufacturers to exclude customary prompt pay discounts extended to wholesalers from the AMP calculation.[36] Pursuant to this statutory provision, CMS has proposed to define customary prompt pay discounts as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time of the payment due date."[37] The Proposed Rule also includes a provision requiring manufacturers to report quarterly customary prompt pay discounts paid to all purchasers during a rebate period.[38]

Baxter requests that CMS provide additional guidance regarding a number of key terms in the definition of customary prompt pay discounts. Baxter asks CMS to clarify that "any discount," means a discount, regardless of amount, that is conditioned on the timing of payment. As to the term "routine[ ]," Baxter suggests CMS clarify that term as limiting qualifying discounts to only those that are provided to entities that satisfy manufacturer-defined, objective criteria.

The Proposed Rule also implements the new statutory requirement on manufacturers to report customary prompt discount data.[39] The Proposed Rule directs the reporting of discounts "paid" by the manufacturer in a quarter. In Baxter's experience, manufacturers do not "pay" these discounts, but rather the purchasing entities deduct the discount amount from the invoice payment they make when made within the specified period. Manufacturers typically can quantify with relative ease the amount of prompt payment discounts offered on sales in a quarter. Manufacturers also may be able to quantify the amounts of such discounts taken or deducted from payments made in a quarter, but that is

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[36] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6002(c)(1).
[37] 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(c)).
[38] Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(a)(3)).
[39] Id. at 77,182, 77,198 (proposed 42 C.F.R. pt. 447.510(a)(3)).

often more difficult as it requires reconciling all deductions taken and segregating those that relate to prompt payment discounts from those that do not (e.g., for shortages in product shipped or for returned goods). This latter amount also will not relate to sales made in a quarter, but rather to invoices paid in the quarter.

For all of these reasons, Baxter urges CMS to clarify that manufacturers may comply with the reporting and exclusion requirements by reporting and excluding the customary prompt payment discounts offered on sales made in the quarter. This figure is the least burdensome to determine and also ties to the sales figures used to calculate the quarterly AMP and Best Price.

3. CMS Should Clarify That the Definition of Net Sales in the Proposed Rule Is Not Tied to Revenue Recognition or General Financial Accounting Principles.

CMS proposes to define "net sales" as the "quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the [Social Security] Act or price reductions specifically excluded by statute or regulations) which reduce the amount received by the manufacturer."[40] The definition of net sales is crucial because it is the basis of the AMP calculation itself.[41] It is Baxter's understanding that the term "revenue" in the Proposed Rule is not intended to refer to the revenue recognized for a particular sale for financial accounting purposes or the timing of that recognition, but instead only the dollar amount associated with the sale net of all statutorily applicable price reductions. As CMS has stated, its concern is calculating net drug price,[42] and the determination of net drug price is not altered by including sales dollars rather than revenue recognized for financial accounting purposes.

This approach is consistent with that taken by CMS in relation to the calculation of ASP. In the preamble discussion of the bona fide service fee definition in the 2007 PFS Final Rule, CMS noted that "guidance on the treatment of service fees for ASP calculation purposes may differ with the treatment of service fees for financial accounting or other purpose."[43] Baxter asks CMS to adopt similar guidance in the AMP Final Rule and specify that "revenue" in the "net sales" definition does not require use of revenue recognized for financial accounting purposes.

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[40] Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(d)).
[41] Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(i)(2)).
[42] Id at 77,179.
[43] 71 Fed. Reg. at 69,667.

4. CMS Should Provide Additional Guidance to Aid Manufacturers in Including Data from Authorized Generics in the AMP and Best Price Calculations.

The Proposed Rule interprets Section 6003 of the DRA to require sales of authorized generics marketed by another manufacturer or a subsidiary of the brand manufacturer to be included in the AMP and Best Price calculation of the related branded drug.[44] Baxter asks CMS to (i) clarify that intercompany transactions between the branded and authorized generic manufacturer need not be included in the branded product calculation, (ii) confirm that the blended AMP and Best Price figures are to be used only for the branded drug, and (iii) agree that use of a summary level data is acceptable in determining the blended figures.

A. CMS Should Clarify That Intercompany Transactions Between the Brand and Authorized Generic Manufacturer Are Not Included in the AMP and Best Price of the Branded Drug.

The Proposed Rule directs that the manufacturer of a branded product include the sales of the authorized generic in its AMP and Best Price calculations.[45] The preamble to the Proposed Rule describes the authorized generic sales data that is to be incorporated into the branded calculations as the "sales of the authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs."[46] Baxter interprets this language as referring to the authorized generic manufacturer's sales of the product to that manufacturer's own AMP-eligible and Best Price-eligible purchasers, and not including any intercompany transactions between the brand and authorized generic manufacturers, such as transfer price, royalty, and/or license payments made by the authorized generic manufacturer to the brand manufacturer. This approach ensures that the blended AMP and Best Price figures reported for the branded product tie to the AMP and Best Price figures reported for the authorized generic, so as to reflect the true market prices for the overall product. This approach also avoids the significant operational and compliance complexities presented by incorporating such intercompany transactions. Baxter requests CMS confirm the appropriateness of this interpretation in its Final Rule.

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[44] 71 Fed. Reg. at 77,183-84; see Deficit Reduction Act, Pub. Law No. 109-171, § 6003(b)(1)(B).
[45] Id. at 77,198 (proposed 42 C.F.R. pts. 447.506(a), (b)).
[46] Id. at 77,184.

B. CMS Should Clarify That AMP and Best Price for the Authorized Generic Are Derived From the Authorized Generic Sales Alone.

The Proposed Rule provides that the "manufacturer holding title to the original NDA of the authorized generic drug must include the direct and indirect sales of this drug in its AMP . . . [and] in the computation of best price for the single source or innovator multiple source drug."[47] Baxter interprets this provision to mean that the brand manufacturer should include sales of the authorized generic in the calculation of the AMP and Best Price for the branded drug, but that the AMP and Best Price for the authorized generic are derived from its sales alone. Baxter believes that this is the appropriate interpretation of the regulation language and also is consistent with the DRA itself, and so requests that CMS confirm this interpretation in the Final Rule.

C. CMS Should Clarify That the Brand Manufacturer May Rely on the AMP and Best Price Reported by the Authorized Generic Manufacturer in Determining the AMP and Best Price for the Brand Drug.

The Proposed Rule does not address the methodology a brand manufacturer is to use to incorporate authorized generic sales data into a brand product's AMP and Best Price. Baxter believes one reasonable means for developing a blended AMP involves the authorized generic manufacturer supplying the brand manufacturer with the authorized generic's AMP, number of AMP-eligible units (the denominator of the AMP fraction), and Best Price. The brand manufacturer would develop a weighted average AMP from that data and report that for the brand product. For Best Price, the brand manufacturer would report the lower of the two products' Best Price. This approach allows manufacturers to avoid the administrative burden and operational complexity of incorporating the raw sales data of the authorized generic into the brand product calculations, and should not affect the accuracy of the resulting blended figures. Baxter urges CMS to acknowledge the acceptability of this approach in the Final Rule.

5. CMS Should Clarify a Number of Issues Regarding Recalculation of Base Date AMP.

CMS has proposed permitting manufacturers to recalculate base date AMP to account for changes in the definition of the retail class of trade.[48] Baxter supports CMS' decision to allow manufacturers to restate

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[47] Id.
[48] 71 Fed. Reg. at 77,185.

the base date AMP but requests that CMS clarify a number of important issues relating to the performance and timing of the recalculation effort.

First, the Proposed Rule does not require recalculation of base date AMP but instead provides manufacturers with the "option" to do so, recognizing that "some manufacturers may not have the data needed to recalculate base date AMP or may find the administrative burden to be more costly than the savings gained."[49] Baxter believes that other factors also may affect the recalculation decision and requests CMS to clarify that manufacturers retain complete discretion in deciding whether to recalculate these figures and that the decision can be made on a product by product basis.

Second, Baxter requests that CMS provide manufacturers with more time to perform the base date AMP recalculations. The Proposed Rule would require manufacturers to submit the revised figures "with their data submission for the first full calendar quarter following the publication of the final rule."[50] Manufacturers will be unable to make the recalculation decision until the Final Rule is issued, as the final definition of retail class of trade will affect that decision. The Proposed Rule's timeline would require manufacturers to evaluate the issues, make the recalculation decision, and perform the recalculation in less than two quarters, all at the same time that manufacturers are implementing the provisions of the Final Rule itself. Given these factors, Baxter asks CMS to revise the Proposed Rule to permit submission of recalculated base date AMPs within four full quarters following publication of the Final Rule. Baxter also ask CMS to confirm that the revised base date AMPs will be applicable beginning the first quarter of 2007 and that CMS will issue revised rebates once recalculated base date AMPs are available.

Third, the Proposed Rule states that manufacturers that choose to recalculate base date AMP must do so "in accordance with the definition of AMP in §447.504(e) of this subpart."[51] Section 447.504(e) of the Proposed Rule refers to the definition of retail pharmacy class of trade.[52] CMS should clarify that manufacturers also are to exclude customary prompt pay discounts from any base date AMP recalculations. The new statutory provision excluding customary prompt pay discounts from AMP has a significant effect on AMP. This change should be included in the recalculations to ensure that the exclusion of customary prompt pay discounts from current quarter AMP calculations does not increase the additional rebate component of the unit rebate amount.

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[49] Id.
[50] Id. at 77,185, 77,198 (proposed 42 C.F.R. pt. 447.510(c)(1)).
[51] Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(c)(2)).
[52] Id. at 77,196.

Finally, Baxter requests CMS confirm that manufacturers should use their current AMP methodology when recalculating base date AMP, inclusive of the retail pharmacy definition in the Final Rule, and not the methodology in place at the time the base date AMP originally was calculated. CMS also should acknowledge that changes in information systems and methodologies likely will require manufacturers to employ reasonable assumptions in their application of current methodologies to base date quarter data, and that such assumptions are appropriate when documented and consistent with the statute, agreement, and Final Rule. Baxter asks CMS to clarify that this approach to base date AMP recalculation is appropriate.

6. CMS Should Permit Quarterly AMPs To Be Derived from Monthly AMPs and Without Restatement and Adopt the ASP Methodology for Smoothing Lagged Data.

The DRA requires manufacturers to report AMP on a monthly basis and to continue to report AMP and Best Price on a quarterly basis.[53] The Proposed Rule directs that monthly AMP figures will not be subject to restatement but that quarterly AMP figures will continue to be so subjected.[54] Baxter asks CMS instead to permit manufacturers to derive their quarterly AMP from a weighted average of the quarter's three monthly AMP figures. Baxter also urges CMS to adopt the same smoothing methodology for lagged price concessions that it already has adopted for use in the ASP calculation, and to permit manufacturer to use their ASP methodology for lagged ineligible sales to estimate those sales for the AMP calculation.

A. Manufacturers Should Be Able To Calculate Quarterly AMP Using a Weighted Average of Monthly AMPs and Without Restatement.

The Proposed Rule adopts two distinct approaches to the calculation and reporting monthly and quarterly AMP data. The Proposed Rule requires manufacturers to report monthly AMP within 30 days of the end of the month and does not permit restatement of monthly AMP beyond that date.[55] The Proposed Rule continues to require manufacturers to report quarterly AMP within 30 days of the end of the quarter and permit submission of revised AMP data within twelve quarters of the reporting quarter.[56] Baxter requests that manufacturers be given the option of calculating their quarterly AMP using a weighted average of the three monthly AMPs and thereby avoid the obligation of updating the

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[53] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6003.
[54] 71 Fed. Reg. at 77,185-86.
[55] Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(d)).
[56] Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(a)).

quarterly figure for late-arriving data. This approach would account for such late-arriving data because the monthly AMP figures would include estimates of that data through an estimation methodology that CMS is to define in the Final Rule, while eliminating the significant administrative burden on manufacturers, States, and CMS of recalculating prior quarter rebate liability due to restatements of AMP.[57] This approach also will tie monthly and quarterly AMP figures, both of which will be public, so as to ensure consistency in any reimbursement rates based on those amounts. This approach will not impact quarterly reporting or subsequent restatements of Best Price and would still permit restatements of quarterly AMPs where necessary to correct an error. Baxter asks CMS to approve these provisions in its Final Rule.

B. CMS Should Adopt the ASP-Methodology for Smoothing Lagged Eligible Price Concessions and Allow Manufacturers To Use Their Current ASP Smoothing Methodology for Lagged Ineligible Sales.

As noted above, CMS has proposed requiring manufacturers to report monthly AMP data within 30 days after the end of the month and not permitting restatement of monthly AMPs.[58] In recognition of the fact that all data may not be available within that reporting period, CMS has proposed allowing manufacturers "to rely on estimates regarding the impact of their end-of-quarter rebates or other price concessions and allocate these rebates or other price concessions in the monthly AMPs reported to CMS throughout the quarter."[59] CMS also requested comments on approaches for estimating this data.[60] Baxter urges CMS to adopt the same smoothing methodology for lagged price concessions in AMP as CMS has adopted for the ASP calculation.[61] CMS has not required use of a particular methodology in ASP for lagged ineligible sales, and so Baxter urges CMS to permit manufacturers to use in their calculation of AMP the same approach employed by the manufacturer for ASP purposes.

The ASP estimation methodology for lagged eligible price concessions utilizes a 12-month rolling average ratio of ASP-eligible lagged price concessions to ASP-eligible sales. The methodology applies that ratio to the ASP-eligible sales for the reporting period to derive the estimate of lagged eligible price concessions for that period. This methodology could be applied with equal success in the calculation of

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[57] Baxter's experience is that changes in AMP rather than Bet Price are the more frequent cause of changes to prior quarter unit rebate amounts.
[58] 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. pt. 447.510(d)).
[59] Id. at 77,186.
[60] Id.
[61] 69 Fed. Reg. 55,763 (Sept. 16, 2004).

monthly AMP: a manufacturer would calculate the ratio of lagged AMP-eligible price concessions to AMP-eligible sales for the twelve-month period that ends with the quarter before the quarter in which the month in question falls. That ratio would be applied to the AMP-eligible sales each month in the quarter to determine the estimated lagged price concessions for that month. Using this methodology, the manufacturer would update its eligible lagged price concession ratio on a quarterly basis and apply that ratio to each month in the quarter.

This approach permits a manufacturer to use quarterly data to derive the ratio, which generally is subject to greater validation than monthly data, and decreases the likelihood of volatility in the monthly AMPs, which is an important factor when those figures are used to set reimbursement rates. Use of the ASP methodology also decreases risk of error and administrative burden for those manufacturers with ASP drugs, as there will be no need to have different smoothing methodologies for the different average price calculations.

As CMS likely knows, manufacturers also use lagged price concessions to identify ineligible sales that are to be removed from the AMP calculation, such as 340B sales. For this reason, manufacturers also will need to develop an estimation methodology for these lagged ineligible sales. CMS has not yet specified a methodology that manufacturers must use to estimate these sales in the ASP calculation. Baxter asks CMS to clarify that manufacturers may use whatever methodology they currently use to estimate lagged ineligible sales for ASP when calculating monthly AMP. If CMS were to issue specific guidance on how to calculate such estimates in the ASP context, manufacturers would then be able to apply that methodology in the AMP monthly context as well.

7. CMS Should Limit Rebate Amounts Where Medicaid Is a Secondary Payor.

The DRA requires States to seek rebates for single source physician-administered drugs as of January 2006, and, beginning in January 2008, States also will have to seek rebates for the 20 physician-administered multiple source drugs that are determined to have the highest dollar volume of all physician-administered drugs dispensed to Medicaid beneficiaries.[62] Medicaid is often a secondary payor on physician-administered drugs, covering only those costs not paid by Medicare. In previous guidance, CMS has directed that States are entitled to the full amount of a Medicaid rebate even when Medicaid has only paid a portion of the claim.[63] Baxter believes this guidance is both inconsistent

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[62] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6002(a).

