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February 20, 2007

Via Hand Delivery

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

RE: CMS-2238-P Medicaid Program, Prescription Drugs; Proposed Rule Implementing Provisions of the Deficit Reduction Act of 2005

Dear Ms. Norwalk:

Novo Nordisk Inc. (Novo Nordisk) appreciates this opportunity to comment on CMS-2238-P, the proposed rule implementing provisions of the Deficit Reduction Act of 2005 (DRA). Given the sweeping changes which affect not only pharmaceutical and biotechnology manufacturers, but state Medicaid programs and Medicaid beneficiaries, we respectfully request that the Centers for Medicare and Medicaid Services (CMS) thoughtfully consider our comments.

Novo Nordisk is a healthcare company and a world leader in diabetes care. The company has the broadest diabetes product portfolio in the industry, including the most advanced products within the area of insulin delivery systems. In addition, Novo Nordisk has a leading position within areas such as hemostasis management, growth hormone therapy and hormone replacement therapy. Novo Nordisk manufactures and markets pharmaceutical products and services that make a significant difference to patients, the medical profession and society.

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Below we address a number of issues, and identify the applicable section of the proposed rule. We comment on the determination of average manufacturer price (AMP), providing an overview of our concerns about several items that CMS proposes to include or exclude from the calculation, as well as CMS's intention to provide future clarification. Then we discuss the proposed definition of best price, followed by requirements for manufacturers and end with FFP – conditions relating to physician-administered drugs.

I. Determination of Average Manufacturer Price

A. Sales, Rebates, Discounts, or other Price Concessions Included in AMP (§447.504(g))

1. *Discounts, Rebates, and Price Concessions to Pharmacy Benefit Managers (§447.504(g)(6))*

While Novo Nordisk appreciates the additional clarity CMS is attempting to provide regarding transactions with pharmacy benefit managers (PBMs) and agrees generally with CMS that "discounts, rebates, or other price concessions to PBMs associated with sales for drugs provided to the retail pharmacy class of trade,"[1] be included in AMP, we are concerned by feasibility of the proposal. As CMS acknowledges in the preamble to the proposed rule, it is difficult for manufacturers to distinguish between discounts that are kept by PBMs to cover costs, and those which are passed on to the insurers and other entities with which the PBM has a contractual relationship[2]. Of those discounts that are passed on to insurers or other entities, it is less clear to manufacturers what, if any, portion is seen by the retail class. Therefore, we believe all PBM discounts, rebates, and price concessions should be treated the same for the purposes of calculating AMP, whether or not the PBM keeps the discounts or passes them on.

We understand CMS's concern that AMP could be artificially inflated if all discounts, rebates, and price concessions were excluded from AMP[3]; likewise, AMP could be artificially deflated if all were included in AMP. We encourage CMS to balance PBM transactions against other factors that could have a similar result in determining whether to include or exclude PBM

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[1] Federal Register, Vol. 71, No. 246, December 22, 2006, at 77,197.
[2] Id. at 77,179.
[3] Id.

discounts, rebates, and price concessions from AMP. The proposal as it is will likely and unfortunately prove unworkable.

2. Sales and Associated Rebates to Medicaid Programs (§447.504(g)(12))

CMS proposes that, "sales and associated rebates, discounts, other price concessions under the...Medicaid programs that are associated with sales of drugs provided to the retail pharmacy class of trade,"[4] be included in AMP. We request that CMS clarify that any supplemental rebates manufacturers may pay to state Medicaid programs are to be considered "other price concessions" for the purposes of this section, and thus should be included in AMP calculations. As supplemental rebates are offered by manufacturers to lower the costs to the Medicaid program for the specified product, we believe this clarification is in keeping with the intent of this section.

3. Sales and Associated Rebates to State Pharmaceutical Assistance Programs (SPAPs) (§447.504(g)(12))

Although Novo Nordisk appreciates CMS's recognition that sales and rebates to State Pharmaceutical Assistance Programs (SPAPs) should be included in AMP, we ask that CMS clarify that all SPAP sales and rebates be included regardless of the administrative structure of the SPAP. There are a number of ways states structure these programs, and it would be administratively burdensome for manufacturers to be required to determine the mechanisms that each SPAP uses to provide needed therapies to low-income residents.

B. Sales, Rebates, Discounts, or other Price Concessions Excluded from AMP (§447.504(h))

1. Bona Fide Service Fees (§447.502 and §447.504(h)(11))

The proposed rule requires that manufacturers include in AMP administrative, service, and other fees that do not satisfy the definition of bona fide service fees.[5] Novo Nordisk requests that CMS specify that administrative fees paid to GPOs be specifically excluded from AMP and best price.

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[4] Id. at 77,197.
[5] Id.

GPOs are entities that negotiate contracts with manufacturers on behalf of their health care provider members which include hospitals, nursing homes and physician practices. GPOs do not act as purchasers of drugs and biologicals, but instead negotiate contracts that providers use in making their own purchases. As GPOs are not purchasers, any fees paid by a manufacturer to a GPO should not be considered a price concession for the purposes of AMP calculation.

Therefore, we request that CMS specifically exclude fees paid to GPOs from both AMP and best price calculations.

C. Future Clarifications of AMP

In the preamble to the proposed rule, CMS has asserted that it, "believe[s] that we need to have the ability to clarify the definition of AMP in an expedited manner in order to address the evolving marketplace for the sale of drugs. We plan to address future clarifications of AMP through the issuance of program releases and by posting clarifications on the CMS Web site..."[6] Novo Nordisk appreciates the agency's recognition that our marketplace is constantly changing and commends CMS for anticipating the necessity of flexibility. However, we believe that any 'future clarifications' by CMS should be prospectively effective, providing manufacturers with a reasonable period of time to implement necessary changes in order to ensure accuracy.

II. Determination of Best Price

A. Definition of Best Price (§447.505(a-b))

CMS states in the proposed rule that "best price means...the lowest price available from the manufacturer during the rebate period to any **entity** in the United States..."[7] (emphasis added). However, the Medicaid Rebate Agreement defines best price as "...the lowest price at which the manufacturer sells the covered outpatient drug to any **purchaser** in the United States..."[8] (emphasis added).

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[6] Id. at 77,181.
[7] Id. at 77,197. (emphasis added)
[8] Sample Rebate Agreement, section I(d), on page 2; available at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf. (emphasis added)

Novo Nordisk is concerned by CMS's use of the word "entity" rather than "purchaser." It is unclear whether by doing so, CMS is intending to materially change the definition of best price which manufacturers and States have been working under for more than 15 years. If so, we ask that CMS provide greater specificity and consistency around the definitions that have been established in the market. However, if CMS has not intended to change the definition of best price, we encourage the agency to adopt the definitional language of best price from the Medicaid Rebate Agreement in the final rule.

B. Prices Excluded from Best Price (§447.505(d)

1. Bona Fide Service Fees (§447.505(d)(12))

Please refer to our request that CMS specify that administrative fees paid to GPOs be specifically excluded from AMP and best price in section I.B.1. on pages 3-4.

III. Requirements for Manufacturers (§447.510)

A. Base Date AMP Report (§447.510 (c))

Novo Nordisk welcomes the opportunity to have the option to recalculate base date AMP under the new guidelines once finalized. We request that CMS provide additional guidance, however, as to some logistical considerations. For example, it is not clear from the proposed rule whether manufacturers could recalculate for products that entered the market before the Rebate Agreement went into effect, or only those that have launched since 1990.

In addition, manufacturers may be more likely to have the data necessary for recalculation for more recently launched products versus those launched a number of years ago. We request that CMS specify that manufacturers have the option to recalculate for each product (by NDC), rather than an all-or-nothing approach of recalculating across the entire product portfolio.

Again, we appreciate CMS's recognition of the importance of base date AMP and for providing manufacturers with a more level playing field.

IV. FFP: Conditions Relating to Physician-Administered Drugs (§447.520)

Although Novo Nordisk supports the initiative to require that all states collect rebates on physician-administered drugs, we believe that CMS should provide manufacturers with some certainty regarding our liability by limiting the amount of time states have to submit rebate claims. We believe limiting claims to the previous six months is reasonable – giving states ample time to collect the necessary data yet providing manufacturers with some level of predictability.

V. Conclusion

Again, thank you for the opportunity to comment on this important proposal. As we would be happy to discuss these matters and others CMS may encounter in promulgating a final DRA implementing rule, our contact information is provided below.

Sincerely,

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200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear Administrator Norwalk:

TAP Pharmaceutical Products Inc. ("TAP") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS" or the "agency") proposed rule implementing the provisions of the Deficit Reduction Act of 2005 ("DRA" or the "act") related to payment for prescription drugs under the Medicaid program (the "Proposed Rule"). TAP is one of the nation's leading pharmaceutical companies and is committed to delivering high quality pharmaceutical products for patients. We provide innovative and effective products in diversified treatment areas, including oncology, gastroenterology, and gynecology.

TAP supports CMS' effort to provide additional guidance to manufacturers in calculating the average manufacturer price ("AMP") and Best Price. AMP previously has been used solely to calculate Medicaid rebates,[1] but now also will form the basis for federal upper payment limits.[2] We agree with many of CMS' proposals. There are, however, certain provisions in the Proposed Rule that we believe require further consideration to ensure Medicaid beneficiaries have continued access to the prescription medicines they need. Each of these issues is discussed in detail below, generally following the order in which they are addressed in the Proposed Rule.

[1] Social Security Act ("SSA") §1927(c), 42 U.S.C. §1396r-8(c) (2006).
[2] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001 (2006).

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Background

I. CMS Should Not Finalize the Revised Definition of Bundled Sales.

The Proposed Rule includes a significantly revised definition of the term "bundled sales," currently defined only in the rebate agreement.[3] CMS did not provide any explanation for the change or guidance on implementing the new definition, leaving significant confusion as to what types of arrangements are "bundled" and how to reallocate the discounts involved. TAP also disagrees with the definition's requirement that drugs in the same product family be treated as different products where they have different product code portions of their respective National Drug Codes (NDC).

A. CMS Should Not Finalize the New Definition Absent Further Explanation and Opportunity For Comment.

The Proposed Rule newly defines a bundled sale as "an arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug or drugs of different types . . . or some other performance requirement . . . where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement."[4] This definition differs significantly from the prior definition of bundled sale the agency had provided.

CMS' current definition of the term bundled sale, which has remained unchanged since the inception of the Medicaid program, is "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."[5] The Proposed Rule fails to discuss the reason for, and implications of, changing this long-standing definition and provides no guidance on implementing it. The Proposed Rule also fails to provide any details as to the appropriate methodology to be used when implementing the definition's direction to reallocate discounts among the products involved in a bundled arrangement.

This complete lack of commentary is in stark contrast to the extensive discussion and guidance accompanying the proposed definition of retail pharmacy class of trade.[6] TAP is unable to fully comment on this issue without CMS first providing a rationale for, or discussion of the policy behind, the new definition. Because this revision may well have significant implications for manufacturer contractual relationships and changes long term policy, we urge the agency to provide an additional period for notice and comment on this issue before any changes to the definition are finalized.

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[3] 71 Fed. Reg. 77,174, 77,195 (Dec. 22, 2006) (proposed 42 C.F.R. pt. 447.502); 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991).
[4] 71 Fed. Reg. at 77,195 (proposed 42 C.F.R. pt. 447.502).
[5] 56 Fed. Reg. at 7050. The term does not appear at all in the Medicaid Rebate statute.
[6] See 71 Fed. Reg. at 77,177-81.

B. The Bundled Sales Definition Should Not Apply to Arrangements Involving Products Belonging to a Single Product Family.

The revised bundled sales definition applies where a price concession is conditioned upon the purchase of "the same drug or drugs of different types."[7] This new definition for the first time defines "drugs of different types" to mean drugs with different nine-digit national drug codes (NDC-9s).[8] This definition is overbroad. TAP believes that arrangements involving products with different NDC-9s in the same product family should not trigger the application of the bundled sale definition.

Manufacturers often market different strengths and formulations of a product that are all part of the same product family. These drugs typically are identified with the same name but come in different dosage forms or strengths, and therefore have different NDC-9s. TAP believes that drugs that are part of the same product family and sold under the same contract do not constitute a "bundled" arrangement.

CMS has not explained the purpose of the new definition of bundled sale. TAP asks CMS to provide that where a manufacturer sells multiple drugs that are part of the same product family there is no bundled sale and any discounts offered by the manufacturer do not have to be reallocated.

II. CMS Should Further Clarify Other Entities Considered Part of the Retail Pharmacy Class of Trade and Provide Additional Guidance Regarding the Tricare Program.

TAP appreciates CMS' effort to provide a comprehensive definition of retail pharmacy class of trade through the Proposed Rule and its preamble. The Proposed Rule did not specifically address other entities including physicians and non-purchaser HMOs, however, and its limited reference to the Tricare program does not address whether payment of rebates by a manufacturer on Tricare utilization is a prerequisite for concluding that such utilization is a depot sale. TAP urges CMS to clarify the treatment of physicians and non-purchaser HMOs in the Final Rule and also to provide additional clarity regarding the Tricare program in the Final Rule.

A. CMS Should Further Clarify Retail Class of Trade.

We note that a number of other entities to which manufacturers have direct or indirect sales are not expressly listed. We are hopeful that this was purposeful and that CMS's intent is to continue to allow manufacturers to treat an entity as either included or excluded in the retail class of trade based on its function, provided that the manufacturer can provide sound rationale. It would be helpful if CMS clarify in the Final Rule whether our assumption regarding the treatment of such unlisted entities is acceptable. For example, TAP believes there are several bases for concluding that direct and indirect physician sales should be included in AMP and details each below.

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[7] Id. at 77,195 (proposed 42 C.F.R. pt. 447.502).
[8] Id.

First, direct and indirect physician sales should be included in AMP because direct purchasers are wholesalers under the definition of that term in the Medicaid rebate agreement and both direct and indirect purchasers are wholesalers under the revised definition of that term in the Proposed Rule. Wholesalers are included in the retail pharmacy class of trade.[9] The Proposed Rule defines AMP as a measure of the average price received by manufacturers from wholesalers for covered outpatient drugs.[10] The Proposed Rule defines a wholesaler 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 drug, but that does not relabel or repackage the covered outpatient drug."[11] When a manufacturer sells drugs directly or indirectly to a physician, the physician is a wholesaler as that term is defined in the Proposed Rule and should be included in AMP.

Second, physicians independently satisfy the criteria for inclusion in the retail pharmacy class of trade. Physicians are not specifically excluded from the retail pharmacy class of trade by any statutory or agreement term, and, under the Proposed Rule, any entity that meets the proposed definition is included, unless specifically excluded.[12] The retail pharmacy class of trade is broadly defined in the Proposed Rule and extends to any "outlet that purchases" drugs and "subsequently sells or provides the drugs to the general public."[13] Physicians should be included in the retail pharmacy class of trade pursuant to this definition because they purchase drugs, either directly from the manufacturer or through a wholesaler, and then provide these drugs to the "general public," their patients. In this regard, physicians are directly analogous to outpatient clinics, and the Proposed Rule specifically states that outpatient clinics are part of the retail pharmacy class of trade.[14]

Third, the Proposed Rule clarifies that units associated with Medicaid sales are included in AMP.[15] CMS explained that such units (and associated sales dollars) should remain in the AMP calculation because they were dispensed to a Medicaid beneficiary by a retail entity.[16] As physicians purchase drugs and then administer them to Medicaid beneficiaries, such sales should be included in AMP.

Finally, the DRA now requires that AMP be used to determine federal upper payment limits ("FULs") for multiple source drugs.[17] While there is no requirement that States also use AMP to set

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[9] Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(f)); 56 Fed. Reg. at 7051 (Medicaid Rebate Agreement at I(ee)).
[10] 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).
[11] Id. (proposed 42 C.F.R. pt. 447.504(f)). This definition is consistent with, although not identical to, the definition of "wholesaler" in the Medicaid rebate agreement. See 56 Fed. Reg. at 7051 (Medicaid Rebate Agreement at I(ee)).
[12] See 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)) ("AMP shall be calculated to include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation.").
[13] Id. (proposed 42 C.F.R. pt. 447.504(e)).
[14] Id. at 77,197 (proposed 42 C.F.R. pt. 447.504(g)(8)).
[15] Id. at 77,180
[16] Id.
[17] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(a)(2).

reimbursement rates, the Proposed Rule notes that Congress intended the public availability of AMP data to encourage such a result, with AMP reflecting actual prices to those entities reimbursed by Medicaid programs for drug costs.[18] To achieve this goal, AMP must reflect the acquisition costs for those entities subject to separate Medicaid reimbursement for drugs and that necessarily includes physicians. For all of these reasons, TAP requests CMS clarify that physicians are part of the retail class of trade and included in the AMP calculation.

B. CMS Should Clarify That Sales to HMOs That Do Not Purchase and Take Possession of Product Are Included in the AMP Calculation.

The Proposed Rule explicitly excludes sales to HMOs from the AMP calculation.[19] In this blanket exception, adopted from the Medicaid rebate statute and Medicaid rebate agreement,[20] CMS does not distinguish between HMOs that do and do not purchase and take possession of product. TAP requests that CMS clarify that non-purchasing HMOs are included in AMP.

Possession-taking HMOs purchase drugs and distribute them through closed-door pharmacies to their members and so, like long-term care facilities, do not sell or provide drugs to the general public. For this reason, the Proposed Rule appropriately provides that such HMOs are not part of the retail pharmacy class of trade and sales to them should not be included in AMP. The Proposed Rule does not distinguish between HMOs that purchase product and those that do not take possession or dispense drugs themselves, but rather allow their members to purchase drugs at retail pharmacies and act as third-party payors. Non-purchasing HMOs function more like Medicaid , Medicare Part D prescription drug plans ("PDPs"), or State pharmaceutical assistance programs ("SPAPs") – all of which the Proposed Rule directs to be *included* in AMP.