[63] See, e.g., Medicaid Drug Program Release No. 6 to Participating Drug Manufacturers (1993).

with the Medicaid rebate statute and also not binding on manufacturers. As one of a limited number of manufacturers who distribute therapies that are covered for outpatient use under Medicare Part B and administered by Medicaid pharmacy programs and subject to rebates for many years, we have significant experience and concern regarding the administration and potential abuse of this policy. In particular, we are aware of one State that attempted to take advantage of this policy by implementing a "revenue enhancement" program designed to profit from the rebate program. This program reviewed the opportunities to collect rebates through a slight increase in provider reimbursement or the payment of an administration fee with no payment for the drug.

The Medicaid rebate statute requires manufacturers to pay States a rebate for covered outpatient drugs for which States make payments.[64] Congress enacted the statute to ensure that State Medicaid programs had access to the discounted drug prices available to other large volume purchasers.[65] Importantly, the purpose of the statute is to put States on a level playing field with other purchasers, not to provide States with a windfall that subsidizes the overall funding of the program.[66] CMS' interpretation of the statute may aid such windfalls where Medicaid is a secondary payor, as the rebate amounts paid may exceed the State's expenditure, frequently by several multiples.

For example, if a dually eligible beneficiary receives a drug with an AMP of $100.00, which has a Medicare allowable of $106.00, the Medicare program will be responsible for $84.80. The State will be responsible for the lesser of $21.20 or the additional amount which will result in total reimbursement that equals the State's reimbursement rate for that drug. In such a situation the State could set their product reimbursement at $85.00, resulting in State liability of only $.20. If the Agency does not clarify that rebates paid in relation to utilization for which Medicaid is the secondary payor are limited to the proportion of the Medicaid allowable cost paid, in this scenario, the State may collect a $15.10 rebate on a $0.20 expenditure. We believe that this violates the intent of the rebate statute and are hopeful that CMS will put an end to these practices. Baxter asks CMS to clarify that rebates paid in relation to utilization for which Medicaid is the secondary payor are limited to the proportion of the Medicaid allowable cost paid by the State, and further,

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[64] Social Security Act § 1927(b)(1), 42 U.S.C. §1396r-8(b)(1).
[65] See 136 Cong. Rec. S12954-01 (1990) (statement of Sen. Pryor).
[66] See H.R. Rep. No. 101-881, pt. 1, at 2108 (1990) ("The Committee believes that Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchases 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.").

we ask that the Agency clarify that the payment of a dispensing fee does not implicate the rebate requirement

This central tenet of the Medicaid statute was confirmed by Senator Grassley, former chairman of the Committee on Finance, in a letter he sent to CMS upon the passage of the DRA. In that letter, Senator Grassley stated that "[f]ederal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program."[67] Senator Grassley explained that Congress intended the amendment to the Medicaid rebate statute contained in section 6002 of the DRA to clarify that States can claim rebates only for the "Medicaid payments" made for such drugs and that "[i]t is also clear that this language certainly does not grant states the authority to collect rebates for prescription drug expenses covered by the Medicare program."[68]

Although the statute directs manufacturers to pay the rebate amount defined in "subsection (c) of this section" for each unit of a drug for which payment is made under a State plan, and subsection (c) provides only for the full rebate amount,[69] this provision must be read in conjunction with the requirement in the paragraph that the rebate be considered "a reduction in the amount expended," which clearly presumes the rebate amount will not and should not exceed the State's payment amount.[70] The statutory text, legislative history, and Senator Grassley's letter together lead to the single conclusion that Congress did not intend or provide for the payment of rebates that exceed a State's expense and CMS should implement the statute accordingly.

To date, CMS has issued its direction that manufacturers pay full rebate amounts in these circumstances only through informal, non-binding, program releases. Guidance in this form cannot bind manufactures because it has not been subject to notice-and-comment rulemakng,[71] and also is not entitled to deference.[72] Although informal agency guidance may be respected if it is persuasive,[73] CMS' interpretation in this instance is not, for all of the reasons noted above. Baxter strongly encourages CMS to take the opportunity in the Final Rule to revise its former position and direct that rebates are only required in proportion to the Medicaid allowable cost expended by the States.

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[67] Letter from Senator Charles Grassley to The Honorable Mark B. McClellan, Aug. 14, 2006.
[68] Id.
[69] Social Security Act § 1927(b)(1)(A), 42 U.S.C. §1396r-8(b)(1)(A).
[70] Id. at § 1927(b)(1)(B), §1396r-8(b)(1)(B).
[71] See United States v. Mead Corp., 533 U.S. 218 (2001).
[72] See Pharmaceutical Research and Manufacturers of America v. Thompson, 251 F.3d 219, 224 (D.C. Cir. 2001) (citing Christensen v. Harris County, 529 U.S. 576 (2000)).
[73] See Christensen v. Harris County, 529 U.S. 576, 587 (2000).

8. CMS Should Implement the Statutory Deadline on State Submission of Rebate Claims.

The Medicaid rebate statute requires States to submit rebate claims within 60 days of the end of the rebate period.[74] The statute contains neither exceptions to this deadline nor provisions for exceptions. CMS nevertheless interpreted this provision, in 1995, to not excuse manufacturers from rebates claimed after the expiration of the 60 days.[75] CMS did not explain why it believed that manufacturers remained liable for claims submitted beyond this period and Baxter can find no support for such an interpretation in the statutory language. To the contrary, Baxter believes that States are prohibited from submitting drug utilization data for rebates beyond the 60 days given by statute.

At the same time it made this pronouncement in 1995, as part of a proposed rule that has never been finalized, CMS did propose limiting manufacturer liability to rebates claimed within one year of the end of the rebate period.[76] The current Proposed Rule does not make any mention of such a limitation, and Baxter strongly urges CMS to finalize some limitation in this Final Rule given the clear statutory mandate. As CMS recognized in 1995, imposing a one-year statute of limitations on States' right to claim rebates "translates into a manufacturer being responsible for rebates for more than 3 years after the drug is dispensed."[77] The three-year record retention requirement is consistent with general business practices and Internal Revenue Service obligations. Allowing States to submit claims for rebates more than three years after the drug was dispensed increases the likelihood that the manufacturer will not have the records necessary to dispute the claim, and, as CMS has noted, increasing the number of disputes for "data where no records may exist is not . . . a cost effective or efficient manner of operating the drug rebate program."[78]

In the context of physician-administered drugs, these concerns are now particularly significant. As discussed above, the DRA requires States to submit rebate claims for physician-administered drugs.[79] Although States have always been entitled to seek rebates for these drugs, they have done so infrequently in the past. The new statutory mandate to seek

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[74] Social Security Act §1927(b)(2)(A), 42 U.S.C. §1396r-8(b)(2)(A).
[75] 60 Fed. Reg. 48,442, 48,460 (Sept. 19, 1995).
[76] Id.
[77] Id. The pharmacy or other entity that dispenses the drug to the patient has up to one year to submit a claim for reimbursement to the State. The State has one year to pay the claim. The one-year statute of limitations for the State to submit the rebate claim to the manufacturer would begin to run after the State has reimbursed the entity dispensing the drug.
[78] Id.
[79] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6002(a).

such rebates raises a particular concern that States now may try to seek rebates for these products for periods that are several years past. Manufacturers cannot be exposed to such open-ended liability. Baxter therefore asks CMS to clarify that States have a limited time frame in which to claim rebates.

9. CMS Should Define a Process for Bringing Concerns Regarding Federal Upper Payment Limits and Publicly Available Monthly AMP Data to CMS' Attention.

CMS has proposed setting federal upper payment limits (FULs) whenever the "FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent."[80] Baxter urges CMS to define a process through which manufacturers or other stakeholders can alert CMS to issues relating to the FUL process. Examples include FULs that are based on the AMP for a drug that is available in only limited volumes or sold exclusively to certain outlets, and thus not available generally and inappropriate for use as the basis for a FUL. Baxter believes it is imperative to have some means of communicating such issues and concerns to CMS and urges the agency to provide some method for doing so in the Final Rule.

Baxter also requests that CMS permit manufacturers to review monthly and quarterly AMP data prior to its publication by CMS to ensure its accuracy. Baxter urges CMS to allow manufacturers the opportunity to access and review the AMPs for their own products, for example by entering a user identifier and password linked to the manufacturer's DDR access, before the information is made public to give manufacturers the opportunity to bring any concerns about the accuracy of such data to CMS' attention. Such an opportunity for review would provide a critical safeguard for the accuracy of this data before it is used by States' for reimbursement purposes.

10. CMS Should Study the Effect of the Revised AMP Definition on the Applicable Threshold Percentage for Readjustment of ASP.

Changes to the definition of AMP that result from the DRA and the Final Rule have the potential to affect Medicare reimbursements normally determined by ASP. The ASP statute requires the Secretary to disregard ASP in calculating Medicare reimbursement when the ASP for the drug or biological exceeds the widely available market price (WAMP) or AMP by the "applicable threshold percentage."[81] The applicable threshold percentage was established initially at 5% and has remained at that

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[80] 71 Fed. Reg. at 77,199 (proposed 42 C.F.R. pt. 447.514).
[81] Social Security Act § 1847A(d)(3).

amount to date,[82] although it is subject to adjustment.[83] If this threshold percentage is surpassed, the Secretary must substitute the ASP-based payment for the lesser of WAMP or 103% of AMP.[84]

There is a significant likelihood that the Final Rule will cause the AMP for many drugs to change. Where the effect is a reduction in the AMP, there also is an increased likelihood that the difference between ASP and AMP will exceed the applicable threshold percentage, forcing the substitution of AMP for ASP. This possibility is particularly troublesome for biologics. Multiple biologics often share the same HCPCS code even though they are not truly equivalent. A significant decrease in one product's AMP could drive the code's AMP below the threshold, and trigger the use of AMP-based reimbursement. This in turn could limit access to products in the code with higher AMPs, which is particularly troublesome for those patients who achieve better therapeutic outcomes through those products with the higher AMPs.

Baxter is concerned that the changes to the AMP definition could have unintended consequences for the ASP applicable threshold and resulting Medicare payment rates. Baxter asks CMS to study this issue and account for the revised AMP definition when setting the applicable thresholds for future years.

11. CMS Should Encourage States To Adequately Reimburse Retail Entities for Dispensing Medications.

As CMS may know, providers incur greater than average administrative costs in relation to certain drugs and biologics because of difficulties associated with procuring or administering those products. We believe that hemophilia clotting factor and intravenous immune globulin (IVIG) are two such therapies. The Medicare program pays an additional fee to entities that purchase and administer these drugs to address these added costs. We are hopeful that CMS will work closely with States to provide background on these therapies and encourage the establishment of reimbursement that is adequate to sustain access.

Congress addressed hemophilia clotting factor reimbursement in the Medicare Modernization Act through the inclusion of a provision which established a "furnishing fee," which is a separate payment to entities providing blood clotting factors, to take into account the mixing and delivery of such agents, special inventory management and storage requirements, as well as additional supplies or necessary patient

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[82] 71 Fed. Reg. at 69,680.
[83] Social Security Act § 1847A(d)(3)(B).
[84] Id. § 1847A(d)(3)(C).

training.[85] IVIG access has been an ongoing concern since January 2005. Many Medicare beneficiaries have faced significant barriers to IVIG access[86] in the physician office and home health[87] settings as a result of inadequate reimbursement. The 2007 PFS Final Rule provided a pre-administration fee for IVIG. While not a permanent, or universal solution to the current reimbursement challenges, the additional funds available as a result of the pre-administration fee have been an important resource that restored access to some beneficiaries using a subset of products. CMS should encourage States to provide similar additional payments in the Final Rule.

Baxter asks CMS also to explicitly encourage States to take Medicare-mandated dispensing fees into consideration when setting dispensing fee rates. CMS proposed adopting the Medicare Part D definition of "dispensing fee" in the Proposed Rule because it will "assist States in the evaluation of facts in establishing a reasonable dispensing fee to pharmacy providers."[88] Under the Proposed Rule, therefore, States determine the appropriate dispensing fee to pay to pharmacies, although CMS prompts States to "analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs."[89] Encouraging States to take Medicare-mandated dispensing fees into consideration when establishing Medicaid dispensing fees will help ensure continued patient access to these drugs.

There is reason to be concerned about the adequacy of reimbursement for prescription drugs given the DRA amendment providing for AMP-based FULs. The Government Accountability Office (GAO) prepared a report late last year comparing estimated AMP-based federal upper limits with retail pharmacy acquisition costs.[90] Using data from the

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[85] 71 Fed. Reg. at 69,680.

[86] Patient organizations have received numerous calls from patients, physicians, home health care companies and other sites of care concerning treatment problems related to Medicare reimbursement of IVIG. Access concerns were quantified in an Immune Deficiency Foundation (IDF) survey of 287 physicians treating a total of 4189 patients with primary immune deficiency disease and 935 patients with other disorders currently receiving IVIG. The survey found that 31% of physicians who treat primary immune deficient patients with IVIG reported patients experiencing significant problems related to reimbursement of IVIG. Of this group, 43% reported adverse health effects on patients as a result of reimbursement. The impact on patients included: 21% switched to a different site of care, 22% postponed infusions, 13% switched brands, and 8% had the interval between infusions increased.

[87] IVIG is covered under Part B for primary immune deficient patients.

[88] 71 Fed. Reg. at 77,176.

[89] Id.

[90] United States Accountability Office, Medicaid Federal Upper Limits (GAO-07-239R) (Dec. 22, 2006), available at http://www.gao.gov/docsearch/app_processform.php?app_id=docdblite_agency&page=2.

first quarter of 2006 as a basis, the GAO concluded that AMP-based FULs for that quarter would have been an average of 36 percent lower than the average retail pharmacy acquisition costs for 59 of the 77 drugs it included in the sample.[91] Encouraging States to provide Medicare-mandated additional payments and to set dispensing fee rates consistent with the Medicare rates will help ensure that retail entities are adequately reimbursed and continue to provide the medications that patients need.

CONCLUSION

Baxter appreciates the opportunity to comment on this Proposed Rule. CMS has made great strides in providing clarity to the administration of the Medicaid drug rebate program and Baxter is confident that the Final Rule will help ensure that patients have access to the medicines that they need. Baxter believes that, by providing additional clarity and guidance, and implementing the few changes outlined above, the Medicaid drug rebates program will function effectively and efficiently for manufacturers, States, and CMS. Please feel free to contact Sarah Creviston, Vice President, U.S. Government Affairs and Public Policy by phone at 847-948-4278 or email at sarah_creviston@baxter.com if you have any questions or would like additional information.

Sincerely,

Sarah Creviston
Vice President
U.S. Government Affairs and Public Policy
Baxter Healthcare Corporation

[91] Id. at 4

#136

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February 27, 2007

Centers for Medicaid and Medicare Services
Department of Health and Human Services
Attn: Ms. Christina Lyon
PO Box 8015
Baltimore, MD 21244

RE: Correction to #CMS-2238-P; Medicaid Program; Prescription Drugs

Dear Ms. Lyon:

The American Society of Health-System Pharmacists (ASHP) recently responded to the Centers for Medicare and Medicaid Services (CMS) December 22, 2006 proposed rule that would implement provisions of the Deficit Reduction Act of 2005 (DRA) regarding prescription drugs under the Medicaid program. Enclosed in our comments were the results of a recent survey of pharmacy directors to estimate the impact of this new requirement on hospitals and health systems. Unfortunately, the survey results contained the following two errors:

1. Data Error in Survey Results, key findings (4th paragraph, third sentence on page 3):

   "Over sixty percent replied that this occurs with over 10% of doses dispensed by their pharmacy, and 36% **(wrong, should be 22%)** of the respondents indicated that this occurs with more than 30% of their doses dispensed."