In the preamble to the Proposed Rule, CMS explained why Medicaid sales, and other similar sales under SPAP and Part D agreements, are included in AMP: "As a general matter, Medicaid does not directly purchase drugs from manufacturers or wholesalers but instead reimburses pharmacies for these drugs. Therefore, Medicaid sales are determined by the entities that are actually in the sales chain and because Medicaid beneficiaries, integrated into the chain of sales otherwise included in AMP ." (sic)[21] This rationale applies equally to non-purchasing HMOs and dictates including such sales in AMP. For these reasons, TAP asks CMS to clarify that sales to HMOs that do not purchase and take possession of product are included in AMP.

C. CMS Should Provide Additional Guidance on the Treatment of Tricare in AMP and Best Price.

In 2004 the Department of Defense ("DoD") restructured its pharmaceutical benefit plan, called Tricare, and placed the pharmacy benefit under contract with pharmacy benefit managers ("PBMs").

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[18] 71 Fed. Reg. at 77,178.
[19] Id. at 77,197.
[20] Id. at 77,179.
[21] Id. at 77,180.

DoD determined, and CMS agreed, that the Tricare transactions, known as the Tricare Retail Pharmacy Initiative or TRRx, were depot sales that qualified for Federal Ceiling Prices ("FCP").[22] Manufacturers paid rebates, called refunds, on TRRx utilization, and those rebates were calculated in a manner intended to provide DoD with the FCP as to that utilization. In Release 69, CMS directed that both TRRx sales and refunds be excluded from AMP and Best Price as depot sales.[23] In September 2006, the Federal Circuit invalidated the TRRx drug program holding that DoD could not require manufacturers to pay refunds without issuing a regulation through formal notice-and-comment rulemaking.[24]

The Proposed Rule explicitly adopts the provision of the Medicaid rebate statute exempting depot prices from AMP and Best Price.[25] CMS includes "Tricare" as an example of a depot price in that provision.[26] DoD has ceased the TRRx program in response to the Federal Circuit opinion and has refunded (or is in the process of refunding) to manufacturers any rebates previously paid under the program. There currently is no requirement for payment of such rebates. For this reason, TAP asks CMS to clarify whether Tricare sales continue to be considered as depot sales even when no rebate is paid.[27]

If it is CMS' position that Tricare is a depot sale even when no refund is paid, TAP asks that CMS also specify that manufacturers are obligated to remove such utilization from the AMP calculation only if such utilization can be identified. With the cessation of the TRRx program, DoD no longer is supplying manufacturers with the utilization data manufacturers previously used to quantify this utilization for removal from AMP. TAP requests that CMS include a provision in the Final Rule stating that manufacturers are not required to remove Tricare from AMP when the manufacturer lacks the data necessary to quantify utilization.

Finally, TAP also notes that prices to DoD also are excluded from AMP and Best Price.[28] TAP asks CMS to clarify that voluntary price concessions provided to DoD by manufacturers on direct purchases, sales to the Tricare mail order pharmacy, or through rebates on Tricare utilization, are exempt from AMP and Best Price under CMS' current guidance.

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[22] Medicaid Drug Rebate Program Release #69 for Participating Drug Manufacturers (May 13, 2005).

[23] Id.

[24] The Coalition for Common Sense in Government Procurement v. Secretary of Veterans Affairs, 464 F.3d 1306 (Fed. Cir. 2006).

[25] 71 Fed. Reg. at 77,180-81.

[26] Id. at 77,197 (proposed 42 C.F.R. pt. 447.505(d)(4)).

[27] Should CMS conclude that Tricare utilization is not a depot sale in the absence of rebate payments, CMS should clarify that manufacturers are under no obligation to recalculate prior quarter AMP figures to include such utilization because manufacturer treatment of the Tricare utilization in those prior quarters conformed to the CMS guidance that existed at that time, i.e. Release 69.

[28] SSA § 1927(c)(1)(C)(i)(I); 42 U.S.C. § 1396r-8(c)(1)(C)(i)(I); 71 Fed. Reg. at 77,197 (proposed 42 C.F.R. pt 447.504(h)(1)).

III. Direct Patient Sales Should Not Be Included in AMP or Best Price.

TAP disagrees with CMS' position that direct patient sales should be included in the AMP calculation.[29] The Proposed Rule itself notes that neither the Medicaid rebate statute nor the Medicaid rebate agreement address direct patient sales.[30] Rather than conclude that this silence prevents the consideration of such transactions in the calculations of AMP and Best Price, CMS directed their inclusion in these calculations. The stated rationale is that these sales normally occur though a "direct distribution agreement," that CMS considers the distributor in such cases to be a "wholesaler," and the sales to be to the "retail pharmacy class of trade."[31] TAP believes that this analysis is erroneous and asks that CMS revise this position.

The Proposed Rule defines AMP as "the average price received by the manufacturer for the drug in the United States from wholesalers for drugs distributed to the retail pharmacy class of trade."[32] This definition includes only sales to retail entities. Manufacturer sales to patients that occur through a retail pharmacy, such as a distributor, but that do not involve a sale to that retail pharmacy do not satisfy this requirement. The Proposed Rule recognizes that the distributors in these arrangements do not purchase drugs, only taking responsibility for storage, delivery, and billing, for which the distributor receives a fee.[33] Such arrangements cannot constitute sales to the retail pharmacy class of trade where the patients rather than distributors purchase the product from the manufacturer.

The inclusion of direct patient sales in AMP also is inconsistent with CMS' position on patient coupons, which are excluded from AMP and Best Price in the Proposed Rule.[34] The legal basis for excluding patient coupons from the AMP and Best Price necessarily is that patients are not considered purchasers for the purposes of determining AMP or Best Price. This conclusion is supported by the statutory definitions of AMP and Best Price, which do not include patient transactions.[35] For all of these reasons, TAP requests CMS to revise its position on direct patient sales in the Final Rule and excludes these sales from AMP and Best Price.

IV. CMS Should Provide Additional Guidance Regarding Treatment of Patient Coupons in AMP and Best Price.

The Proposed Rule specifically excludes manufacturer coupons from the calculation of AMP and Best Price where redeemed by a consumer directly to the manufacturer.[36] TAP supports this position but

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[29] See 71 Fed. Reg. 77,180-81.
[30] Id.
[31] Id.
[32] Id. at 77,196 (proposed 42 C.F.R. pt. 447.504(a)).
[33] Id. at 77,180-81
[34] See id.
[35] SSA § 1927(c)(1), (k)(1); 42 U.S.C. § 1396r-8(c)(1), (k)(1).
[36]/ 71 Fed. Reg. at 77,197 (proposed 42 C.F.R pts. 447.504(g)(11), 505(a)(12)); id. at 77,181 ("In this rule, we propose to include coupons redeemed by an entity other than the consumer in the calculation of AMP."); id. at

asks CMS to clarify that this exclusion extends to coupons redeemed to non-purchaser, third-party vendors, retained by a manufacturer to administer the coupon program. TAP also requests that CMS expand the exception to also include coupons redeemed through entities, such as retail pharmacies, because TAP does not believe that in that situation the "redemption of coupons by an entity other then the consumer ultimately affects the price paid by the entity."[37]

A. Coupons Redeemed to a Non-Purchasing, Third-Party Vendor Should Be Excluded from AMP and Best Price.

TAP agrees with CMS that manufacturer coupons redeemed by a consumer should be excluded from AMP and Best Price. As noted above, such patient discounts should be excluded from the calculation of AMP and Best Price because patient transactions are not included in the statutory definitions of those terms. In certain circumstances, however, a coupon may not be redeemed directly to the manufacturer, but rather to a non-purchaser third-party vendor or clearinghouse retained by the manufacturer to administer the patient coupon program. The vendor is responsible for receiving the coupons, processing the rebate claim, and providing the funds to the consumer. Where the vendor is not a purchaser of the manufacturer's product, the vendor's involvement can have no affect on the price of the drug realized by any AMP or Best Price-eligible purchaser. TAP requests CMS to clarify that manufacturer coupons redeemed by the consumer through these vendors are to be treated as if they were redeemed directly to the manufacturer and excluded from AMP and Best Price.

B. Patient Coupons Redeemed by Entities Other Than the Customer Should Not Be Included in AMP and Best Price If They Do Not Affect the Price of the Drug.

As noted above, the Proposed Rule directs the inclusion of patient coupons in the calculation of AMP and Best Price where redeemed through an entity other than the manufacturer.[38] The Proposed Rule implies that whenever a coupon is redeemed through an entity other than the manufacturer the coupon necessarily affects the price realized on the manufacturer's product by that redeeming entity and, for that reason, such arrangements in all cases must be included in AMP and Best Price.[39] TAP believes that this direction is overbroad because most, if not all, coupon arrangements do not affect the price realized by the redeeming pharmacy.

There are generally two types of patient coupons – those that reduce the patient's out-of-pocket cost for a prescription, either by offsetting a copayment or co-insurance amount or, where the patient has

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77,183 ("In this rule, we propose to include coupons redeemed by any entity other than the consumer in the calculation of best price.").