   Correction: The sentence should read as follows:

   "Over sixty percent replied that this occurs with over 10% of doses dispensed by their pharmacy, and 22% of the respondents indicated that this occurs with more than 30% of their doses dispensed."

2. Table 4 (page 6):
   Time per order—the numbers were entered incorrectly; they were identical to the results from Table 3.

Correction: ASHP has changed Table 4 with the correct data.

In closing, we have reviewed our comments and survey and no additional errors were found. We would request that the corrected comments be added to the record for consideration and apologize for any inconvenience.

Enclosed are copies of the relevant changes and a full copy of ASHP's comment letter and corrected version of the survey results. If you have questions or need additional clarification please do not hesitate to contact me directly at 301.664.8698 or via email at bmeyer@ashp.org

Sincerely,

Brian M. Meyer
Director, Government Affairs Division

Enclosure

CORRECTION #1—Percentage Changed in Paragraph from 36% to 22% (Bold and Underlined)

Information Technology

Those respondents that provide outpatient services were asked to describe their organization's information technology system's ability to operationalize the proposed requirement. The results addressed the pharmacy system as it related to patient care order entry, bar coding of medications and administration processes, documentation, and its interface with hospital patient care systems including the interface with the financial and/or patient accounting information systems.

Six percent of respondents from hospitals with outpatient services utilized bar-coding in their outpatient environments, with only 28 percent of the respondents indicating that they utilized bar-coding in *any* of their organization's medication processes. All of the respondents that utilize bar-coding indicated that they must prepare special packaging for doses within the pharmacy that result in utilizing a bar-code numerical identifier other than the manufacturers NDC number. **Over sixty percent replied that this occurs with over 10% of doses dispensed by their pharmacy, and 22% of the respondents indicated that this occurs with more than 30% of their doses dispensed.**

CORRECTION #2—Correct Data Included in Chart

Table 4

Assume that starting *tomorrow*, your organization is required to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid outpatients (hospital clinic, emergency department services, and outpatient infusion centers).

Approximately how much time per order would this take for each item below:

Item	Less than 5 minutes	5 to 10 minutes	10 to 20 minutes	20 to 30 minutes	More than 30 minutes
Recording and tracking NDC from order entry, preparation, to administration	16%	36%	26%	11%	11%
Provision of NDC information to finance/patient accounts	19%	34%	23%	8%	16%
Total Responses: 637					

ASHP Survey Results:

Provision of NDC Numbers on Outpatient Medicaid Claims

February 2007
Corrected February 23, 2007

Key Findings

- Only 18% of respondents were aware of notification of the new NDC requirement from their state Medicaid program.
- The estimated cost per medication order to include the NDC number on a Medicaid claim was $10.80 if this requirement were to be implemented today.
- Only 40% of respondent's pharmacy information systems are able to store and cross reference alternate NDC numbers for the same generic entity, functionality considered essential since more than one product is stocked for any generic drug entity.
- Only 16% of respondents that provide outpatient services indicated that their pharmacy information system had the ability to send an NDC number for each drug dispensed and administered to the organization's finance and/or patient accounts system.
- Bar coding of outpatient medication administration is thought to be the only possible way to implement this provision, yet only 6% of respondents utilized bar-coding for their outpatient mediation doses.

Introduction

On December 22, 2006, The Centers for Medicare and Medicaid Services (CMS) published a proposed rule in the Federal Register describing their plans to implement certain provisions in the Deficit Reduction Act of 2005 (DRA). Under the DRA, hospitals will be required to provide NDC information on billing submissions to Medicaid so that states are able to seek manufacturer rebates. Specifically, it requires the reporting of the 11-digit unique NDC number of the outpatient drug administered in clinic settings. This survey was designed to gauge the feasibility of hospitals and health systems meeting this requirement with current systems and processes.

Objective

The objective of this survey was to determine the impact of the proposed requirement that for all drugs administered to Medicaid outpatients be billed including the 11 digit National Drug Code (NDC). This would include physician offices, outpatient infusion centers, emergency departments, and ambulatory clinics. To determine the impact of this proposed rule the survey posed questions about information technology, workload, operational, and financial implications.

Methods

The survey was sent electronically on February 5, 2007 to 3,200 ASHP members that are primary members of the Section of Pharmacy Practice Managers. This sample included directors of pharmacy, associate directors of pharmacy, and other pharmacy managers from across the United States. The survey was conducted via an e-mail invitation containing a link to an online survey instrument; with a reminder e-mail sent on February 8, 2007 and was closed on February 13, 2007. Of the invitations sent, 718 surveys were completed resulting in a 22% return rate.

Detailed Results

The key findings of this survey included respondent's awareness of any notification from their State Medicaid programs of intentions to implement this DRA rule, the technical ability of pharmacy and hospital information systems, the impact on organization resources and costs, and the anticipated time consumption per outpatient order this NDC reporting requirement would have on health systems.

Notification by State Medicaid Programs

Reponses received included pharmacists representing hospitals in all states except Alaska. Of these responses, 48 states had greater than 5 responses each. Ninety-one percent of the respondents provided outpatient services with the range of outpatient volume from 12,000 visits per year to more than 180,000 visits per year (Table 1). These respondents represented a wide range of hospitals sizes with an average daily census ranging from less than 50 to greater than 500 (Table 2).

The survey recipients that indicated they provide outpatient services were asked whether their State Medicaid program had announced their intention to implement the requirement that NDC numbers be submitted on outpatient Medicaid claims so that the state might seek rebates from manufacturers. Eighteen percent replied YES, 5 percent replied NO, and 77 percent replied that they were not aware of any announcements.

Information Technology

Those respondents that provide outpatient services were asked to describe their organization's information technology system's ability to operationalize the proposed requirement. The results addressed the pharmacy system as it related to patient care order entry, bar coding of medications and administration processes, documentation, and its interface with hospital patient care systems including the interface with the financial and/or patient accounting information systems.

Six percent of respondents from hospitals with outpatient services utilized bar-coding in their outpatient environments, with only 28 percent of the respondents indicating that they utilized bar-coding in *any* of their organization's medication processes. All of the respondents that utilize bar-coding indicated that they must prepare special packaging for doses within the pharmacy that result in utilizing a bar-code numerical identifier other than the manufacturers NDC number. Over sixty percent replied that this occurs with over 10% of doses dispensed by their pharmacy, and 22% of the respondents indicated that this occurs with more than 30% of their doses dispensed.

Sixty percent of the respondents that provide outpatient services stated that their pharmacy information system could not store and cross reference alternate NDC numbers for the same generic entity. This means that these institutions could not track or bill an alternate NDC number in the event a therapeutic equivalent generic entity was utilized. Seventy- three percent of the respondents replied that their information systems are not able to identify the unique NDC number of a product utilized in preparing an IV admixture, which is noted to be due to the fact that current systems are designed to ensure accuracy of a specific generic drug charge code versus multiple NDC numbers that could be represented by the charge code.

In addition, only 16% of respondents that provide outpatient services indicated that their pharmacy information system had the ability to send an NDC number for each drug dispensed and administered to the organization's finance and/or patient accounts system.

Operational Impact on Resources

To determine what the operational impact would be on organizations, including both staff resources and time to make process changes, respondents were asked to indicate what this would be for their organizations. Seventy-eight percent of respondents indicated that it is a significant impact on the pharmacy department and staff time required to implement any manual short term solutions. Seventy percent of respondents indicated that the staff hours required making soft-ware changes for long term solutions would also be significant. And sixty-eight percent of respondents felt that any process changes to develop long term solutions would have a significant impact on their organization (Table 3).

Time Per Outpatient Order to Implement DRA Provisions

Respondents that indicated that they provided outpatient services were asked to consider the amount of time it would take per outpatient order to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid outpatients, assuming such a requirement were to go into effect "tomorrow" for their organization. For the process of recording and tracking the NDC number from order entry to preparation to administration more than 48 percent indicated that it would be greater than 10 minutes per order and 36 percent indicated it would take between 5 to 10 minutes. For the process of providing the patient specific NDC number information for utilization in the finance and/or patient billing accounting more than 47 percent indicated that it would be greater than 10 minutes per order and 34 percent indicated that it would take between 5 to 10 minutes (Table 4).

Utilizing an average pharmacy personnel hourly rate of $27.00 (less benefits), this would translate into an estimated average cost to meet the proposed requirements of the DRA of $10.80 per outpatient drug order (average reported time of 24 minutes per order); with the current technology and processes in place in the United States as of February 2007.

Conclusion

In order to meet the requirement to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid outpatients it would result in significant operational and financial hardship for the United States' health systems. Additionally, the current information technology infrastructure would need to be substantially altered to accommodate this requirement.

Contact information

For more information on this survey and it's results, please contact Brian Meyer, Director, Government Affairs, American Society of Health-System Pharmacists at 301-664-8698 or bmeyer@ashp.org.

Table 1

What is the estimated number of outpatient visits (hospital clinic, emergency room services, and outpatient infusion centers) per month at your organization?

Visits	*Number of Responses*	*Percentage*
Less than 1,000 visits	95	15%
Between 1,000 to 5,000 visits	219	34%
Between 5,000 to 15,000 visits	139	22%
More than 15,000 visits	140	22%
Don't know	47	7%
Total responses: 640		

Table 2

Please indicate the average daily census at your organization.

Average Daily Census	*Number of Responses*	*Percentage*
Not applicable	9	1%
Less than 50	109	17%
50-99	87	14%
100-199	139	22%
200-299	98	15%
300-399	78	12%
400-499	30	5%
500 or more	84	13%
Total responses: 634		

Table 3

For each of the resources/costs below, please indicate the impact that you foresee at your organization:					
	None	Insignificant	Moderate	Significant	Don't know
Pharmacy and other staff time for manual short-term solutions	1%	3%	14%	78%	4%
Staff time for software changes for long-term implementation	2%	2%	18%	70%	9%
Process changes for long-term implementation	1%	2%	21%	68%	8%
Total Responses: 637					

Table 4

Assume that starting *tomorrow*, your organization is required to capture the unique 11 digit NDC number on the bills for drugs administered to all Medicaid outpatients (hospital clinic, emergency department services, and outpatient infusion centers).

Approximately how much time per order would this take for each item below:

Item	Less than 5 minutes	5 to 10 minutes	10 to 20 minutes	20 to 30 minutes	More than 30 minutes
Recording and tracking NDC from order entry, preparation, to administration	16%	36%	26%	11%	11%
Provision of NDC information to finance/patient accounts	19%	34%	23%	8%	16%
Total Responses: 637					

State of California—Health and Human Services Agency
Department of Health Services

California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

February 20, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8015
Baltimore, MD 21244-8015

Attention: CMS-2238-P

Dear Sir or Madam:

SUBMITTAL OF FORMAL COMMENTS REGARDING THE PROPOSED FEDERAL RULE IMPLEMENTING THE MEDICAID PRESCRIPTION DRUG PROVISIONS OF THE DEFICIT REDUCTION ACT OF 2005 – NPRM ISSUED IN THE FEDERAL REGISTER (VOLUME 71, NUMBER 246) ON DECEMBER 22, 2006

This responds to the Centers for Medicare & Medicaid Services (CMS) request for comments on the Notice of Proposed Rule Making dated December 22, 2006, regarding the implementation of Medicaid prescription drug provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to the calculation of Average Manufacturer Price (AMP) and the Federal Upper Limit (FUL) of drugs provided in the Medicaid program.

The proposed rule attempts to clarify how AMP and FUL are to be calculated. More specifically the rule provides definitions, calculations, timeframes and other related aspects that have, to date, been generally provided through policy letters issued by CMS. Though CMS has done an admirable job on a very difficult task, there are problems in the proposed rule that could harm the state Medicaid programs, pharmacy providers and more critically, Medicaid beneficiary access to medically necessary care. The following are comments and recommended solution for these issues.

Bundled Sale Definition

The definition of a bundled sale includes that "the discounts are allocated proportionally 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."

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This language should be clarified so there is not room for interpretive error regarding the intent. The phrase "allocated proportionally to the dollar value of the units" should be slightly modified to state "allocated proportionally to the total dollar value of the units" and the word "should" in the last sentence amended to "shall."

Dispensing Fee Definition

The definition of dispensing fee includes "...pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid recipient" and that the fee includes, "measurement or mixing of the covered outpatient drug" and "special packaging." This definition is inclusive of many different types of drugs dispensed by pharmacies. Of special concern are compounded drugs that are more complex and may include non-drug products (diluents, surfactants, suspending agents, special containers, etc.) whose cost cannot be accurately captured within a dispensing fee structure. These products are necessary to provide the "appropriate covered outpatient drug" to the Medicaid recipient.

Therefore this definition should include language that recognizes these additional cost elements as not included in the dispensing fee but as costs that can be paid by the Medicaid agency in addition to the dispensing fee and the cost of the covered outpatient drugs.

Estimated Acquisition Cost Definition

The definition of Estimated Acquisition Cost includes the qualifier of the "package size of drug most frequently purchased by providers." In California Medicaid (Medi-Cal), estimated acquisition cost is spread pursuant to package sizes listed in regulations. As an example, for solid oral dosage forms (i.e. tablets and capsules), the per unit price from the 100s size container is used to price all package sizes (e.g. 30s, 50s, 500s, or 1000s). The requirement that the most frequently purchased package size could change from time to time.

The final rule should provide more specific guidance and a source from which to draw this information from. For example, the language could be altered to read, "package size of drug most frequently purchased by providers within the previous 12 months as provided to state Medicaid agencies by the Centers for Medicare and Medicaid Services."

Retail Pharmacy Class of Trade Definition

The definition of Retail Pharmacy Class of Trade is a key in the calculation of the Average Manufacturer Price (AMP) in that federal statute specifically states that AMP is "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." The proposed rule defines retail pharmacy class of trade to include traditional independent and chain

retail pharmacies, mail order pharmacies, pharmacy benefit managers (PBM) and "other outlets that purchases, or arranges for the purchase of drugs.....and subsequently sells or provides the drugs to the general public." Health Maintenance Organizations (HMO) and long term care pharmacies are not included in the definition.

The inclusion or exclusion of various entities in this definition creates several issues:

- The Centers for Medicare & Medicaid Services (CMS) indicate they decided to include discounts provided by manufacturers to PBMs that affect the net price recognized by the manufacturer. This appears contrary to CMS' own admission that manufacturers cannot accurately determine if discounts provided to a PBM actually affects the price. This decision also appears to be contrary to statute which indicates the AMP reflects prices paid by wholesalers and not rebates provided to entities that neither distribute nor receive shipment of drugs.

- The inclusion of "other outlets" provides for a number of entities that are typically not considered retail pharmacies. For example, physician offices and outpatient clinics are outlets the purchase drugs and provide these drugs to the general public; however, they are not retail pharmacies. The calculation would have to include these entities since they are not expressly excluded in subsequent paragraphs of the rule.

- Also not clear in the proposed rule is how HMO owned PBMs, and the mail order pharmacies of the HMO/PBM should be included or excluded in the calculation of AMP.

- The definition excludes long term care pharmacies because, according to CMS, these pharmacies do not dispense to the general public. Based on this description, dispensing drugs to the general public is an important feature of a retail pharmacy. PBMs and many non-pharmacy entities do not dispense drugs to the "general public" therefore the inclusion of these various entities appears contrary to this CMS established attribute.

- It is clear from the discussion in the proposed rule that the decision to include non-pharmacy entities in the definition of AMP was made primarily as a means to decrease pharmacy reimbursement and also decrease manufacturer rebate liabilities. Though the attempt to adjust pharmacy reimbursement to acquisition cost is in line with federal requirements for states to pay at estimated acquisition cost, the inclusion of PBMs and other non-pharmacy groups would likely depress AMP below a level at which most independent and some chain pharmacies can purchase. In many instances this would put many rural or ethnically sensitive pharmacies with high Medicaid volumes at risk and could cause access

problems. To avoid these access problems, states would have to increase the dispensing fee or provide additional payments as a means to maintain a an adequate provider network.

Additionally, the reduction in manufacturer rebate obligation is contrary to the intent of the federal Medicare drug rebate program to obtain the best price (i.e. largest discount) as evidenced by inclusion of best price language in federal Medicaid statutes.

The proposed rule should define retail pharmacy class of trade to more accurately reflect the wholesaler to pharmacy relationship and provide Medicaid the best price by:

- The definition should add PBMs to the list of entities excluded from the definition.
- The definition should not use general, undefined descriptions such as "independent" or "mail-order" pharmacy or "other outlet."
- The definition should be amended to mean any entity in the United States that is licensed as a pharmacy which provides drugs to the general public.
- Though mail order pharmacies have a tendency to decrease AMP they should be included because they are licensed pharmacies and provide drugs to the general public.

It is clear from the final rule discussion that CMS has struggled to balance AMP-based rebate collection and AMP-based reimbursement through the inclusion of non-pharmacy entities. Should CMS believe it important to maintain these entities in AMP for the purposes of reducing manufacturer rebates, then an alternative would be to have monthly and quarterly rebates calculated differently. Monthly and quarterly AMP affords CMS the opportunity to use the monthly AMP to establish the Federal Upper Limit (FUL) in a way that would provide a more accurate reflection of tradition retail pharmacy purchasing (i.e. including only licensed pharmacies and excluding other entities such as PBMs) and maintain the CMS decision to reduce manufacturer rebate liabilities by the inclusion of the various non-pharmacy entities in the quarterly AMP reporting.

Reporting of AMP and FUL – Units of Measure

Manufacturers must report AMP information to CMS and CMS must relay this information to state Medicaid agencies monthly and quarterly. The value reported is a specific dollar amount per unit. States continue to encounter problems with the units used by manufacturers to report AMP information as they are not always in compliance with the National Council of Prescription Drug Programs (NCPDP) claiming standard. Medicaid agencies, like all other third party payers, are required to use the NCPDP standard units to pay claims and use these same units for Medicaid rebate invoicing. With changes to and AMP based FUL, it is important that the AMP match the NCPDP claiming standard.

The proposed rule should be amended to require manufacturers to report AMP and best price information and CMS to report the FUL using NCPDP standard units.

Reporting of FUL – Timeframe

CMS is required to "establish and issue listings that identify and set upper limits for multiple source drugs." In issuing FUL prices to state Medicaid agencies, CMS has traditionally made the FUL changes effective 30 days from the date on the notification letter from CMS. This timeframe typically makes it difficult for the state Medicaid agency to adequately notice pharmacy providers of the change. Additionally, pharmacy providers have to alter their inventory to make it economically feasible to dispense drugs under the FUL and the short notification period makes it difficult for them to do so.

The proposed rule should be amended to require CMS to provide a 60-day implementation timeframe for any changes to the FUL list of drugs.

FUL and Capitation Arrangements

The proposed rule indicates that the FUL also applies to payment for drugs "under prepaid capitation arrangements." This requirement appears to include capitation arrangements that state Medicaid agencies have with managed care organizations. Because the FUL can change frequently and managed care capitation arrangements are negotiated for longer periods of time, it will be difficult for state Medicaid agencies to comply with this provision.

The proposed rule should be amended to exclude capitation arrangements with health maintenance organizations, including managed care organizations, that contract under section 1903(m) of the Social Security Act. This is same as the exclusionary language used for the federal Medicaid rebate.

We appreciate the opportunity to provide input. If you have any questions, please do not hesitate to contact me at (916) 440-7800.

Sincerely,

Stan Rosenstein
Deputy Director
Medical Care Services

ACK H. EATON

GERALD GOLD

138

S. Bros Pharmacy Inc.

176 LEE AVENUE
BROOKLYN, N. Y. 11211
ULster 5-3070

02/20/07

Dear C.M.S.,

On July 1st 2007 Centers for MEDICARE & MEDICAID PLANS TO REIMBURSE GENERICS WITH FEDERAL UPPER LIMIT BASED ON AVERAGE MANUFACTURERS PRICE. INDEPENDANT PHARMACIES DO NOT HAVE ACCESS TO REBATES AND PRICE CONCESSIONS. WE WILL NOT BE ABLE TO PROVIDE OUR CUSTOMERS THESE PRESCRIPTIONS FOR GENERICS BELOW COST. RETAIL PHARMACY WILL GO UNDER WITH THE WEIGHT OF THE (GAO)s PLAN. WE ASK FOR A LEVEL PLAYING FIELD AND AN OPPORTUNITY TO SERVICE OUR COMMUNITIES AT A FAIR RETURN FOR OUR SERVICES. WE CANNOT ACCEPT THIS UNFAIR REIMBURSEMENT

THANK YOU

Mark

139

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH CARE FINANCING AND POLICY
1100 E. William Street, Suite 101
Carson City, Nevada 89701

JIM GIBBONS
Governor

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

February 21, 2007

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

Attention: CMS-2238-P

Re: Proposed Rule: Medicaid Program; Prescription Drugs

Dear Ms. Norwalk:

The Division of Health Care Financing and Policy respectfully submits this comment letter on behalf of Nevada Medicaid in regards to the Medicaid prescription drug benefit. These comments are for the proposed rule published in the December 22, 2006 Federal Register (71 FR 77174) for the Centers for Medicare and Medicaid Services (CMS). Nevada Medicaid supports the comments submitted by The American Public Human Services Association (APHSA) and National Association of State Medicaid Directors (NASMD).

Definitions- Section 447.502

Definition of Dispensing Fee
The proposed dispensing fee definition infers a specific methodology – that is a cost-based calculation not reflective of economies and competition in the marketplace. This is inconsistent with the intent of Congress and the administration to provide states' with the flexibility to set their own dispensing fee levels. In addition, it may result in Medicaid rates that are not representative of a marketplace in which other insurers consistently pay lower rates for ingredient costs and dispensing fees together than most Medicaid programs. States also have noted that the proposed definition allows payment of a dispensing fee each time a drug is dispensed, regardless of whether such dispensing is consistent with economical practices. States have identified situations where some pharmacies, sometimes colluding with prescribers, fraudulently split maintenance drug prescriptions to obtain additional dispensing fee payments. States request that CMS clarify the proposed definition so that it does not preclude states from preventing such behaviors.

Determination of AMP – Section 447.508
It is unclear at this time if there will be a negative effect on access to care due to the AMP-based FUL. We are requesting that CMS create an appeals process to assure providers who do not possess the influential buying power such as rural providers, may appeals the rates.

FFP: Conditions Relating to Physician Administered Drugs – Section 447.520

This proposed regulation would require National Drug Code collection on claims for all outpatient pharmaceuticals. CMS proposed rule had indicated that this would not be a significant impact for either physicians or hospitals. The impact for rural hospitals was unknown. This billing change would be a significant impact on a majority of both the hospitals and physician practices within the State of Nevada. A majority of the physician practices are considered small businesses. Of the fifty-seven (57) licensed hospital in the State of Nevada, 39 of them are considered rural hospitals with less than 100 beds.

The AMP regulation specifically excludes sales to inpatient hospitals that are delivered within the inpatient setting due to the purchasing mechanism. It is unclear why the outpatient pharmaceuticals is requiring NDC collection for rebates when the hospitals do not purchase their drugs differently based upon their outpatient pharmacy, ambulatory surgical centers, End Stage Renal Disease (ESRD) clinics or their inpatient services.

Nevada has been proactively modifying the current Medicaid Management Information System (MMIS) to accommodate the NDC number on both the CMS 1500 and the 837 transaction. The outpatient hospitals, ambulatory surgical centers and ESRD facilities utilize the UB-04. At this time there is not an allowable field for NDC collection on the UB-04. Until this field is defined system modifications will be delayed.

Nevada Medicaid does not have the resources required to successfully educate all physicians and hospitals on the NDC billing requirements. The NDC billing requirements are based upon the NCPDP format which is different than the current HCPC billing units. This discrepancy will cause inaccurate claim submission. As an outcome, the reimbursement to the providers may be negatively impacted. In addition, it will complicate the rebate reconciliation process.

We request clarification on how the NDC proposed regulation will impact the crossover billing for Medicaid dual eligibles. It is unclear how Medicaid will reimburse the required copay and deductibles for physician administered drugs with the new billing formats.

Hardship Waiver

CMS in previous conversations with States and in the proposed regulations indicated that there will not be any states requiring hardship waivers. Currently, Nevada Medicaid has placed all available programming for the MMIS and Point of Sale (POS) in

implementation for NPI and the new billing forms. In addition, without having CMS guidance as to the appropriate field for the UB-04, programming for NDC collection on UB-04 will not be feasible until this summer. For effective programming and quality assurance procedures it is unlikely that Nevada Medicaid will be operationally able to collect NDC for the UB-04 by January 1, 2008.

Thank you for the time to submit comments on this proposed regulation. Nevada Medicaid is willing to provide any additional information that you may need. We believe that the intent of the proposed regulations may be attained if there is a collaborative partnership with CMS and the Medicaid agencies to fully account for proper effective dates, State's operational procedures, and provider education.

Sincerely,

Charles Duarte, Administrator

140

Fairview Pharmacy
4480 Broadway, New York, NY 10040
(212) 567-3384

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

As an owner of an independent pharmacy store in New York City servicing a diverse Medicaid patient population for pharmacy care needs, I am very troubled by the CMS proposed regulation referenced above that seeks to define and establish an average manufacters' price (AMP) for generic prescriptions for the Medicaid program. This proposed rule has many problems that must be corrected in order to ensure that my independent pharmacy can afford to continue providing prescription services to Medicaid population without incurring unsustainable financial losses.

Below are my specific comments on and recommended changes to the proposed rule:

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.

Public Access Defines Retail Pharmacy Class of Trade

CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be "publicly accessible." Mail order facilities are operated almost exclusively by PBMs, (conflict of interest) and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in calculating the AMP.

"Retail pharmacy class of trade" definition should only include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

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

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

Treatment of Manufacturer coupons with regard to Best Price.

Inclusion of Direct-to-Patient Sales with regard to AMP.

AMP Must Differ From Best Price

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

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

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

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

PBM price concessions reporting to CMS.

PBM Transparency Necessary to Assess Manufacturer Rebates

PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.

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

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

AMP Must Be Reported Weekly

There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly rather than by using a 12 month rolling average.

Use of the 11-digit NDC to calculate AMP.

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

We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.

Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.

Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. **The 11-digit NDC must be used when calculating the FUL.**

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

Impact on small pharmacies demonstrated by (General Accountability Office (GAO) findings

The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.

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

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

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

CMS Must Employ a Complete Definition on Cost to Dispense

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

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

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

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

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

In summary, the proposed rule needs to be seriously revised and resubmitted for public comments in order to address the following issues:

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.
- To be an appropriate benchmark, AMP must be defined to reflect the actual cost paid by retail pharmacy. This will be accomplished by

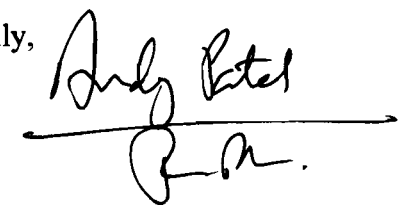
    1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.

    2. Excluding all mail order facilities and PBM pricing from AMP calculation. *Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.*

- Reporting AMP at the 11-digit NDC level to ensure accuracy.

Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,



Okeechobee Discount Drugs

203 Southwest Park Street
Okeechobee, Florida 34972

February 14, 2007

Centers for Medicare & Medicaid Services
Dept of Health & Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

Dear Ms. Leslie V. Norwalk, ESQ:

This letter is for the purpose of supporting and identifying with the sentiments set forth in a letter sent to you by Jon Copeland. I am the owner of two independent pharmacies in a rural community in southern Florida. My intent with this letter is to emphasize Mr. Copeland's assertion that if CMS and the legislature put these new programs into place independent pharmacies will cease to exist. This may not be something that happens immediately but the eradication of the independent pharmacy/pharmacist will soon follow. I cannot speak for others but I ask you to make sure the final ruling is a responsible ruling allowing for the co-existence of independent and chain pharmacies alike.

Thank your for your responsible consideration to this matter.

Sincerely,

Steven D. Nelson, RPH
Pharmacist and Owner
Okeechobee Discount Drugs

142

FEB 20 2007

4:45pm
ok to hand write
+1 ml per Veronica
+ the stamp broken

Walgreens
The Pharmacy America Trusts

Government and Community Relations Department

February 20, 2007

20

VIA ELECTRONIC SUBMISSION

Centers for Medicare and Medicaid Services
Department of Health and Human 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 Sir or Madam:

Walgreen Co. ("Walgreens") appreciates the opportunity to comment on Proposed Rule CMS-2238-P published in the *Federal Register* on December 22, 2006, which concerns the definition and use of "Average Manufacturers Price" ("AMP"), as well as the new federal upper limits (FUL) program for generic drugs in the Medicaid program pursuant to changes mandated by the Deficit Reduction Act of 2005 ("DRA"). Walgreens is the nation's leading community pharmacy, with more than 5,600 pharmacies in the 48 contiguous states and the Commonwealth of Puerto Rico. We employ more than 200,000 people, including more than 20,000 pharmacists, and we fill in excess of 529 million prescriptions each year. Walgreens participates in the Medicaid programs in each state in which we operate, providing critical access to pharmacy services to millions of Medicaid beneficiaries, many who live in medically underserved areas.

Walgreens is a proud member of the National Association of Chain Drug Stores ("NACDS") and we join, in their entirety and without reservation, their detailed comments submitted on this topic. We are writing separately to reiterate and amplify their comments.

We ask that CMS address the following critical issues for our industry, both through modifications to the proposed regulation, as well as through changes to the proposed timeline for the release and use of AMP data.

SUMMARY

Public Release and All Use of AMP Data Should be Delayed

CMS should not post any AMP data on a public website before CMS finalizes its regulation with a clear, validated definition of AMP that accurately reflects the prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies.

CMS acknowledges that present AMP data are flawed, yet CMS indicates it will publish these data on a public website this spring. Release of flawed AMP data will adversely affect community retail pharmacies if Medicaid programs and the commercial market use these data for reimbursement purposes. Because of its inherent flaws, CMS has already delayed release of this data, and we urge continued delay in the release of AMP data until a final definition of AMP has been promulgated and data collected and verified pursuant to it.

Moreover, CMS has already released existing, flawed AMP data to Medicaid programs and indicated its intent to recalculate federal upper limits ("FULs") using this data in the spring. It is imperative that CMS not use this flawed data to recalculate FULs and that CMS instruct state Medicaid programs not to use this flawed AMP data for purposes of determining pharmacy reimbursement.

AMP data should not be publicly released or used at all as a pharmacy reimbursement metric until CMS has (1) promulgated a final rule that appropriately defines AMP to reflect retail pharmacy purchasing costs and (2) collected and verified data submitted by pharmaceutical manufacturers according to that rule.

AMP Definition Should be Revised to Reflect Retail Pharmacy Purchasing Costs

CMS's proposed regulatory definition of AMP is problematic because it would result in AMP values that would not reflect the approximate prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs distributed to traditional community retail pharmacies should be included in the AMP definition.

Most troublingly, the proposed definition of AMP provides for the inclusion of PBM rebates and discounts in the calculation of AMP. Because retail pharmacies do not benefit from these rebates and discounts -- indeed such amounts are passed on to the PBM's clients, if to anyone, and in no way accrue to the benefit of retail pharmacies -- AMPs calculated with these amounts included will not approximate the drug acquisition costs of traditional retail pharmacies. Accordingly, the proposed definition of AMP should be revised to exclude PBM discounts and rebates.