[37] See id. at 77,183. CMS did not specifically state its reason for including in AMP coupons redeemed by an entity other than the consumer. See id. at 77,181. TAP assumes that CMS' explanation for including such coupons in BP extends to AMP. See id. at 77,183. If this is not the case, TAP would ask that CMS provide an explanation for its position that coupons redeemed by entities other than consumers should be included in AMP and allow interested parties an opportunity to comment before issuing a Final Rule.

[38] Id. at 77,197 (proposed 42 C.F.R. pts. 447.504(g)(11), .505(c)(12)).

[39] See id. at 77,183.

no insurance, by reducing the overall cost of the prescription ("co-pay coupons"), and those that provide the patient with the drug at no charge ("free goods" coupons). A co-pay coupon can take one of two forms. The first is a mail-in co-pay rebate, which the patient sends in to the manufacturer along with proof of purchase. Under the Proposed Rule, these coupons are specifically excluded from AMP and Best Price.[40]

The other type of co-pay assistance coupon is a point-of-sale co-pay assistance coupon or card. A patient who has a co-pay assistance card or coupon presents it to the pharmacy filling the prescription and receives money off his or her co-pay or amount due at the time of the transaction. The manufacturer then reimburses the pharmacy for that uncollected amount and also usually pays the pharmacy a fair market value processing fee. The Proposed Rule would require that this type of coupon be included in AMP and Best Price because the entity redeeming the coupon to the manufacturer is the entity filling the prescription, not the consumer.[41] TAP submits that this is an inappropriate result because the pharmacy's redemption of such a coupon does not affect the price it realized on the manufacturer's drug. The manufacturer payment to the retail pharmacy is limited to the amount that the retail pharmacy itself did not collect from the patient plus a bona fide service fee. The price of the drug is unaffected and the transaction should be excluded from AMP and Best Price.

Free goods coupons also are presented by the patient at the time the prescription is filled. The entity filling the prescription provides the drugs to the patient at no cost and then redeems the coupon to the manufacturer for reimbursement. The Proposed Rule also directs the inclusion of such free goods coupons in AMP and Best Price because they are redeemed to the manufacturer by an entity other than the consumer. TAP believes that these coupons also should be excluded from AMP and Best Price because they do not affect the price realized by the entity filling the prescription, as described below.

When a retail pharmacy or other entity accepts a free goods coupon from a patient and then redeems the coupon to the manufacturer, the manufacturer reimburses that entity either through replacement product or monetary reimbursement, and also usually pays a fair market value dispensing fee. If the pharmacy is reimbursed with replacement product, there is no effect on the price it realized because the pharmacy receives in kind exactly that which it dispensed for free. If the manufacturer instead reimburses the redeeming pharmacy in cash, the price realized by the pharmacy will be affected only if the redeeming entity is reimbursed in an amount that exceeds the pharmacy's acquisition cost for the drug. Manufacturers typically have no way of determining the pharmacy's actual acquisition cost and so employ a formula, often based on Wholesale Acquisition Cost ("WAC") or Average Wholesale Price ("AWP"), to determine the amount to reimburse the pharmacy. These formulas are intended to approximate pharmacy acquisition cost and therefore also should not have an impact on the price realized by the redeeming pharmacy.

CMS previously has accepted the use of such a standardized formula for determining the appropriate price for drug products in the context of a patient discount program, and permitted pharmacy

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

reimbursement transactions using that formula to be exempt from AMP and Best Price. Specifically, CMS did so in relation to the TogetherRx drug discount card program, and should adopt the same approach here. The TogetherRx program is a drug discount program created by a group of manufacturers. It supplies enrolled patients with TogetherRx program cards that allow them to purchase the products of the sponsoring manufacturers at a discount at participating pharmacies. The TogetherRx program defined the formula that the pharmacy could use to determine the cost of each prescription to an enrollee, the lower of the pharmacy's usual and customary charge or an AWP based formula, and then provided the patient with a discount off of that amount, funded by the sponsoring manufacturer. CMS reviewed this program, including the formulas used to determine the price of the drug products, and agreed that the patient discount transactions, inclusive of the manufacturer reimbursements to the participating pharmacies, could be excluded from AMP and Best Price. Use of a similar if not the same reimbursement formula to reimburse pharmacies for product dispensed under a free goods program should be exempt from the AMP and Best Price calculations for the same reason.

Patient coupon programs play a very important role in ensuring patient access to important therapies and, as explained above, do not result in windfalls to those pharmacies that honor the programs. Rather, these programs are designed to compensate pharmacies for their out-of-pocket costs only, along with a reasonable fee for their services. TAP requests that CMS exclude these programs from AMP and Best Price for the reasons addressed above and ensure the continued viability of patient coupon programs. Should CMS determine that these patient coupon programs must be included in AMP and Best Price, TAP urges CMS to provide additional details regarding that proposal and the opportunity for further comment by industry, particularly in relation to the methodology for including such transactions in the calculations.

V. CMS Should Exclude GPO Administrative Fees from AMP and Best Price and Adopt the CMS Discussion of the Bona Fide Service Fee Definition Contained in the Preamble to 2007 Physician Fee Schedule Final Rule.

The Proposed Rule seeks to adopt the definition of bona fide service fee contained in the 2007 Physician Fee Schedule ("PFS") Final Rule: "fees paid by a manufacturer to an entity, which represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and which are not passed in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug."[42] This proposed definition would apply to fees paid to any entity, whether or not it takes title to product, and require inclusion of fees in AMP and Best Price whenever the definition is not met.[43]

CMS' prior guidance on service and administrative fees, contained in Manufacturers' Release 14, directed the inclusion of such fees in AMP and Best Price only when the entity to which the fee was paid was included in those calculations and only when those fees adjusted the price realized by the

[42] 71 Fed. Reg. at 77,180, 77,195 (proposed 42 C.F.R. pt. 447.502).
[43] Id. at 77,179-80.

recipient.[44] Under this prior guidance, fees paid to Group Purchasing Organizations ("GPOs") were not included in AMP or Best Price: GPOs generally are not purchasers and therefore the fees paid to GPOs are not paid to an entity included in the calculations and also are not capable of affecting the price realized by any entity that is. In apparent recognition of these facts, and despite the definition's putative application even to entities that do not take title, CMS explicitly noted in its preamble to the PFS Final Rule that it was "premature" for the agency to provide specific guidance with respect to treatment of GPO fees.[45] CMS instead stated that it would continue to study the issue and directed manufacturers to continue to make reasonable assumptions regarding the treatment of fees paid to such non-purchasers.

TAP believes that administrative fees paid to GPOs that are not purchasers should not be included in the calculations of AMP or Best Price. GPOs generally do not act as purchasers, but rather negotiate discounts on behalf of their members who are purchasers. TAP asks that CMS clarify that fees paid to non-purchaser GPOs continue to be excluded from AMP and Best Price and need not be evaluated under the bona fide service fee definition. At a minimum, CMS should adopt as to the AMP and Best Price calculation the same approach that it currently takes as to the calculation of average sales price ("ASP"): permit manufacturers to document their reasonable assumptions as to the treatment of such fees.

If CMS nevertheless concludes that GPO fees should be considered in these calculations, TAP urges CMS to implement such a requirement prospectively only, given its departure from CMS' prior guidance, and also limit such a requirement's application to fees that exceed the 3% threshold referenced in the regulatory safe harbor to the federal healthcare program antikickback law, 42 C.F.R. § 1001.952(j). The inclusion of the 3% threshold in the safe harbor reflects the prevalence of fees that are at or below that amount and also the Office of Inspector General's recognition that fees in that amount raise only minimal risks for abuse.

TAP asks that CMS also explicitly adopt all guidance related to the definition of bona fide service fee contained in the preamble to the 2007 PFS Final Rule. The preamble to the 2007 PFS Final Rule included extensive discussion of how CMS interprets and intends to apply that definition.[46] Manufacturers should be able to rely on this important guidance resource when calculating AMP and Best Price, as well as ASP. TAP asks that CMS specifically adopt this guidance in relation to the AMP and Best Price calculations.

VI. CMS Should Clarify Several Issues Related to Recalculation of Base Date AMP.

TAP supports CMS' proposal to permit manufacturers to recalculate base date AMP to ensure that additional rebates do not increase because of the changes in the definition of AMP. TAP asks CMS

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[44] Medicaid Drug Rebate Program Release #14 for Participating Drug Manufacturers (Dec. 20, 1994).
[45] 71 Fed. Reg. 69,623, 69,669 (Dec. 1, 2006).
[46] See 71 Fed. Reg. at 69,668-69. For example, the definition of bona fide service fee includes fees paid for services performed "on behalf of" the manufacturer. The preamble clarified that "services 'on behalf of' the manufacturer include both those the manufacturer has the capacity to perform and those that can only be performed by another entity."

to clarify that manufacturers retain complete discretion regarding whether to recalculate base date AMP for their drugs, and that the decision can be made on a drug-by-drug basis. TAP also asks to CMS to recognize the potential need for use of reasonable assumptions in the application of a manufacturer's current methodology to data generated using legacy systems and methodologies, and to provide manufacturers with more than one quarter in which to perform these recalculations. Finally, TAP requests CMS clarify that any recalculation accounts both for the revised definition of the retail class of trade as well as the exclusion of customary prompt payment discounts, and that CMS will recalculate manufacturer rebate liability using any revised base date AMPs for quarters starting with the first quarter 2007.

The preamble to the Proposed Rule proposes to "allow manufacturers the option to decide whether they will recalculate" 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" (emphasis supplied).[47] The availability of data, the burden of recalculating, and the value to be gained will vary from drug-to-drug. For these reasons, TAP asks CMS to clarify that manufacturers retain complete discretion in determining whether or not to recalculate base date AMP and that the decision to recalculate may be made on a drug-by-drug basis.

Even when a manufacturer has the data available, and believes that the savings to be gained by recalculating outweigh the associated costs, recalculation likely will be a difficult task, particularly for those drugs not launched in the recent past. Manufacturers may need to make reasonable assumptions where necessary when recalculating base date AMPs to be able to process data using existing methodologies and systems. TAP asks CMS to include a provision in the Final Rule that allows manufacturers to make reasonable assumptions about prior data when recalculating base date AMP.

CMS should provide manufacturers with more than one quarter in which to perform any recalculations. TAP proposes instead that manufacturers have up to four quarters to perform this work. The evaluation of whether even to perform recalculations cannot begin until the retail class of trade definition is finalized, and the recalculations themselves will take substantial time after that. One quarter simply is not enough time to accomplish these complicated tasks. TAP urges CMS to revise its guidance in the Final Rule and permit submission of recalculated base AMPs for up to four quarters after the effective date of the Final Rule.

The preamble to the Proposed Rule explains that the recalculation of base date AMP is designed to prevent an increase in additional rebates "due to changes in the definition of AMP."[48] The actual text of the proposed regulation appears to limit recalculation to those "revisions to AMP as provided for in § 447.504(e),"[49] which provides the new definition of retail pharmacy class of trade. Notably, the DRA also changed the definition of AMP by excluding from the AMP calculation customary prompt pay discounts.[50] TAP asks CMS to clarify that in recalculating base date AMP manufacturers should take

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[47] 71 Fed. Reg. at 77,185.
[48] Id.
[49] Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(c)).
[50] Deficit Reduction Act of 2005, Pub. Law. No. 109-171, § 6001(c)(1)

into account not only the changes to the retail pharmacy class of trade definition, but also the exclusion of customary prompt pay discounts. This clarification is necessary to ensure that recalculated base date AMPs reflect all changes in the definition of AMP.

Finally, while the DRA requires manufacturers to calculate AMP without including customary prompt pay discounts beginning with their first submissions for 2007, the Proposed Rule does not permit submission of recalculated base date AMPs until several quarters later. For the quarters starting with the first quarter 2007 and ending with the last quarter before recalculated base date AMPs are applied, a manufacturer's rebate liability will be determined using non-recalculated base date AMPs. TAP asks CMS to clarify that it will recalculate manufacturer rebate liability during this period using the revised base date AMPs once those revised figures have been submitted.

VII. CMS Should Allow Manufacturers To Use 12 Month Rolling Average Estimates of Lagged Data for Both Monthly and Quarterly AMP, with the Option of Restating Quarterly AMP When Actual Data Is Available.

The Proposed Rule solicits comments on allowing the use of 12-month rolling average estimates of all lagged discounts for monthly and quarterly AMP.[51] TAP supports use of this approach, and urges CMS to adopt the methodology approved by CMS for use in the calculation of ASP, both as to lagged eligible prices concessions as well as lagged ineligible sales. Use of the same approach to estimate lagged transactions for both monthly and quarterly AMPs will work to decrease disparities between the monthly AMP figures used for reimbursement and the quarterly AMP figures used for rebates. If CMS adopts this approach in the Final Rule, TAP would ask that CMS also clarify that it will continue to permit but not require manufacturers to restate their quarterly AMPs when actual data becomes available.

VIII. CMS Should Implement the Statutory Limitation on the Rebate Amount Where Medicaid Is a Secondary Payor.

The DRA added a new provision to the Medicaid rebate statute requiring States to seek rebates for single source physician-administered drugs after January 1, 2006 and certain multiple source physician-administered drugs starting in January 2008.[52] In connection with this provision, States are required to obtain drug utilization data, which will identify the manufacturer of the physician-administered drugs and enable the States to submit rebates.[53] The language of the original Medicaid statute as well as the amendments in the DRA indicate, however, that the States may obtain rebates only for that portion of the cost actually paid by Medicaid when Medicaid is the secondary payor. TAP asks that CMS clarify in the Final Rule that such proportionality is required.

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[51] 71 Fed. Reg. at 77,186.
[52] Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6002.
[53] Id.

The DRA explicitly requires States to secure rebates for physician-administered drugs "for which payment is made under this title."[54] Senator Charles Grassley, former Chairman of the Senate Finance explained in a letter to former CMS Administrator McClellan, the language quoted above "makes clear that the Medicaid rebate is only available for the Medicaid portion of the payment" when Medicaid is the secondary payor for physician-administered drugs.[55] Contrary to previous CMS guidance, which allowed States to recover the full Medicaid rebate even when Medicaid paid only a fraction of the cost,[56] "[f]ederal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program."[57] Senator Grassley concluded his letter by requesting that CMS issue guidance stating that the rebate for physician-administered drugs is limited to "that portion of the Medicaid allowable payment that the state actually pays as a copayment or deductible on the claim paid by Medicare as primary payor."[58]

The DRA provision, as explained in Senator Grassley's letter, makes clear that State Medicaid rebates should be prorated when Medicaid is a secondary payor. This limitation prevents the anomolous result of requiring a manufacturer to pay a rebate amount that exceeds the State's own expenditure, often by several multiples. This DRA provision serves to reiterate the Medicaid statute's pre-existing direction that rebates be considered "a reduction in the amount expended" by the State – language that clearly presumes the rebate amount will be less than that expended by the State itself.[59] Congress's clarification of the issue renders CMS' prior inconsistent interpretation obsolete.[60]

Even in the absence of statutory language in support of rebate pro-ration, CMS' previous interpretation is not entitled to deference because CMS has outlined this approach only through informal guidance, not notice-and-comment rulemaking.[61] Such informal guidance is entitled to deference only to the extent it is persuasive,[62] and a position that ignores the authorities cited above and works to ensure a windfall to the states lacks any persuasive authority. TAP agrees with Senator Grassley's position and asks CMS to issue the suggested guidance as described above.

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[54] Id.

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

[56] This interpretation of the Medicaid Drug Rebate statute, which does not specifically address prorating, has been advanced by CMS in program releases, but never through formal notice-and-comment rulemaking.

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

[58] Id.

[59] See SSA § 1927(b)(1)(B), 42 U.S.C. § 1396r-8(b)(1)(B). The statute's legislative history also supports this interpretation, with its repeated descriptions of the Rebate Program as one providing discounts on Medicaid expenditures. See, e.g., 136 Cong. Rec. S12954-01 (Sept. 12, 1990) ("[The Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act] mandates that . . . a prescription drug manufacturer must provide the Medicaid Program the same substantial discounts it is now giving to other purchasers of that medication."); H. Rep. 101-881, at 96 (1990), as reprinted in 1990 U.S.C.C.A.N. 2017, 2108. ("Specifically, the [Budget] Summit agreement assumed that for single source drugs manufacturers would be limited to charging Medicaid the best price given any bulk purchaser, subject to a minimum discount of 10 percent, with savings returned to Medicaid through a quarterly rebate.").

[60] See Chevron U.S.A. v. National Resource Defense Council, 467 U.S. 837, 843 n.9 (1984).

[61] See United States v. Mead Corp., 533 U.S. 134 (1944).

[62] See Christensen v. Harris County, 529 U.S. 576, 587 (2000).

IX. CMS Should Implement the Statutory Time Limit on State Submission of Rebate Claims.

Section 1927(b)(2)(A) of the Social Security Act requires States to submit drug utilization data to manufacturers no more than 60 days after the end of each rebate period.[63] Despite this explicit statutory time limit, CMS has stated that manufacturers are obligated to pay rebates claimed by States after the 60 day period has expired.[64] CMS has never explained the basis for this requirement or reconciled this position with the explicit statutory deadline for the States. In 1995, CMS proposed a one-year time limit on a State's ability to revise its claim after the close of a rebate period, but CMS never finalized this proposal.[65] TAP asks that CMS implement the statutory deadline, or at a minimum, finalize its proposed one-year limit, and, as of the effective date of the Final Rule, prohibit States from submitting rebate claims for periods that exceed the limitations period.

CMS already has taken the position that a one-year limit for States to claim rebates is fair.[66] Such a limit is consistent with the timeframe for other provider and States responsibilities, namely the time for pharmacies to submit claims to States and for States to make payments to pharmacies. It also provides flexibility to the States that, for whatever reason, are unable to report utilization data within 60 days. There is nothing to indicate that States would have a difficult time complying with the one-year deadline, nor, as CMS recognizes, is there an incentive for them to delay. The one-year limit ensures that manufacturers are not open to liability for an extensive period of time when States fail to make timely rebate submissions, yet provides States sufficient time to seek rebates.