The proposed rule also includes in the definition of AMP sales to mail order pharmacies, nursing home pharmacies, hospital outpatient facilities, and clinics, as well as manufacturers' coupons sales. Traditional retail pharmacies do not have access to the special prices offered to these classes of trade. Accordingly, because these are not sales within the retail class of trade, they should be excluded from the calculation of AMP.

CMS must also address how to account for the potential lag between the time the manufacturer calculates the AMP data and the time it is posted on a website or provided to states. Without an adjustment to AMP, the posted AMPs may be outdated and may not reflect the existing prices at which retail pharmacies purchase medications.

FULs Should Be Calculated on the Basis of the Weighted Average of Reported AMPs for a Particular Drug Entity

CMS's proposal to use the lowest reported AMP for a particular drug entity in setting the federal upper limit (FUL) for that drug entity is not required by the DRA. A recent report from the Government Accountability Office ("GAO") found that pharmacies would be reimbursed, on average, 36% less for generics than their acquisition costs under the AMP-based FUL system proposed by CMS. Such a reimbursement system will threaten the viability of the network of pharmacies that service Medicaid patients.

In place of the lowest reported AMP, we believe that in determining FULs CMS should use a weighted average of the 11-digit AMPs for generic products that are: (1) AB-rated in the FDA Orange Book, (2) widely and nationally available to pharmacies for purchase from the three major national wholesalers in adequate and consistent supplies, and (3) sold in package sizes of 100s (or the most commonly dispensed package size). In addition, CMS must include an appeals mechanism in the final regulation which would allow providers, manufacturers and states an opportunity to seek removal or modification of an FUL which is not consistent with rapidly-changing market conditions.

States Need to Increase Pharmacy Professional Dispensing Fees

CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset anticipated losses on generic drug reimbursement. Pharmacists are on the front line of the nation's health care delivery system, and the professional counseling services that they provide can often make the difference between a completely successful treatment and a less than optimal outcome. According, pharmacy dispensing fees should be increased to cover a pharmacy's true cost of dispensing, including these critical professional services and a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies will have reduced incentives to dispense lower-cost generic drugs.

DETAILED COMMENTS

Background

I. Calculation and Reporting of AMP

In order for AMPs properly to be used as a metric for determining retail pharmacy reimbursement they must reliably reflect pharmacy drug acquisition costs actually realized by retail pharmacies. The proposed rule fails to accomplish this goal by including in the calculation of AMP certain rebate payments, price concessions and class of trade pricing that are not

available to or realized by retail pharmacies. Prior to using AMP data as a reimbursement metric we urge CMS to correct these deficiencies.

Specifically, § 447.504(g)(6), § 447.504(g)(9) and § 447.504(g)(10) would, respectively, allow manufacturers to deduct "rebates, discounts or other price concessions to PBMs associated with the sales for drugs provided to the retail pharmacy class of trade;" "sales to mail order pharmacies;" and "rebates, discounts, or other price concessions...associated with sales of drugs provided to the retail class of trade." Stated simply and directly -- there is no basis in the statute, nor in the congressional discussion surrounding its enactment, to have manufacturers include these amounts in the calculation of AMP. Had Congress wanted to do so, it would have expressly provided for these items to be included in AMP, as it had done in establishing the Average-Selling Price-based reimbursement system for Medicare Part B drugs.

Moreover, there is a significant difference between requiring manufacturers to deduct rebates and price concessions that are realized by the retail pharmacy class of trade as compared to those that are associated with the retail class of trade. Many of the manufacturer price concessions that may be associated with the retail class of trade are not realized in any way by the retail class of trade, *i.e.*, traditional community retail pharmacies. Therefore, CMS has proposed to adopt an overly expansive definition of the retail class of trade and the amounts that should be included when calculating an AMP for the retail class of trade. Finally, because AMP is calculated based on prices paid to manufacturers by wholesalers, and none of these rebates and price reductions are part of the payments made by wholesalers to manufacturers, they cannot be included in the calculation of AMP.

a. Rebates Paid by Manufacturers to PBMs Must be Excluded from the Calculation of AMP

There is wide documentation in government agency reports (by both the Department of Health and Human Services Office of Inspector General ("OIG") and the GAO) that manufacturers have not been consistent in how they have handled PBM rebates in the calculation of AMPs since they were created as the basis for manufacturer rebates under the Omnibus Budget Reconciliation Act of 1990. According to these reports, some have included, excluded or only partially included rebates paid by them to PBMs and health plans. *See* GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States, 2005 (GAO-05-102). In response to this confusion, CMS issued a Medicaid drug rebate program labeler release in April 1997 that attempted to clarify how these PBM rebates should be handled both in the calculation of a drug's "best price" as well as it's AMP. CMS Manufacturer Labeler Release # 28, April 1997. In that release, CMS stated that: "Drug prices to PBMs have no effect on the AMP calculation unless the PBM is acting as a wholesaler."

The proposed regulation would suddenly change this policy by requiring that drug prices to PBMs, which heretofore have only been included where the PBM was acting as a wholesaler, be included in the calculation of the AMP. In addition, and most disturbing, is the proposed inclusion of "discounts, rebates or other price concessions to PBMs associated with the sales for drugs provided to the retail pharmacy class of trade." Proposed § 447.504(g)(6).

Today most prescriptions are paid for through a third party entity -- such as a PBM -- that receives rebates and other payments from pharmaceutical companies. These rebates and other payments, which include payments such as market share movement payments and formulary placement discounts, are not available to traditional retail pharmacies. These payments and discounts are either retained by the PBM or passed through, in whole or part, by the PBM to the payer -- the PBM's client. Manufacturers should not deduct these amounts when calculating AMPs because retail pharmacies do not receive these payments or discounts nor do they benefit from them in any way.

Including PBM rebates and payments unfairly lowers the AMP, making it unreflective of sales to retail pharmacies. This fact was confirmed by a recent Congressional Budget Office ("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." CBO Paper, Prescription Drug Pricing in the Private Sector, Congressional Budget Office, 2007 (Publication No. 2703). The report also said that "conventional retail outlets generally do not receive rebates for single source drugs." Therefore, including these rebates would lower the AMP for traditional retail pharmacies below their approximate acquisition costs. It is immaterial whether the PBM that receives the rebates passes through some or all of these rebates to the plan sponsor. These rebates ultimately do not affect the prices paid by retail pharmacies for prescription medications.

b. Sales to Mail Order Pharmacies and Nursing Homes Must be Excluded from the Calculation of AMP

We believe that CMS has made the correct decision in the proposed regulation to remove "sales to nursing facilities, including long term care pharmacies" from the calculation of AMP. Sales to these entities are not sales to the retail class of trade. Proposed § 447.504(h)(6). However, CMS has improvidently proposed that manufacturers should include sales of pharmaceuticals to mail order pharmacies (and sales to wholesalers that are eventually sold to mail order pharmacies) in the calculation of AMP. Proposed §§ 447.504(g)(1) & (9). Sales to and for mail order pharmacies should be excluded from the calculation of AMP for the same reasons that sales to or for nursing homes are excluded – they are not sales to the retail class of trade.

In justifying its decision to excluded nursing home sales, CMS correctly indicates that long term care pharmacies do not generally dispense prescriptions to the general public. Because their sales are limited to patients of their facilities, sales to nursing homes should be excluded from the calculation of the AMP. However, CMS concludes that it considers mail order "simply another form of how drugs enter into the retail pharmacy class of trade". This is simply wrong. The same logic used to exclude nursing home sales applies with equal force to mail order pharmacies. Mail order pharmacies are not generally "open to the public" like most traditional retail pharmacies. Individuals cannot "walk into" a mail order pharmacy to obtain a prescription, and there is limited ability for patients to obtain a prescription from a mail order pharmacy unless they belong to a health care plan that includes mail order as part of its benefit design. Moreover, given that there is extremely limited distribution of prescription drugs to Medicaid recipients

through the mail, it is not reasonable to include these prices, or associated rebates, in the calculation of AMP.

CMS indicates in the proposed rule that, in directing manufacturers in the calculation of AMP, it "considered limiting mail order pharmacy prices to only those prices that are offered to all pharmacies under the same terms and conditions." 71 Fed. Reg. at 77179. Through this statement, CMS explicitly recognizes that there are different prices available to different purchasers in the marketplace. And, in fact, the discounts for brand name drugs provided to mail order pharmacies generally are not available to retail pharmacies.

Indeed, CMS recognizes that retail pharmacies may be disadvantaged by inclusion of these sales in the calculation of AMP when its states that "retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for manufacturer price concessions". 71 Fed. Reg. at 77178. Thus, CMS itself makes the argument as to why sales to mail order pharmacies should be excluded from the calculation of the AMP: Inclusion of these sales and rebates -- which are not available to traditional retail pharmacies -- would result in an AMP that is not reflective of the prices paid by traditional retail pharmacies.

c. AMP Must Include Only Sales, Rebates, Discounts and Price Concessions Actually Realized by Retail Pharmacies

Since 1990, federal law has defined AMP, with respect to a covered outpatient drug, as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1). A change made by DRA, requires manufacturers to calculate AMP without regard to customary prompt pay discounts extended to wholesalers beginning on January 1, 2007. The proposed rule fails properly to implement each of these requirements. Specifically, it (1) fails properly to define the "retail class of trade," (2) fails properly to define sales "to" the retail class of trade, and (3) fails properly to define amounts paid by "wholesalers".

i. Proposed Rule Fails Properly to Define Retail Class of Trade

In proposed § 447.504(e), CMS attempts to define the retail class of trade. In the proposed regulation, CMS has adopted an overly expansive definition of "retail class of trade". The definition proposes to include "any outlet that purchases or arranges for the purchase of drugs from a manufacturer, wholesalers, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public". Overall, the proposed regulatory definition of AMP does not achieve the goal of giving Medicaid and other payers a benchmark that accurately reflects the "true market price for prescription drugs" paid for by retail pharmacies.

CMS itself indicates that "while there is no requirement that States use AMPs to set payment amounts, we believe that Congress intended that States have drug pricing data based on actual prices, in contrast to previously available data that did not necessarily reflect actual manufacturer prices to the retail pharmacy class of trade". 71 Fed. Reg. 77178 (emphasis added). State Medicaid programs pay traditional retail pharmacies for the overwhelming majority of drugs provided to Medicaid recipients. Therefore, it stands to reason that providing states with

"drug pricing data based on actual prices" would logically require AMPs based on prices paid by traditional retail pharmacies.

With respect to the retail class of trade, only manufacturers' sales to wholesalers for products that are ultimately sold to traditional community retail pharmacies – traditional chain pharmacies, independent pharmacies, mass merchandise pharmacies, and supermarket pharmacies – should be included in the calculation of AMP. These are the only entities that should be considered to be the "retail class of trade".

This approach would be consistent with congressional intent when AMP was developed in the Omnibus Budget Reconciliation Act (OBRA) 90. It would also be consistent with the intent of DRA to make AMP an approximation of the prices that retail pharmacies pay for medications so that it could be used as another potential reimbursement benchmark. The pharmaceutical market has changed significantly since 1990, but the fact still remains that AMP was created to approximate the revenues received by manufacturers for drugs dispensed to Medicaid recipients so that a basis could be established for the calculation of rebates. Given that almost all fee-for-service Medicaid prescriptions are dispensed by retail pharmacies, it makes sense that the AMP reflect the revenues received by manufacturers from wholesalers for drugs sold to retail pharmacies.

CMS's definition of retail pharmacy in this proposed regulation is inconsistent with that used in the Medicare Part D final rule. In the final rule implementing the Medicare Part D prescription drug benefit program, the agency defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy". 42 CFR § 423.100. Thus, it would be consistent with CMS's current Part D definition of "retail pharmacy" for the agency to indicate that only sales to true retail pharmacies represent the "retail class of trade" for the purpose of calculating the AMP.

Moreover, as early as 1997, in studies of drug acquisition costs the Department of Health and Human Services—Office of Inspector General ("OIG") considered the retail pharmacy class of trade as only independent and chain pharmacies that sold drugs directly to the public. *See* OIG, Medicaid Pharmacy: Actual Acquisition Cost of Generic Prescription Drug Products, 1997 (A-06-97-00011); OIG, Medicaid Pharmacy: Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs, 1997 (A-06-97-00030). More recently, the OIG has recommended that CMS ask the manufacturer to exclude from the calculation of AMP transactions that the OIG determined were to non-retail entities such as mail order pharmacies, nursing home pharmacies, independent practice associations, and clinics. *See* Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States; February 2005. It is clear that the OIG has recognized that the definition of retail class of trade should not be as expansive as recommended by CMS.

ii. Proposed Rule Fails Properly to Define Sales "To" the Retail Class of Trade

Sales to Other Outpatient Channels. Sales to hospitals and outpatient clinics should be omitted from the calculation of AMP because these entities do not fall within the definition of a traditional retail pharmacy. Direct sales to patients through entities such as specialty pharmacies should also not be included in AMP because the entities that arrange for these sales do not conform to a traditional definition of wholesaler. Only sales to wholesalers for drugs distributed to traditional retail pharmacies can be included in the definition.

Patient Assistance Programs. The proposed regulation would include in the AMP "manufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail class of trade." These coupons might refer to manufacturer promotional programs where the manufacturer provides a certain discount off the price of the medication to a patient. If the coupon is used by the patient but redeemed by the pharmacy, CMS would appear to require manufacturers to include those sales in AMP.

Similarly, there are many patient assistance programs where the pharmacy fills a prescription based on a coupon that the manufacturer provides to the physician, where the patient redeems these coupons at the pharmacy. The manufacturer reimburses the pharmacy for the drug that was dispensed, so in theory the manufacturer receives no revenue from the sales of those drugs. Deducting these sales from the AMP (essentially recording a $0 sales for these drugs), but including the units sold in the AMP, would further lower the per-unit amount received by the manufacturer.

However including these sales has nothing to do with the price paid by the wholesaler or the pharmacy, and would inappropriately lower the AMP. For this reason, drugs provided to patients through manufacturer assistance programs should not be included in the AMP. These items cannot by law be included in the AMP because they do not reflect prices paid by wholesalers to manufacturers for drugs distributed to the retail class of trade.

Medicare and Related Programs. Proposed § 447.504(g)(12) would require manufacturers to include sales and associated rebates, discounts and other price concessions under the Medicare Part D, Medicare Advantage Prescription Drug Program, SCHIP program, SPAP programs and Medicaid programs, other then rebates provided under Section 1927. Manufacturers do not sell drugs to these programs directly. They sell drugs to wholesalers who sell to retail pharmacies that dispense these drugs to enrollees of these programs. Retail pharmacies are then paid by these entities for the drugs they dispense.

Thus, manufacturers' sales of drugs to wholesalers that are sold to retail pharmacies would already include drugs that are dispensed to enrollees of these programs. However, including the rebates and discounts manufacturers provide to these programs would be inappropriate because retail pharmacies do not benefit from these discounts and rebates. Moreover, there are several different types of MA-PD programs including staff model HMOs and regional PPOs. Including sales of drugs to HMOs is explicitly proposed to be excluded from the calculation of AMP under proposed § 447.504(h)(5).

iii. Proposed Rule Fails Properly to Define Wholesaler

Proposed § 447.504(f) attempts to define wholesaler. Wholesaler is defined as "any entity (including a pharmacy, chain of pharmacies, or PBM) to which the manufacturer sells, or arranges for the sale of, the covered outpatient drugs, but that does not relabel or repackage the covered outpatient drug". The proposed definition of wholesaler is overly broad and inconsistent with other Federal and state statutes that define wholesalers.