For all of these reasons, CMS should adopt no more than a one-year time limit on State submission of rebate claims. As the statute has always imposed a 60 day limit on State submission of claims, CMS should implement the time limit on the effective date for the Final Rule and prohibit States from submitting rebate claims for prior quarters as of that date where in excess of the time limit defined in the Final Rule.

X. CMS Should Specify a Time Frame for Review of Manufacturer Methodology Change Requests.

TAP urges CMS to specify a time frame in which it will review and resolve manufacturer requests for changes to AMP and Best Price calculation methodologies. Release 61 specifies that manufacturers must submit written requests to CMS for approval of the application of any revised calculation methodologies to prior quarters.[67] CMS has been very slow to act on these requests, if it has acted on any at all, and should identify its time period for reviewing and resolving these requests so that manufacturers can resolve their financial liability for those past quarters.

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[63] SSA § 1927(b)(2)(A), 42 U.S.C. § 1396r-8(b)(2)(A).
[64] 60 Fed. Reg. 48,442, 48,460 (Sept. 19, 1995).
[65] Id.
[66] See id.
[67] Medicaid Drug Rebate Program Release #61 for Participating Manufacturers (Aug. 29, 2003).

Impact Analysis

XI. CMS' Estimation of the Startup Burden to Manufacturers Is Grossly Understated.

The Anticipated Effects portion of the Proposed Rule includes the conclusion that the startup burden of operationalizing the Final Rule will be "minimal" and estimates that the "one-time systems upgrade" will cost each manufacturer $50,000.[68] Actual expenditures to implement the Final Rule will significantly exceed this estimate. CMS not only underestimates the cost of the "systems upgrade" but also does not take into account additional personnel costs that manufacturers will incur. TAP's expenses in preparing for implementation already have surpassed this estimate and likely will total many multiples greater. CMS should conduct industry surveys on implementation costs before making such proposals in the future to ensure that more appropriate costs estimates are known prior to issuing such far-reaching reforms.

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TAP appreciates the opportunity to comment on these important issues, and we look forward to working with CMS to ensure that beneficiaries have continued access to vital medicines. We sincerely hope that the agency will give thoughtful consideration to our comments and will incorporate our suggestions in the Final Rule. Please contact me if you have any questions regarding our comments or need any additional information.

Respectfully Submitted,

Laura Cline

Laura Cline
National Manager, Government Affairs

[68] 71 Fed. Reg. at 77,192.

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

February 20th, 2007

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

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

The National Association of Chain Drug Stores (NACDS) is pleased to submit the attached comments to the Centers for Medicare and Medicaid Services (CMS) regarding our views on the proposed regulation published on Friday, December 22nd, 2006 in the *Federal Register*. That proposed regulation would provide a regulatory definition of AMP, as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

413 North Lee Street
P.O. Box 1417-D49
Alexandria, Virginia
22313-1480

NACDS represents the nation's leading retail chain pharmacies and suppliers. Chain pharmacies operate more than 38,000 pharmacies, employ 112,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of nearly $700 billion.

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 of AMP data.

Public Release and 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.

We believe 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 could 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 these data, and we urge continued delay in the release of these data.

(703) 549-3001
Fax (703) 836-4869
www.nacds.org

AMP Definition Should be Revised to Reflect Retail Pharmacy Purchasing Costs

CMS' 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.

Sales to mail order pharmacy, nursing home pharmacy, hospital outpatient, clinic sales, and manufacturers' coupons must be excluded because these are not sales to traditional retail pharmacies. Pharmacies do not have access to the special prices offered to these classes of trade. In addition, manufacturers should not be allowed to deduct rebates and discounts paid to PBMs when calculating the AMP because those discounts and rebates do not affect prices paid by wholesalers.

Given that wholesalers and retail pharmacies do not benefit from these PBM rebates and discounts, the resulting AMP would be lower than the average prices paid to manufacturer by wholesalers for drugs distributed to retail pharmacies. For these reasons, we think this proposed definition needs to be significantly modified.

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. Without an adjustment to AMP, the posted AMPs may be outdated and may not reflect the existing prices at which retail pharmacies purchase medications.

New Generic FULs Should be Suspended

The new FULs for generic drugs proposed in the regulation – calculated as 250 percent of the lowest average AMP for all versions of a generic drug – will reduce Medicaid generic payments to pharmacies by $8 billion over the next 5 years. These cuts will be devastating to many retail pharmacies, especially in urban and rural areas.

We ask that the implementation of these FULs be suspended because these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office (GAO) found that pharmacies would be reimbursed, on average, 36 percent less for generics than their acquisition costs under the new proposed AMP-based FUL system.

If AMP data are used to set the FUL, CMS should not use the lowest AMP. We believe that CMS should use a weighted average of 11-digit AMPs for generic products that are: 1) AB-rated in the FDA *Orange Book*; 2) widely and nationally available to retail pharmacies for purchase from the major national wholesalers in adequate and consistent supplies; 3) sold in package sizes of 100's or the most commonly dispensed package size. 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 Dispensing Fees:

CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset anticipated losses on generic drug reimbursement. Fees should be increased to cover pharmacy's cost of dispensing, including a reasonable return. Without these increases in fees, many prescriptions may be dispensed at a loss, and pharmacies may have reduced incentives to dispense lower-cost generic drugs.

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

Sincerely,

Robert W. Hannan
President and CEO

NATIONAL ASSOCIATION OF CHAIN DRUG STORES (NACDS)
Comments on Medicaid Program: Prescription Drugs
CMS 2238-P RIN 0938-AO20
February 20, 2007

I. Section 447.504 – Determination of AMP

This section defines the sales that manufacturers must include and the price concessions that they must omit when calculating their Average Manufacturers Price (AMP). Appropriate calculation of the AMP depends upon several factors, including an accurate definition of the retail class of trade, an accurate identification of manufacturers' prices paid by wholesalers for drugs distributed to retail pharmacies, and an appropriate definition of wholesaler. CMS proposed definition of AMP is problematic in all three areas.

a. The Law Requires that AMP Must Include Only Prices Paid by Wholesalers

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. *Id.*

The law clearly limits AMP calculations to prices paid by wholesalers and discounts received by wholesalers. Yet, CMS proposes to require that manufacturers include in the AMP calculation prices that are not paid by wholesalers, as well as discounts on drugs that are not received by wholesalers. Only payments to manufacturers by wholesalers, for drugs that are subsequently distributed to the retail class trade, can by law be included in the AMP. Any other payments must be as a matter of law, excluded from the calculation of AMP.

The proposed rule would include many payments that have nothing to do with payments by wholesalers to manufacturers. As examples, the proposed rule would include in AMP calculation the following payments, regardless of whether the entities involved are acting as wholesalers making payments to manufacturers:

- 447.504(g)(3): Direct sales to hospitals;
- 447.504(g)(4): Nominal sales to "any entity" (with a few enumerated exceptions);
- 447.504(g)(5): Sales to retail pharmacies;
- 447.504(g)(6): Rebates, discounts and other price concessions paid to PBMs;
- 447.504(g)(7): Direct sales to patients;
- 447.504(g)(8): Sales to outpatient clinics;
- 447.504(g)(9): Sales to mail order pharmacies;
- 447.504(g)(10): Rebates, discounts and other price concessions "associated with" sales of drugs that are "provided to" the retail pharmacy class of trade;
- 447.504(g)(11): Coupons redeemed by "any entity other than the consumer" that are "associated with" sales of drugs that are "provided to" the retail pharmacy class of trade;

- 447.504(g)(12): Sales under Medicare Part D, SCHIP, SPAPs and Medicaid that are "associated with" sales of drugs that are "provided to" the retail pharmacy class of trade;
- 447.504(i): Discounts, incentives, contingent free goods, fees and "any other discounts or price reductions" that reduce the income received by a manufacturer

Because the law is clear, CMS must revise the final rule to exclude all of these sales from calculations of AMP. AMP must only reflect payments by wholesalers to manufacturers for drugs that are distributed to retail pharmacies.

CMS appears to recognize that it is not following its prior practices regarding this issue. In the preamble to the proposed rule, CMS acknowledges that for years "our position has been that PBMs have no affect on the AMP calculations unless the PBM is acting as a wholesaler...." 71 Fed. Reg. at 77179. Now, however, CMS proposes to change this longstanding position and instead include "any" price adjustments or discounts provided by manufacturers, regardless of whether those price adjustments or discounts have anything to do with the prices paid by wholesalers. *Id.* This represents a complete reversal of CMS'S longstanding interpretation of the statute, which clearly defines AMP as the prices paid by wholesalers.