We note initially that pharmacies, chains of pharmacies and PBMs are inappropriately included in the definition of wholesaler. Pharmacies -- both chains and independents -- are licensed by states as retail pharmacies, not as wholesalers. And PBMs, if they are licensed at all, are regulated by state insurance departments. Drug "wholesaler" does exist as a state licensure category, but it simply does not, and should not, apply to pharmacies and PBMs as those entities do not carry out the functions of wholesalers.

For example, according to the National Association of Boards of Pharmacy ("NABP"), "Wholesale Distribution":

" means the Distribution of Prescription Drugs or Devices by Wholesale Distributors to Persons other than consumers or patients, and includes the transfer of Prescription Drugs by a Pharmacy to another Pharmacy if the value of the goods transferred exceeds five percent (5%) of total Prescription Drug sales revenue of either the transferor or transferee Pharmacy during any consecutive twelve (12)-month period. "

NABP goes on to say that "Wholesale Distribution" does not include:

- The sale, purchase, or trade of a Prescription Drug or Device, an offer to sell, purchase, or trade a Prescription Drug or Device, or the Dispensing of a Prescription Drug or Device pursuant to a Prescription;
- The sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device for Emergency Medical Reasons;
- Intracompany Transactions, unless in violation of own use provisions;
- The sale, purchase, or trade of a Prescription Drug or Device or an offer to sell, purchase, or trade a Prescription Drug or Device among hospitals, Chain Pharmacy Warehouses, Pharmacies, or other health care entities that are under common control;
- The sale, purchase, or trade of a Prescription Drug or Device or the offer to sell, purchase, or trade a Prescription Drug or Device by a charitable organization described in 503(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- The purchase or other acquisition by a hospital or other similar health care entity that is a member of a group purchasing organization of a Prescription Drug or Device for its own use from the group purchasing organization or from other hospitals or similar health care entities that are members of these organizations;
- The transfer of Prescription Drugs or Devices between Pharmacies pursuant to a Centralized Prescription Processing agreement;
- The sale, purchase, or trade of blood and blood components intended for transfusion;

- The return of recalled, expired, damaged, or otherwise non-salable Prescription Drugs, when conducted by a hospital, health care entity, Pharmacy, or charitable institution in accordance with the Board's regulations; or
- The sale, transfer, merger, or consolidation of all or part of the business of a retail Pharmacy or Pharmacies from or with another retail Pharmacy or Pharmacies, whether accomplished as a purchase and sale of stock or business assets, in accordance with the Board's regulations.

Based on this NABP definition, it is clear that wholesale services are distinct from any services offered by retail pharmacies or PBMs. Accordingly, those entities should be excluded from the definition of "wholesaler" in the final rule.

Indeed, it is especially clear that PBMs do not perform any wholesaling functions. In fact, most PBMs are not entities that handle drugs in any way -- they are administrative service organizations that contract with health plans and other entities to provide prescription drug benefits. PBMs that own mail order operations may obtain their drugs from wholesalers or may obtain them directly from manufacturers, but they do not perform traditional wholesaling functions in either case. Thus, PBMs should be excluded from the definition of "wholesaler."

We urge CMS to adopt an appropriately limited and realistic definition of pharmaceutical wholesaler that is more consistent with the intent of the law by drawing on existing Federal and state definitions of wholesaler:

- The Federal Food, Drug and Cosmetic Act defines wholesale distributor as any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.
- Under the PDMA regulations, wholesale distributor means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.[1]

To the extent that chain pharmacy distribution centers are licensed as wholesalers in the states in which they are located, such locations may appropriately be included in the definition of "wholesaler". *See* Note 1. Chain pharmacy distribution centers typically are eligible for the same customary prompt payment discounts as traditional pharmaceutical wholesalers. We urge CMS to clarify that customary prompt payment discounts that apply to sales to chain pharmacy distribution centers be excluded from the definition of AMP, consistent with the statutory requirement that all prompt pay discounts are excluded from such calculation.

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[1] We do not object that warehousing pharmacy chains, mass merchants and supermarkets be treated as wholesalers only with respect to, and to the extent of, direct sales of drugs to specific locations owned by such entities that are licensed as wholesalers. We do object, however, to the inclusion of individual pharmacies of any sort within the definition of "wholesaler."

d. Other Issues Concerning Calculation of AMP.

i. AMP Data Should be Smoothed

CMS should require manufacturers to "smooth" any discounts or rebates that are passed through to retail pharmacies over a rolling 12-month period. This will help reduce the potential for any significant fluctuations in AMP from quarterly and monthly calculations, and maintain some consistency in reimbursement levels. Such a process was developed by CMS for manufacturer's calculation of the Average Selling Price ("ASP"), which is used as the basis for Medicare Part B drug reimbursement. Without such smoothing, it is very possible that upper limits for generics could be based on AMPs that simply are not reflective of the current market prices for drugs, further reducing generic dispensing incentives.

A recent GAO report confirmed that AMPs for generic drugs can fluctuate widely from quarter to quarter. GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, 2006 (GAO-07-239R). The study calls into question the credibility and reliability of AMP as a benchmark for generic reimbursement. These conclusions are based on the fact that GAO found that 66 of the 77 drugs examined (almost 85%) had significant variation in their lowest AMP between the first and second quarters of 2006. For example, 30 of the 77 drugs -- or almost 40% of the drugs -- had a decrease in their lowest AMP, averaging 33%. Fluctuations in AMP are concerning to pharmacies because their reimbursement would similarly fluctuate, which may not reflect similar variation in their own acquisition costs.

In the proposed rule, CMS is allowing manufacturers to "estimate the impact of its end-of-quarter discounts and allocate these discounts in the monthly AMPs reported to CMS throughout the rebate period". 71 Fed. Reg. at 77186. We believe that a much better process would be to require manufacturers to calculate the impact of these discounts based on a rolling 12-month average, rather than allowing manufacturers to simply estimate what these discounts might be in order to make its monthly AMP calculation. The process described in the regulation seems arbitrary as compared to the smoothing process used by manufacturers to determine the impact of their discounts when calculating ASP.

ii. Clarify Terms Relative to Sales, Rebates Discounts and Other Price Concessions Excluded from the Calculation of the AMP

Bona Fide Service Fees: We strongly support the proposal that bona fide service fees should be excluded from the calculation of AMP, especially where those fees are not ultimately passed through to the product's ultimate purchaser. A bona fide service fee pays for a bona fide service, so it does not reduce its cost of purchasing the drug. Accordingly, they are appropriately excluded from the calculation of AMP.

We do not support any attempt to list specific bona fide service fees in the final regulation. This will allow for future flexibility and innovations to occur in a highly competitive marketplace. Manufacturers rely on wholesalers and others to perform various functions to allow

their products to come to market in a safe and effective manner. A significant number of new biological products are likely to come to market over the next few years. For that reason, it is unclear as to what types of new services will be needed to be performed by wholesalers and chain pharmacy warehouses on behalf of manufacturers to assure that their products get to the ultimate purchaser for dispensing or administration to the ultimate user.

Having said this, we believe that the preamble to the final rule should provide examples of the types of bona fide service fee payments that would be acceptable for exclusion from the AMP calculation at this time. For example, as example of bona fide service fees, payments made by manufacturers to entities such as wholesalers and pharmacies acting as wholesalers for inventory management agreements or distribution service agreements should not be deducted from a manufacturer's sales when calculating AMP. These payments do not lower the cost of purchasing prescription drugs. Moreover, not all purchasers are able to participate in these agreements, so deducting them when calculating ASP would be unfair to some smaller purchasers.

In addition, pharmacies sometimes receive payments from manufacturers for performing certain patient care programs, such as patient education and compliance and persistency programs. These payments should be omitted from the AMP calculation because they do not reflect prices paid by wholesalers for drug products. These services provide valuable benefits to patients and the health care system because they improve patients' understanding of their medications and enhance patient compliance. They do not reduce the retail pharmacy's cost of purchasing the drugs.

If these payments are included in AMP, pharmacies would not have incentives to conduct these programs because it would reduce the value of the AMP, thus potentially reducing reimbursement. This could make it appear that the pharmacy's acquisition cost for the drug is lower than it actually is. Moreover, since not all pharmacies participate in these programs, it would be unfair to include these payments in the AMP.

Definition of Return Goods. Proposed § 447.504(h)(13) would allow manufacturers to omit from the AMP "returned goods when returned in good faith." Although we applaud CMS's willingness to exclude returned goods from the calculation of AMP when returned in good faith, the additional condition that the return must be made "pursuant to manufacturer policies" does not take into consideration that negotiated return goods policies exist between manufacturers and retail pharmacies.

We urge that the return goods exclusion be interpreted in such as manner as to exclude from the AMP calculation amounts based on "a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, which is designed to reimburse pharmacies for the replacement cost of product as well as the associated return related expenses and not designed to manipulate or artificially inflate or deflate the AMP".

These negotiated return goods policies take into consideration the unique burdens which retail pharmacies must absorb in order to effectuate the efficient return of expired pharmaceutical

products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from the calculation of AMP, CMS is voiding by default these negotiated return goods policies (which were negotiated in good faith between manufacturers and retailers) and could be forcing retailers to accept manufacturers' policies and their inherent deficiencies.

Such action ignores the fact that retailers absorb considerable cost through replacement value of returns, inventory carrying cost, reverse logistics cost, and administrative expense. In order to remedy this imbalance, returned goods made in good faith and pursuant to a commercial agreement, written or otherwise, between a manufacturer and a purchaser of its product, including wholesalers and pharmacies, must also be excluded from the calculation of AMP.

Definition of Manufacturer: We recommend that the definition of manufacturer, found at proposed § 447.502, be narrowed such that entities that repackage drugs simply for distribution to retail pharmacies – also known as retail pharmacy service repackagers – not be considered manufacturers. These entities should not be responsible for signing rebate agreements with the Secretary of HHS, or paying the rebates to Medicaid because these repackagers simply perform a function for thousands of retail pharmacies, *i.e.* preparing dispensing quantities in a highly efficient manner, that would otherwise have to be performed individually by retail pharmacies.

Requiring that these entities act like manufacturers, obtain NDC numbers, and sign rebate agreements would likely result in their elimination. That is because these repackagers are low-margin businesses, who could not afford to pay the rebates. Thus, the proposed definition of manufacturer should be revised to reflect an exemption for "retail pharmacy service repackagers" who purchase drugs from the manufacturer solely for the purpose of repackaging in unit of use quantities for dispensing by community retail pharmacies.

iii. Prohibit Restatements of Monthly AMP

The proposed rule at § 447.510(d) implements DRA requirements relating to new monthly reporting of AMP by manufacturers. Specifically, manufacturers must report AMP not later than 30 days after each month, including an estimate of rebates or other price concessions that should be included in that month's AMP calculation. In calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary. We support the prohibition on the ability of manufacturers to restate monthly AMP data, but are concerned that incorrect estimates of potential liabilities, *e.g.*, chargebacks, rebates, could inappropriately reduce AMP.

Under proposed § 447.510(b), "a manufacturer must report to CMS revisions to AMP... for a period not to exceed 12 quarters from the quarter in which the data were due." We understand that the regulation would continue to require that manufacturers calculate AMPs on a quarterly basis for rebate purposes, and that these retroactive adjustments only apply to quarterly AMPs reported for rebate purposes, not monthly AMPs. Monthly AMPs will be used for reimbursement purposes.

We are concerned about whether a manufacturer's restatement of AMP could affect the reimbursement amounts already paid to pharmacies by Medicaid. If an AMP value is

recalculated by a manufacturer after the time that it is reported to the states by CMS, these restatements should not be used as the basis for reducing the reimbursements already paid. Restating AMPs could cause significant disruption to pharmacies, as recoupment activities are generally extremely time consuming, labor intensive, and frankly unfair. We believe that CMS should only allow restatements for quarterly-reported AMPs rather than monthly-reported AMPs. This appears to be the case, given that the proposed rule at § 447.510(d)(3) indicates that "in calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary". We request explicit clarification of this point in the final rule.

We are concerned that proposed § 447.510(d)(2) would allow manufacturers, when calculating monthly AMPs, to "estimate the impact of its end of quarter discounts and allocate these discounts in the monthly AMPs reported to CMS". This seems like an arbitrary way for manufacturers to calculate its monthly AMPs, and could be subject to manipulation. Manufacturers have a vested interested in maintaining low AMPs, while retail pharmacies want these AMPs to approximate pharmacy acquisition costs.

Moreover, this approach would not appear to be as auditable as a process that would require that the manufacturers smooth their data in a 12-month rolling average of all discounts and rebates given. This approach is similar to that used for Medicare Part B ASP calculation, although it is done on a quarterly basis for ASP. Nevertheless, the proposed rule seems to develop an arbitrary manner for manufacturers to determine the amount of rebates and discounts that should be deducted from their monthly AMPs, given that there exist other more credible and auditable approaches that would result in potentially more accurate AMPs.

iv. Adjust AMPs to Reflect Lag in Data Reported

We are concerned that, even though AMPs will be reported monthly by manufacturers, the AMPs will still be inaccurate compared to current retail pharmacy purchasing costs because of the reporting delay. Manufacturers have 30 days after the end of each month to report their AMPs. Currently, changes in AWP and WAC -- the existing reimbursement benchmarks -- are passed through from the manufacturer to the ultimate payer within 24 hours, as a result of electronic feeds that re-adjust all pricing when a manufacturer price increase occurs. This assures that pharmacies are being paid consistent with their current purchasing costs for medications.

Under the proposed rule, the monthly AMP reported to CMS is already 30 days old, and this AMP must then still be reported by CMS to States and posted on a public web site. Thus, by the time AMP is posted publicly and available to be used for reimbursement purposes, it will be outdated by at least 60 days. This is of particular concern when manufacturer price changes are announced and implemented immediately. There may be various ways to try to mitigate this impact, such as building in a cushion for price increases and inflation generally, since the impact on a drug-by-drug basis could be significant.

We are concerned that this timing issue has not yet been addressed or even sufficiently recognized and appreciated, and believe that CMS should address it directly and in detail before states and others are encouraged to use AMP as a reimbursement benchmark. One way to do this

is to compare the AMPs for brand name drugs to the WACs, given that this published benchmark does approximate retail pharmacy acquisition costs for brand name drugs.

This was recently confirmed by a CBO study that said "...for single source brand name drugs, WAC approximates what retail pharmacies pay wholesalers." CMS should not publish any AMPs that do not approximate the WAC for a brand name drug.

v. Clarify that Sales to Puerto Rico are Excluded from AMP

Required pharmaceutical pricing under certain public health programs within the Commonwealth of Puerto Rico creates a form of price control that results in certain pharmaceutical sales significantly below market prices obtained in the 50 states. Including sales within Puerto Rico would, as a result, deflate AMP so that it would not accurately effect acquisition costs for retail pharmacies serving the various state Medicaid programs. We request the CMS clarify that sales within Puerto Rico are excluded from the calculation of AMP.

vi. Authorized Generic Drugs

Proposed § 447.506 describes new DRA requirements relating to authorized generics. Specifically, proposed § 447.506(b) would require a manufacturer holding title to the original NDA of the authorized generic to include the direct and indirect sales of this drug in its AMP. The inclusion of the AMP of the authorized generic in the calculation of the originator manufacturer's AMP may be required under DRA. However, manufacturers should be required to report separate AMPs for the originator product and the authorized generic version, and these are the AMPs that should be posted on the public website.

If the AMP for the originator brand name product and authorized generic are averaged together, the AMP value for the originator brand product may be lower than the pharmacy's acquisition cost for the product. While CMS may allow the manufacturer of the originator drug to pay its rebate based on the blended AMP, it is not fair to use this blended AMP to potentially underpay pharmacies for the dispensing of the originator drug when prescribed by the physician.

II. Release and Use of AMP Data

a. Continue to Delay Public Release of the AMP Data

The preamble to the proposed regulation indicates that CMS will release AMP data sometime this spring. CMS should not post any AMP data on a public website until such time as a final AMP definition reflects the approximate prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies, and that these prices have been validated to be accurate. The release and use of flawed AMP data will have a negative impact on patient access, if the resulting reimbursement rates are so inadequate that pharmacies simply may not be able to afford participation in Medicaid or other programs. It is in the interests of all relevant parties – patients, payers and providers – to postpone use and disclosure of AMPs until such time as CMS finalizes a regulatory definition of AMPs, and that definition approximate retail pharmacies purchasing costs.

Previously, CMS prudently recognized that AMPs should not be disclosed until they are properly defined. In announcing that CMS would postpone the AMP website last May, CMS Administrator McClellan stated that "CMS will not publicly release the current AMP figures. They just aren't the right numbers to use." The Administrator added that: "Instead, we are focusing our efforts on developing a proposed regulation that will assure an accurate and effective AMP calculation ahead of implementation of the drug payment reforms." Remarks of Mark B. McClellan, NCPA 38th Legislation and Government Conference (May 22, 2006)(emphasis added). CMS should not now reverse course and use AMPs before they are properly defined and determined to be accurate.

The AMP data that CMS would propose to release this spring are no better than the AMP data that CMS refused to release last year. While DRA made some modest changes to the calculation of the AMP, there would still be wide-ranging documented inconsistencies in the data which would render them useless to states and potentially damaging to retail pharmacies. For example, the OIG has repeatedly concluded that AMPs, as currently calculated, are flawed. GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid To States, 2005 (GAO-05-102) (reviewing several OIG reports on the limitations of current AMP).

The OIG recently reported to CMS that "existing requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent". The OIG added that "because the DRA expands the use of AMPs and creates new reimbursement policy implications, future errors or inconsistencies in manufacturers' AMP calculations could lead to inaccurate or inappropriate reimbursement amounts as well as rebate errors". OIG, Determining Average Manufacturer Prices For Prescription Drugs Under The Deficit Reduction Act of 2005, 2006 (A-06-06-00063). We concur with the OIG's findings.

CMS should not underestimate the impact that faulty AMP data could have on the generic marketplace and the pharmaceutical marketplace in general. FULs act as a price control on generics. Given that dollar margins on generics are slim, inappropriately low FULs may force generic manufacturers to exit the market, resulting in less competition and ultimately higher prices. Such an outcome would have dramatic consequences for the entire marketplace. Disclosing current AMPs could also create confusion with respect to the negotiated prices that Part D plans publish on the CMS website, as well as the prices that cash-paying consumers pay for drugs.

b. Release Only Weighted Average AMPs for Generic Drugs

With respect to generic drugs, CMS should only release, both on the public website and to states, an AMP value for a particular dosage form and strength of a generic drug that represents the weighted average of all the manufacturers' 100-count retail package sizes of that particular dosage form and strength (or the size that is most commonly dispensed by retail pharmacies). This would eliminate the need to report potentially dozens of AMP values for the same dosage form and strength of a particular generic drug. Publication of all these data could

create confusion in the market and lead states and others to set reimbursement rates that would not be reflective of widely-available market prices. Reporting this "average" AMP number -- rather than individual AMP numbers -- would also limit the extent to which manufacturers' individual proprietary pricing information is introduced into the marketplace, which could limit competition and reduce incentives for pharmacies to negotiate for lower generic prices.

c. Prohibit Use of AMP as a Pharmacy Reimbursement Metric Unit Until Final Rule Defining Calculation of AMP is Promulgated and Verified

We believe that any use of AMP for purposes of pharmacy reimbursement, including, but not limited to, the calculation of FULs, be suspended until Congress is given the chance to revisit the use of AMP as a benchmark to set these FULs. Suspension of the FULs would be consistent with a "Dear Colleague" letter that then House Speaker Dennis Hastert sent to Members of the House in February 2006. In that letter, he indicates that a DRA technical corrections bill would include a provision that would "permit the Secretary of HHS to delay the implementation of the new payment rates if the Secretary determines, based on information in the new GAO report, that the new payment rates do not reflect pharmacy acquisition costs". And, in fact, as discussed in Section III, that GAO report found that for a select market basket of high expenditure, high volume multiple source drugs, using 250% of the lowest AMP to set the upper limits would significantly underpay pharmacies.

In no event, however, should AMP data be used as a pharmacy reimbursement metric until a final rule defining the calculation of AMP that reflects the drug acquisition costs of retail pharmacies has been promulgated and verified.

d. Only Publish Last Month's Data for the Quarter on Public Website

In the preamble to the proposed regulation, CMS indicates that it will publish both monthly and quarterly AMP data on the public website because "the statute does not specify that this exception applies only to monthly AMP; therefore we also propose to make the quarterly AMP publicly available." CMS goes on to say further that "we note that the quarterly AMP data would not necessarily be identical to the monthly AMP data due to the differences in AMP from one timeframe to the next." 71 Fed. Reg. 77186.

Publishing both the monthly AMP data and the quarterly AMP data will add more confusion to what is undoubtedly already going to be a confusing situation. The DRA requires that CMS update the public website on a quarterly basis. The final rule must clarify the following questions:

- Does CMS intend to publish on the website the AMP values for the last month of the quarter or each month of the quarter that just ended?

- Does CMS intend to publish each monthly AMP value for a quarter as well as the quarterly AMP, or just the last monthly AMP for the quarter and the quarterly AMP?

- The quarterly AMP is likely to be lower than the monthly AMP, so how will CMS (and providers) explain to the public why these AMP values differ?

The most direct way to deal with each of these questions would seem to us to provide that reporting the last month's AMP data for the quarter is sufficient.

Finally, CMS must include special disclaimers and instructions on this website so that individuals viewing this website clearly know how to interpret these data. We believe that release of inaccurate AMP data or AMP data that do not reflect retail pharmacy purchasing costs could cause irreparable harm to community retail pharmacies.

III. Calculation of FULs Using AMP

Proposed § 447.514(b) would specify how CMS would set the FULs for multiple source drugs. The FULs are proposed to be set by applying for each drug entity 250% of the average manufacturers' price...for the least costly therapeutic agent." However, DRA does not specify that the FUL must be set at 250% of the lowest AMP, as the rule would propose. DRA merely changes a section of the current regulation -- found at section 42 C.F.R. § 447.332(b) – by stating that in that regulation "250 % of the average manufacturers price (as computed without regard to customary prompt pay discounts extended to wholesalers)" shall be substituted for "150 % of the published price."

Because Congress did not expressly state that the FUL had to be set based on the lowest AMP, we encourage CMS to base the FUL on 250% of the weighted average 11-digit AMPs for all the 100 package sizes (or most commonly dispensed package size by retail pharmacies) of all the nationally and widely available therapeutically equivalent products, weighted by sales.

This is particularly important given that a recent GAO report found that using the lowest AMP would underpay pharmacies on average for generic drugs by 36%. See GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, 2006 (GAO-07-239R). Even when GAO examined AMP-based FUL rates for the lowest AMP which had the highest value among several quarters of AMP data, it found that reimbursement rates were lower than pharmacy acquisition costs. This argues for an approach that would use, at a minimum, 250% of the weighted average AMPs (based on 11-digit NDCs) for the 100 package sizes or the package sizes most frequently dispensed by community retail pharmacies.

In fact, that GAO report found that for a select market basket of high expenditure, high volume multiple source drugs, using 250% of the lowest AMP to set the upper limits would significantly underpay pharmacies. Under this new formula, the GAO report found that retail pharmacies will be reimbursed on average 36% lower than their costs to purchase these generic medications. This analysis provides credible, independent evidence that DRA changes to pharmacy reimbursement will be inadequate to cover the pharmacy's costs of purchasing generic medications. The GAO study, which compared the new AMP-based FULs for 77 generic drugs compared to retail pharmacies' average acquisition costs for these drugs during the first quarter

of 2006, found:

- Pharmacies acquisition costs for 59 of the 77 (76%) generic drugs in study were higher as compared to the new FULs.
- For the 26 of the 27 high expenditure Medicaid generic drugs studied, the FULs were on average 65% lower than the average retail pharmacy's acquisition costs.
- For the 17 of the 27 drugs that are frequently used Medicaid generic drugs, the FULs were on average 15% lower than retail pharmacies' acquisition costs.
- For the 16 of the 23 drugs that were both high expenditure and frequently used, the FULs were on average 28% lower than the average pharmacy's acquisition costs. For 11 of these drugs, the FULs were below the lowest acquisition cost available to retail pharmacies.

Another report to the Minnesota Medicaid program found that, under the DRA's new definition of multiple source drug, the number of generic drugs with FULs will increase from about 500 to 3,000 products. In addition, the DRA will reduce payment for generics by approximately 35 % in 2007, 51% in 2008 and 67% less in 2009 to 2011. *See* Implementation of Pharmacy Payment Reform in the Minnesota Medicaid Program, January 15, 2007, prepared by the University of Minnesota PRIME Institute.

Generic drug dispensing by pharmacies is helping to reduce the rate of growth of Medicaid drug spending. It makes no sense to underpay pharmacies for dispensing generic drugs – essentially forcing them to dispense these prescriptions at significantly reduced margins – when multiple source drugs are helping to keep Medicaid drug spending growth in check.

a. Identification of Drug Entities Subject to a FUL

Proposed § 447.514(a) would describe the criteria by which CMS would determine whether a multiple source drug product must have a FUL. The DRA did change the definition of multiple source drug from a covered outpatient drug for which there is at least two other drug products that are AB rated in the Orange Book to a covered outpatient drug for which there is at least one other drug product that is AB rated in the Orange Book. In this regard, CMS proposes that two criteria have to be met before a FUL can be established. First, at least two or more AB rated products have to be listed in the Orange Book. Second, at least two suppliers list the drug in the nationally-available pricing compendia.

If a particular product is on the market and is available from two different brand name manufacturers under two different trade names, it may not necessarily be the case that these products are AB rated to each other. Generic manufacturers may conduct bioequivalence studies using one or the other branded product as the reference product. In these cases, CMS cannot establish a FUL for all the drugs in these categories by considering all these drugs bioequivalent to each other. It should establish subcategories of these products according to the products that are determined to be bioequivalent to each other, and then apply the criteria above to determine whether a FUL should be set.

b. **Identification of AMP to be Used to Determine FUL**

As previously discussed, we strongly urge CMS, for generic products, to publish only the weighted average of AMPs for individual drug entities and use such weighted averages in calculating FULs for individual drug entities. However, if CMS does not use a weighted average of AMPs to calculate the FUL, we urge that the agency publish in its listing of drugs subject to a FUL, the identity of the manufacturer whose product was used to set the FUL. This would be known as the reference product. Publication of the reference product would provide an important "check and balance" in the setting of the FULs, and help assure the integrity of the process used to set the FULs. Identifying the reference product would help pharmacies and generic manufacturers identify for CMS cases in which the reference product used to set the FUL may not be appropriate because it is in short supply or is no longer being produced and distributed.

c. **Use 11-Digit NDC Rather than 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 NDC should be used, but then rejects its own arguments by saying 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." As CMS knows, there are many items that Congress fails to specify in passing legislation, leaving the particulars to the implementing agency to develop the best possible approach. There is no evidence that Congress did not intend that the AMPs be calculated at the 11-digit level for generic drugs in order to determine the FULs.[2]

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, not the 9-digit weighted average AMP for the product. FULs are being set for generic drugs dispensed by retail pharmacies. Thus, 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. There is no legislative history to suggest that Congress intended to change this methodology in the existing regulation.

In fact, had Congress intended to change this, it would have required an amendment to the existing regulation through statute as it did to change the basis on which the FUL is calculated. Including the prices paid by other purchasers in a weighted average AMP, some of

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[2] Indeed, OBRA 90, which originally established AMPs, did not specify what level NDC was to be used in calculating AMPs. 42 U.S.C. § 1396r-8(b)(3). Thus, it is a bootstrap argument, at best, to suggest that Congress's failure to specify use of the 11-digit NDC in the DRA is evidence of its intent to retain the current practice. Considered in the light of the fact that under the DRA AMPs would be used for both rebate and reimbursement calculation, it is reasonable to expect that Congress intended that the AMP calculation be adjusted so that the appropriate NDC level be used. CMS's own explanation indicates that this is the 11-digit NDC and we urge its adoption.

which may buy in volumes larger than the traditional retail pharmacy can buy, can drive down the AMP below the prices traditionally available to retail pharmacies. According to a recent GAO report, the current AMPs are already well below retail pharmacies' acquisition costs for generic drugs. CMS needs to do all it can to assure that the basis of the AMP is high enough to assure that pharmacies will continue to encourage the use of generic drugs in Medicaid.

d. Base the Reference AMP on Nationally-Available Products Only

In proposed § 447.514(c) CMS attempts to ensure that only drugs that are available for sale nationally are used to determine FULs. In order to encourage continued generic drug dispensing in Medicaid, it is critical that FULs be based on prices for products that are currently nationally and widely available in the marketplace.

We believe that only generic products that are AB-rated in the FDA Orange Book, and are widely and nationally available to pharmacies for purchase from the three major national wholesalers in adequate and consistent supplies, should be used in the calculation of the weighted average AMP (or, if CMS rejects this approach, only such products should be eligible to be designated the reference AMP). Unit dose products, larger bulk package sizes (such as drum sizes, which are generally custom packed for a few select customers), and products that are limited and in short supply, should be excluded from the weighted average AMP calculation used to set the FUL. CMS has an obligation to proactively determine whether products are in fact nationally available and in consistent supplies by contacting the manufacturers of these products on a regular basis, or the national wholesalers that stock them.

We also concur with the agency's proposal to not use a terminated NDC to set the FUL beginning with the first day of the month after the actual termination date is reported to the manufacturer by CMS. The terminated NDC issue needs to be further clarified as drugs can remain on the market for years after a manufacturer ships their last lot. The "termination date" must be based on the last shipment date and not the expiration date of the product as community pharmacy will dispense the product long after the final shipment into the market as wholesalers and retailers deplete their stock. It would be inappropriate to set the FUL based on a product that is no longer being distributed in the marketplace.

As CMS notes in its proposed regulation, eliminating AMPs that are outliers would also reduce the chance that FULs would not be set based on products that are not widely and nationally available. CMS goes to great lengths to describe a process that would eliminate an outlier AMP that is 70% lower than the second highest AMP. This outlier AMP would not be used to set the FUL, even though it might be the lowest. It also discusses the option of eliminating an AMP that is 60% lower. It asks for comment on whether these percentages are appropriate to use.

CMS should have offered AMP data to entities to make informed judgments about what appropriate outlier policy might be. However, CMS did not do that, so it is difficult for any entity to offer a percentage within this so-called "outlier" policy that makes sense in the context of the current AMP data. In fact, CMS itself offers no data to suggest why it chose these percentages. Given that CMS is one of the few entities that has access to and can analyze AMP data across

generic drugs, it is in the best position to offer a reasonable percentage that might eliminate outliers.

However, to minimize the possibility that a FUL would be set based on a product that is in limited or in short supply, the use of a percentage relationship between AMPs to determine outlier policies seems arbitrary. We believe that "outlier" policies could be avoided if CMS assures that the product used to set the FUL is nationally and widely available in the marketplace, and that the monthly AMP data for multiple source drugs are subject to a 12-month rolling average smoothing process. Without this smoothing process, there is no way to know whether the so-called "outlier" AMP is actually the AMP of a widely available product whose AMP just happens to be artificially low in that month. That is because all or many of the rebates and discounts provided for that drug might just happen to be reported in a particular monthly AMP calculation period.