CMS also appears to understand that it is not following the plain language of the statute by including payments by non-wholesalers in calculations of AMP. CMS says that "we recognize that the statute defines AMP as the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade...." *Id.* Nevertheless, CMS goes on to state that "however, in light of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such adjustments are provided directly or indirectly by the manufacturer." This newfound "Congressional intent" is not reflected in statute, and is completely inconsistent with CMS's longstanding interpretation of the statute.

This is not just an academic issue of statutory construction. CMS's new position on this issue is problematic because the it will cause AMP to have little or no relation to the prices actually paid by wholesalers, much less the prices paid by retail community pharmacies that CMS relies upon to dispense covered drugs to Medicaid recipients. Retail pharmacies do not realize many of these so-called price adjustments.

This was confirmed by a recent CBO report, when referring to manufacturer rebates paid to plans, which said: "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." (*See* CBO, Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.)

We provide additional explanations as to how other manufacturer sales should be treated with respect to inclusion or exclusion from the AMP calculation:

Mail Order Sales and Nursing Homes: When calculating AMP, manufacturers should omit sales of pharmaceuticals to wholesalers that are eventually sold to mail order pharmacies and nursing home pharmacies. Proposed §447.504(g)(9) would require manufacturers to include sales to mail order pharmacies in the calculation of the AMP. We disagree with this decision. However, we believe that CMS has made the correct decision in proposed §447.504(h)(6) to remove "sales to nursing facilities, including long term care pharmacies" from the calculation of AMP.

In justifying this action, CMS correctly indicates that because long term care pharmacies do not generally dispense prescriptions to the general public – but rather only patients of the facility – their sales should be excluded from the calculation of the AMP. We agree. This same logic, however, applies to mail order pharmacies. These 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 makes little sense 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. In general, the discounts for brand name drugs provided to mail order pharmacies are not available to retail pharmacies.

However, CMS says that it considers mail order "simply another form of how drugs enter into the retail pharmacy class of trade." Yet, CMS also recognizes that retail pharmacies may be disadvantaged by inclusion of these sales in the calculation of AMP because "retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for manufacturer price concessions." 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. This is confirmed by the CBO report which says that mail order pharmacies tend to get lower prices than conventional pharmacies for single source drugs. The report provides an example of how excluding mail order sales from the AMP calculation would increase the AMP. This confirms that including mail order sales would lower the AMP and not approximate the prices at which conventional retail pharmacies purchase medications.

Moreover, given that there is relatively no distribution of Medicaid prescriptions through mail order, including these sales and rebates would create a benchmark that would be of little use to state Medicaid directors to set reimbursement rates for retail pharmacies.

Sales to Other Outpatient Channels: Sales to hospitals and outpatient clinics should be omitted given that these entities do not fall within the definition of a traditional retail pharmacy, even if these drugs are dispensed at outpatient clinics. 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 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 net 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 be law be included in the AMP because they do not reflect priced paid by wholesalers to manufacturers for drugs distributed to the retail class of trade.

PBM Rebates: There is wide documentation in government agency reports (OIG and GAO) that manufacturers have not been consistent in how they have handled PBM rebates in the calculation of the AMP. 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; February 2005). 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 its AMP. (*See* CMS Manufacturer Labeler Release #28, April 1997.) That release said 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 the policy that has been in effect for many years 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. 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". Manufacturers can only include prices paid by wholesalers in the calculation of AMP.

Today most prescriptions are paid for through a third party entity – such as a PBM – that receives rebates and discounts from pharmaceutical companies. Moreover, these purchasers receive discounts, rebates and price concessions that are not available to traditional retail pharmacies, such as market share movement and formulary placement discounts. These discounts are either retained by the PBM, or passed through in whole or part by the PBM to the payer. Manufacturers should not deduct these amounts when calculating the AMP because PBM price concessions are not payments by wholesalers, and retail pharmacies do not receive these price concessions.

Including PBMs' sales and discounts unfairly lowers the AMP, making it unreflective of sales to retail pharmacies. This fact was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies." (*See* CBO, Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.)

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.

To demonstrate how dramatic the impact of the inclusion of PBM rebates would have on deflating the AMP, a recent CBO report indicated that, in terms of the financial transactions in the pharmacy supply chain, "the manufacturer keeps the amount paid to it by the wholesaler (roughly the AMP) minus any rebates paid to the PBM." According to a 2005 Federal Trade Commission (FTC) report on the PBM industry, the average payment made by manufacturers to PBMs is about $6 per prescription (*See* Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies*, August 2005.) So, using this average payment, a product with an AMP of $80 (the price paid by the manufacturer to the wholesaler) would be reduced by $6 under the CMS definition to $74. The AMP would be $74 under the CMS definition, but should in reality be $80.

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 than rebates provided under Section 1927.) Manufacturers don't sell drugs to these programs directly. They sell drugs to wholesalers and retail pharmacies that dispense these drugs to enrollees of these programs. Retail pharmacies are then paid by these respective programs for the drugs they dispense.

Thus, in theory, manufacturers' sales of drugs to wholesalers who sell 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 federal law provides that only payments by wholesalers to manufacturers can be included in AMP calculations.

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). However, rebates paid by manufacturers to PPOs benefit the PPO, not the pharmacy. CMS should be well aware of how the financial transactions flow in Part D, and rebates paid to Part D plans by manufacturers are supposed to be passed through to the beneficiaries, not to the retail pharmacies.

We also do not believe that manufacturers should be able to back out SPAP price concessions, or rebates and discounts associated with the SCHIP program. Like PBM rebates in the private sector, these rebates, discounts and price concessions have nothing to do with the prices paid by manufacturers to wholesalers for drugs distributed to retail pharmacies. In addition, just like retail pharmacies do not benefit from discounts and rebates that manufacturers pay to PBMs in the private, commercial market, retail pharmacies do not benefit from price concessions paid to government-funded programs. CMS is well aware that Medicaid rebates – which are correctly excluded from the definition of AMP – are paid to states, not retail pharmacies. Similarly, manufacturer rebates paid to SPAPs and SCHIP programs are paid to states or are paid to the plan sponsors, not retail pharmacies. It is inconsistent for Medicaid rebates to be excluded from the calculation of the AMP, but not rebates paid in a similar manner by manufacturers to other state-funded programs.

We also urge that the final rule exclude manufacturers' sales to wholesalers for drugs distributed to retail pharmacies that are located in territories of the United States such as Puerto Rico. While these jurisdictions are considered part of the United States, they may have drug pricing systems that do not resemble that of the 50 states and the District of Columbia. While sales in these jurisdictions are admittedly small compared to the rest of the United States, including these sales could distort the true value of the AMP.

b. The Proposed Rule Incorrectly Defines "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 approximates the "true market price for prescription drugs" paid for by the real provider of Medicaid outpatient drugs: retail community pharmacies.

State Medicaid programs pay traditional retail community pharmacies for the overwhelming majority of covered outpatient drugs provided to Medicaid recipients. Therefore, it stands to reason that AMP data, which will be used to calculate reimbursement rates for those retail community pharmacies, should be based only on sales of drugs dispensed by those retail community pharmacies. It is illogical and counterproductive to based Medicaid reimbursement rates for community pharmacies on sales of drugs that are not dispensed by community pharmacies.

Therefore, the "retail class of trade" should be defined as including only traditional community retail pharmacies. Only the community pharmacies that dispense outpatient drugs to Medicaid recipients - traditional chain pharmacies, independent pharmacies, mass merchandise pharmacies, and supermarket pharmacies – should be considered the "retail class of trade." Given that AMP will be used to calculate reimbursement rates for Medicaid outpatient drugs, and given that virtually all of those drugs are dispensed by retail community pharmacies, it makes sense that the "retail class of trade" should be defined to include only retail community pharmacies.

CMS's definition of retail pharmacy in this proposed regulation is inconsistent with that used in the Medicare Part D prescription drug program final rule. (*See* 42 CFR 423.100). 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." 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 community pharmacies represent the "retail class of trade" for the purpose of calculating the AMP.

Moreover, in conducting an audit of the Medicaid rebate program in 1997, OIG defined the retail pharmacy class of trade as only independent and chain pharmacies that sold drugs directly to the public. (*See* OIG: Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs, May 1998). OIG had recommended that CMS ask the manufacturer to exclude from the calculation of AMP transactions that OIG determined were to non-retail entities such as mail order pharmacies, nursing home pharmacies, independent practice associations, and clinics. It is clear that OIG has recognized that the definition of retail class of trade should not be as expansive as proposed by CMS.

c. Scope of Discounts Included in AMP Must be Narrowed

Manufacturers are, by law, required to calculate AMP without regard to customary prompt pay discounts extended to wholesalers. Prompt pay discounts are generally considered to be a form of cash discounts. However, manufacturers are required to include cash discounts when calculating AMP. It is important for CMS to clarify in the final regulation that these types of cash discounts – that is customary prompt pay discounts – can not be deducted by the manufacturer from AMP. For that reason, we recommend that CMS include a definition of "cash discounts" that would be defined as not including "any discount off the purchase price of a drug offered by the manufacturer to a wholesaler for prompt payment of purchased drugs."