Finally, we believe that a process that allows a manufacturer to estimate a certain amount of discounts and rebates for a month and subtract them from their AMP calculation for the month is an arbitrary way of determining AMP. CMS should not be inconsistent and require manufacturers to calculate a reimbursement metric in one manner under one CMS-administered program -- that is the Medicare Part B ASP program -- and specify that it be done in another manner for a different CMS administered program. AMP calculations should be subject to the same 12-month rolling average smoothing process as are ASP calculations. We urge that CMS rethink this issue of an outlier AMP in favor of a more rational approach to determining the reference AMP used to set the FUL.

e. Provide Appeal Mechanism for Published FULs

Providers should have a formal mechanism to appeal (and expeditiously receive a response from CMS) on a questionable FUL established for a particular product. CMS has generally been responsive to cases in which pharmacies have identified problems or issues with a FUL. However, we believe that there should be a formal appeals process for a FUL if one of the following situations exist: (1) the product does not meet the criteria for a FUL because the product is in short supply or there are no longer an adequate number of suppliers to meet the criteria for a FUL, (2) there have been price changes in the market due to raw ingredient shortages or market consolidation, or (3) the product is generally unavailable at the AMP used to generate the FUL.

IV. States Must Be Required to Set Professional Dispensing Fees that Cover All Pharmacy Costs and Provide Reasonable Return

Proposed § 447.512(b) specifies that the state agency establishes a "reasonable" dispensing fee that would be paid to pharmacies for dispensing Medicaid prescriptions. We believe that CMS should give states additional guidance in the final regulation on how to determine the professional fees that are paid to pharmacies for providing Medicaid prescriptions. That is, the states should be required to set the fees such that they cover all pharmacy's costs of dispensing. It is well documented that one of the major congressional goals of Medicaid

pharmacy payment reform was to pay pharmacies more accurately for the cost of the drug they dispense as well as more accurately for their cost of dispensing.

For example in his May 12th letter to Secretary Leavitt, then Senate Finance Chairman Grassley said that, "CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs." Similarly, we reference the strong statements that Chairman Grassley made in a November 3, 2005, colloquy with Senator Reed when the Senate was considering the DRA.

In that colloquy, Senator Grassley said "states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions." *See* Congressional Record, Senate, November 3, 2005, p. S12326. Former CMS Administrator Mark McClellan, in remarks made at the NCPA conference on May 22nd, indicated that: "If states do not maintain the right incentives for generic utilization, any savings will be lost due to higher brand name utilization.... CMS guidance encourages states to align incentives for generic utilization and consider paying pharmacies more in dispensing fees to support state savings from greater use of generics."

The need to increase pharmacy fees was discussed in the context of paying pharmacies more accurately for their drug product acquisition costs by former House Energy and Commerce Committee Chairman Barton. In his opening statement at a December 2004 hearing, Chairman Barton said, "I believe we should pay providers fairly for their services. I have got absolutely no problem with increasing dispensing fees if that is what we need to do." Hearing of the House Energy and Commerce Committee Subcommittee on Oversight and Investigations, December 4, 2004.

When new FULs are phased in this spring, many states are likely to realize significant savings from reduced payments for generic drug products. As Senator Grassley further stated in his colloquy regarding the Medicaid section of the DRA: "The overall assumption made in the bill is that states will increase their fees to account for the fact that states would probably be paying pharmacists a lower amount for the drug product that more accurately reflects the cost of the drug product being dispensed." Congressional Record, Senate, November 3, 2005, p. S12326. Yet, CMS gives little guidance to states about their obligations, consistent with Congressional intent, to increase their dispensing fees.

Today, Medicaid pharmacy dispensing fee payments are lower than the average pharmacy's cost to dispense a prescription. Recent state-specific studies have shown that the average cost of dispensing a Medicaid prescription is anywhere from $9 to $11, while the average current dispensing fee is only about $4.25. A recent national cost of dispensing study conducted by Grant Thornton and released on January 31 found that the average cost to dispense a prescription, weighted by prescriptions, is about $10.50. *See* Grant Thornton LLP, "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies" (January 2007) (the full report can be obtained from the Coalition for Community Pharmacy Action (CCPA) at www.rxaction.org). This amount is higher when weighted by stores. These amounts vary by state. Therefore, while the Medicaid program will be paying pharmacies less for the generic drug ingredient cost when these new FULs take effect, we believe that CMS should mandate states to make sure that the dispensing fee is adequate and accurate for all pharmacies. This would be consistent with congressional intent.

We believe that CMS needs to direct states to conduct (and update annually) a comprehensive pharmacy professional fee study, which would include the components relating to the costs of dispensing Medicaid prescriptions, as well as providing a reasonable return to pharmacies. It is important for these fees to be updated frequently – using a benchmark such as the Bureau of Labor Statistics Employment Cost Index – because pharmacy labor costs, which account for approximately 75% to 80% of the average pharmacy's cost of dispensing, are increasing each year.

Increasing dispensing fees will not threaten the budget savings forecasted by the CBO for DRA. On the contrary, CBO's budget savings projections are based on the "expectation" that states will increase dispensing fees in response to decreased reimbursement for drug acquisition costs. CBO, Cost Estimate: S. 1932 Deficit Reduction Act of 2005, at p. 37 (Jan. 27, 2006) (savings estimates of $3.6 billion and $11.8 billion "reflect CBO's expectation that states would raise dispensing fees to mitigate the effects of the revised payment limit on pharmacies and preserve the widespread participation of pharmacies in Medicaid").

In fact, failing to ensure that dispensing fees cover the full cost of dispensing may actually *increase* overall Medicaid expenditures. Decreasing generic drug reimbursement rates without increasing dispensing fees to cover dispensing costs is likely to create a perverse incentive for pharmacies to dispense more expensive brand name drugs. In 2005, the average brand was $101.71 per prescription and the average generic was $29.82 per prescription. (See NACDS Industry Profile, 2006.) Conversely, government spending can be reduced if dispensing fees are set at levels which encourage pharmacists to dispense less expensive generic drugs.

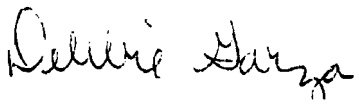
We also ask that CMS expeditiously approve state plan amendments that would increase pharmacies' professional fees that are closer to their actual cost of dispensing, providing for a reasonable return. CMS should also reject those state plan amendments that simply decrease payment for the reimbursement paid to pharmacies for the ingredient cost component without making increases to the dispensing fee.

We believe that the proposed definition of "dispensing fee" found at § 447.502 is overly restrictive. To accommodate any future costs that pharmacies might incur in dispensing prescriptions to Medicaid recipients, we agree that the terminology "includes, but are not limited to" should remain in the final definition. However, it should be made clear to states that they can, indeed, must, provide a reasonable margin or profit to pharmacies when determining a reasonable dispensing fee. Pharmacies cannot be expected to dispense Medicaid prescriptions solely based on their costs. Some margin has to be built in so that pharmacies can remain in business, especially those that do a significant volume of Medicaid prescriptions.

We also urge that states be allowed to provide payment for medication therapy management services (MTMS) in the overall dispensing fee if they so choose, or as a separate payment. Many states have CMS approved demonstrations programs that pay pharmacies for a wide range of MTMS. States should not be discouraged from paying for these services because of an overly restrictive definition of dispensing fee as proposed in the regulation.

We appreciate this opportunity to comment on these proposed rules and we request that the rules be modified as discussed herein.

Very truly yours,



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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

For Cynthia Tucker

February 16, 2007

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

RE: File Code CMS-2238-P

Dear Sir or Madam:

The California State Board of Pharmacy (Board) appreciates this opportunity to submit comments on the proposed rulemaking in 42 CFR Part 447 (File Code CMS-2238-P), the purpose of which is to implement provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. While the Board is pleased that an attempt is being made to clarify this difficult subject area, and recognizes the constraints and mandates placed on CMS by the provisions of the DRA, the Board is concerned that the proposed rules, as written, may result in significant barriers to access necessary medication(s) by California residents who are recipients of Medicaid, particularly in rural and inner city locations.

The primary mandate of the Board is protection of the health and safety of the public in California. In the realm of drug distribution and treatment, this includes helping to ensure a safe, reliable, drug supply, and timely access to medications necessary for treatment.

When such access is impaired, particularly in vulnerable populations such as is often the case for recipients of Medicaid, public health and safety are also impacted. Furthermore, where the concern is overall health system cost savings, any such impairment of access to drugs, particularly among vulnerable populations, may lead to greater overall costs due to increased Emergency Room visits, hospitalizations, or aggravation of preexisting conditions due to an interruption of drug therapy.

We are concerned that the proposed rules may have this detrimental effect on access. We have heard from numerous stakeholders in the pharmaceutical industry, especially but not exclusively community pharmacies both large and small, that the proposed rules would make it economically infeasible for them to continue participating in Medicaid and/or providing drugs to Medicaid recipients in California. They have concluded that

the proposed rules would result in reimbursement and dispensing rates significantly below the lowest prices at which they can purchase the drugs to be dispensed.

Stakeholders in the industry will certainly express to CMS their specific concerns about the text of the proposed rulemaking more comprehensively than the Board, but as articulated to the Board, the difficulties with the current rules include: despite an acknowledgment of flaws in AMP data as a predictor of actual costs-to-dispense, CMS intends to rely on (and to publicly release) that data before resolving its uncertainties and unreliability; the given definition of AMP does not accurately reflect actual acquisition costs by pharmacies; the proposed rules for generics reimbursement will significantly undercount the actual costs of purchasing such drugs, by up to an average of 36 percent;[1] and without any direction to states to increase dispensing fees (particularly for generics), the average dispensing fee payment of $4.50 is significantly below the actual costs-of-dispensing for pharmacies nationwide which has been cited to be between $10.00 and $12.00.[2] The overall message that has been delivered is that the new rules may very well result in a reduction or even elimination of the retail sites that are willing or fiscally able to dispense drugs to Medicaid recipients.

In his May 12, 2006 letter to Secretary Leavitt, Senator Charles Grassley also expressed a similar concern that states must be encouraged or required to reconsider their dispensing fees paid to pharmacies to compensate for presumably lowered drug costs under the new AMP-based calculation protocol. As Senator Grassley said:

> I expect states will very soon begin shifting to a pharmacy payment methodology based on the newly published interim AMP data. CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs. *States may have been working under an assumption borne out in numerous reports of the Office of the Inspector General that pharmacies were being reimbursed well beyond the acquisition cost of the drugs and so dispensing fees were set at levels below the actual cost of the dispensing of a drug. States should carefully consider data regarding the cost of dispensing in determining dispensing fees at the same time they change their reimbursements for acquisition cost to be more consistent with the actual cost of acquisition.*

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[1] See *Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO Report No. GAO-07-239R (December 22, 2006).

[2] See *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, prepared by Grant Thornton LLP for The Coalition for Community Pharmacy Action (January 2007).

The Board agrees that in order to ensure appropriate access to prescription drugs for those residents of California who are recipients of Medicaid, the final result of this rulemaking must be that a combination of reimbursement and dispensing fees paid equals or exceeds the actual cost(s) of drug dispensing. Otherwise, access will be rapidly diminished.

Thank you for this opportunity to provide comments.

Sincerely,

William Powers

WILLIAM POWERS
Board President

144

NATIONAL ASSOCIATION of PUBLIC HOSPITALS and HEALTH SYSTEMS
1301 PENNSYLVANIA AVENUE, NW, SUITE 950, WASHINGTON DC 20004 | 202.585.0100 | FAX 202.585.0101

February 20, 2007

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

Re: Comments for CMS-2238-P
Medicaid Program; Prescription Drugs, Proposed Rule
71 Federal Register 77174 (December 22, 2006)

Dear Ms. Norwalk:

The National Association of Public Hospitals and Health Systems (NAPH) appreciates the opportunity to submit comments on the above-captioned Proposed Rule implementing provisions of the Deficit Reduction Act of 2005 ("DRA," Pub. L. No. 109-171) that pertain to the Medicaid prescription drug program.[1] Our comments are focused on the Centers for Medicare and Medicaid Services' (CMS) interpretation of Section 6002 of the DRA implementing a costly new requirement for states to collect National Drug Code (NDC) information on physician administered drugs in the hospital outpatient setting, as well as regulations implementing Section 6001(c) to alter the formula for calculation of Average Manufacturer Price (AMP) and Section 6001(d)(2) restricting applicability of best-price exemptions to nominal pricing.

NAPH represents more than 100 metropolitan area safety net hospitals and health systems. Our members serve a disproportionate share of low income patients and are deeply reliant on government-sponsored health programs. Approximately 71 percent of our revenues come from government sources, including Medicare, Medicaid, and local subsidies. Approximately 40 percent of the inpatient services provided by NAPH members is to Medicaid recipients and 21 percent is to Medicare patients. Another 23 percent is to uninsured patients. Due to the high percentage of indigent patients served by our member hospitals, many qualify to participate in the federal 340B drug discount program created by Congress to provide substantial discounts on outpatient prescription drugs to entities that serve the nation's most vulnerable patient populations.

NAPH members have expressed deep concern that CMS fully consider the costs of this Proposed Rule to their hospital systems and its impact on their ability to serve the nation's poor and uninsured as supported by the 340B program. We endorse the comments of the American Hospital Association (AHA) and the Safety Net Hospitals for Pharmaceutical Access (SNHPA) that reflect the views of our overlapping memberships. NAPH is a partner of SNHPA

[1] 71 Federal Register 77174 (December 22, 2006). Hereinafter "Proposed Rule."

(formerly the Public Hospital Pharmacy Coalition (PHPC) and a coalition of NAPH) and worked closely with this organization in considering the above-mentioned elements of this Proposed Rule.

In summary, our comments are as follows:

FFP: Conditions Relating to Physician-Administered Drugs—Section 447.520.

- CMS' proposal to apply Section 6002 of the DRA to outpatient drugs furnished as part of a physician's service in hospital outpatient clinics and departments rather than solely in physicians' offices 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.

- This proposed rule to expand the collection of NDC codes to physician administered drugs in hospital outpatient settings would impose a significant financial and administrative burden on hospital systems in order to meet these new billing requirements.

- In addition, expansion of rebates to physician administered drugs in hospital outpatient settings would deprive hospitals of much of the benefit of participating in the 340B program by forcing 340B hospitals to give up critical savings achieved through purchasing drugs at discounted 340B prices for outpatient clinic use in treating Medicaid beneficiaries.

Determination of Average Manufacturer Price—Section 447.504.

- Related to proposed regulation § 447.504, CMS should work with the Health Resources and Services Administration (HRSA) to clarify that the new formula for calculation of AMP is not applicable for purposes of determining the 340B ceiling price of covered outpatient drugs, as the 340B statute expressly provides for continuing to utilize the statutory definition of AMP that existed prior to enactment of the DRA.

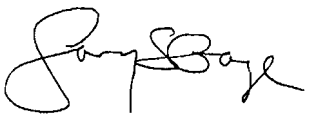
- In addition, CMS should reconsider the proposal to require manufacturers to identify drugs for purposes of AMP calculations through NDC numbers that consist of only 9 digits rather than the full 11 digits, as an 11 digit NDC is critical to providing additional pricing transparency in the 340B program.

Exclusion From Best Price of Certain Sales at a Nominal Price—Section 447.508.

- Related to proposed regulation § 447.508 regarding nominal pricing, CMS should clarify the scope of the best-price exemption for which 340B providers qualify. Specifically, the regulations should clarify that the best-price exemption for nominally priced products sold to a 340B hospital would also apply to nominally priced drugs purchased for inpatient use by the same hospital and that eligibility for best-price-exempt nominal pricing may extend to other components of the larger health system of which a 340B participating DSH hospital is a part.

We appreciate the opportunity to endorse the AHA and SNHPA comments for CMS review and look forward to working with you on these matters. If you have any questions about these comments, please contact Charles Luband at (202) 624-7215.

Sincerely,



Larry S. Gage
President