In addition, there are certain payments made by manufacturers to pharmacies that should not be deducted from the AMP because they reflect concessions relating to the "time value of money" or payments for services performed by the pharmacy on behalf of the manufacturer. These payments are not discounts or rebates off the actual drug product.

In addition to customary prompt pay discounts, these include bona fide service fees, payments for pharmaceutical returns, and payments for patient care programs. Likewise, only incentive-based discounts, rebates or other price concessions that are ultimately passed through to retail community pharmacies through wholesalers should be deducted by the manufacturer in calculating the AMP.

d. Definition of Wholesaler Must be Narrowed

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 Federal and state statutes and regulations that define wholesalers.

Only entities that are licensed by states as wholesalers should be considered wholesalers for the purposes of this final regulation. 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 further 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, PBMs do not perform wholesaling functions either. In fact, most PBMs are administrative service organizations that contract with health plans and other entities to provide prescription drug benefits. Pharmacies do not buy drugs from PBMs like they buy them from wholesalers.

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. Only prices paid to manufacturers by wholesalers can by law be included in AMP. PBMs should not be considered wholesalers.

We urge CMS to adopt a more limited, 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.

Chains pharmacy distribution centers are generally licensed as wholesalers in the states in which they are located. This is important because manufacturers are, by law, allowed to calculate AMP without regard to customary prompt pay discounts extended to wholesalers. Chain pharmacy distribution centers should be eligible for the same customary prompt pay discounts as traditional pharmaceutical wholesalers.

- 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.

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NACDS does not support an 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." We support the exclusion of returned goods from the calculation of AMP when returned in good faith. However, we urge that the term "pursuant to manufacturer policies" be removed from the definition. That is because the final regulation should account for return goods policies that are negotiated in good faith 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 could be voiding by default these negotiated return goods and could be forcing retail pharmacies to accept manufacturers' policies and their inherent deficiencies.

Such action ignores the fact that retail pharmacies 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: NACDS recommends 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 "unit of use" quantities in a highly efficient manner), that would otherwise have to be performed individually by retail pharmacies. Retail pharmacy service repackaging is performed in a central location by wholesalers on behalf of retail pharmacy operators.

This repackaging has allowed manufacturers to continue to use the original manufacturers' NDC number on the repackaged drug, rather than that of the repackager. In many cases, the wholesale repackager may not even have its own NDC, necessitating that the originator's number be used.

This type of repackaging is done so that the repackaging of thousands of "unit of use" quantities for distribution to patients does not have to occur in thousands of individual retail pharmacies. This increases the efficiencies of prescription dispensing for retail pharmacies, and reduces the chance for misfiling of prescriptions that might occur as a result of a pharmacist having to repackage additional unit of use quantities of drugs. For that reason, we urge that a wholesaler be permitted to repackage or relabel a drug, without being defined as a manufacturer, when it is acting as a retail pharmacy service repackager.

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.

II. Section 447.506 – 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 is 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 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. We urge that any AMP website include a specific AMP value for the originator brand and the authorized generic.

III. Section 447.510 – Requirements for Manufacturers

a. 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 (i.e. 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.

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." This appears confusing, given that it sounds like a manufacturer still has the ability to revise its monthly AMP 30 days after reporting its monthly AMP. This should not be the case and needs to be clarified.

We are concerned that proposed §447.510(d)(2) would allow manufacturers, when calculating monthly AMP, 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. There are other more credible and auditable approaches that would result in potentially more accurate AMPs.

b. <u>Adjust AMPs to Reflect Lag in Data Reported</u>

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 <u>current</u> 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.

c. 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 likely already going to be a confusing situation. The DRA requires that CMS update the public website on a quarterly basis. 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? Moreover, CMS indicates that it will also be publishing a quarterly AMP value.

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? If the AMP website is supposed to give the public a general idea of the current prices paid by retail pharmacies for medications (assuming that CMS fixes all the fundamentally flawed definitions in this proposed regulation), then releasing the last month's AMP data for the quarter would appear to be sufficient.

Moreover, CMS must include special disclaimers and instructions on this website so that individuals viewing the data on 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.

d. Continue to Delay Public Release and Use 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 could have a negative impact on patient access, if the resulting reimbursement rates are so inadequate that pharmacies are forced to close. Some may individually decide that they can no longer afford to participate 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.

In the recent past, 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, the CMS Administrator, Mark B. 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." *(See* Remarks of Mark B. McClellan, NCPA 38th Legislation and Government Conference (May 22, 2006). 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 promised not to release. While DRA made some modest changes to the calculation of the AMP, there would still be wide-ranging documented inconsistencies in that data which would render them useless to states and potentially damaging to retail pharmacies.

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." 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." (*See* OIG, *Determining Average Manufacturer Prices For Prescription Drugs Under The Deficit Reduction Act of 2005*, May 2006).

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. 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.

With respect to generic drugs, CMS should only publish an AMP value for a particular dosage form and strength of a generic drug that represents the weighted average of all the 11-digit AMPs for the manufacturers' 100-count retail package sizes of that particular dosage form and strength of the drug (or the one that is most commonly dispensed by retail pharmacies) that are widely and nationally available for purchase by community retail pharmacies. This would eliminate the need to report the 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.

e. Limit Release of AMP Data to Assess Validity

Finally, only a limited number of AMPs should be publicly reported initially to allow the marketplace to assess the validity of the data. Given the potential for AMP data to have implications throughout the supply chain, it behooves CMS to be cautious in how it releases any data. Irreparable harm could be done to industries in the pharmacy distribution supply chain. We urge that CMS interact with the affected industries first before publishing any AMP data.

As an example, the MMA required CMS to use ASP as the basis for Part B drug reimbursement beginning in January 2005. However, CMS required manufacturers to report several quarters of ASP data and published some of these data before implementing the ASP approach. This allowed for necessary public comment on this new and unknown approach for reimbursing physicians and pharmacies for Part B medications.

Before publishing AMP data, CMS must also determine how it will account for the lag from the time that the manufacturers report AMP data to the time that it is reported by CMS. Without such an update, the AMP values that are reported will not reflect the approximate prices at which retail pharmacies purchase medications.

IV. Section 447.512 – Drugs: Aggregate Upper Limits of Payment

Proposed §447.512 would specify that states could not exceed the FULs in the aggregate, and would specify when an FUL would not apply relative to the dispensing and payment of an innovator multiple source drug. CMS indicates that it will set FULs based on the AMP data reported by manufacturers after January 1, 2007 because it will reflect DRA changes such as the omission of prompt pay discounts by manufacturers. However, these AMP data lack consistency in how they are being calculated and reported by manufacturers. They may likely be no more accurate or appropriate to use than the generic reimbursement benchmarks that are in public use. Therefore, the current AMPs should not be used to set the FULs.

a. Suspend Implementation of AMP-Based FULs

In general, NACDS believes that the FUL reforms mandated under the DRA be suspended until Congress is given the chance to revisit the use of AMP as a benchmark to set these FULs. A recent GAO study basically confirmed that retail pharmacies will be significantly underpaid for multiple source drugs if 250 percent of the lowest AMP is used to set FULs.

Suspension of the FULs would be consistent with Congressional intent. In a "Dear Colleague" letter that then House Speaker Dennis Hastert sent to Members of the House in February 2006, 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." Clearly the Congress that enacted the DRA believed that it should not move forward if the payment rates did not reflect pharmacies' acquisition costs. The GAO report has proven that to be the case.

In fact, that GAO report found that for a select market basket of high expenditure, high volume multiple source drugs, using 250 percent 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 percent 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 percent) 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 percent 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 percent 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 percent 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 percent in 2007, 51 percent in 2008 and 67 percent 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.

b. Allow for Electronic Certification of Brand Name Drugs

NACDS asks that CMS clarify proposed §447.512(c)(1) such that a physician has the option to override the dispensing of a generic drug if the physician certifies through electronic means that a brand is medically necessary. This authority would be provided in addition to the current policy that allows a physician to override the dispensing of a generic through "his or her own handwriting." There is a significant increase in the number of prescriptions that are being transmitted to pharmacies electronically. For that reason, it is critical that the state be permitted to be able to obtain Federal matching funds for a brand drug prescription where the physician has certified through a credible electronically-transmitted prescription that a brand is medically necessary.

We also ask that CMS clarify that the physician can indicate in various ways that a brand product is medically necessary, not just through the use of the term "brand medically necessary." States have various laws and regulations relating to how a physician can block generic substitution and require the dispensing of a brand name drug. Some states use "brand medically necessary", others use "no generic substitution", while others use different phrases. CMS should allow states to use their own distinct phrases on written or electronic prescriptions to block generic substitution.

Pharmacies should not be penalized for dispensing a brand name drug to Medicaid recipients where it was the clear intent of the physician to do so, even if the physician did not use the exact term "brand medically necessary." This option appears to be available to states given that the proposed regulation indicates that "...a notation like brand medically necessary is allowable" However, we ask that it be clarified in the final regulation.

c. <u>Dispensing Fees Should Cover All Pharmacy Costs and Provide Reasonable Return</u>

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.

- In his May 12th, 2006 letter to HHS 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." In another colloquy, Senator Grassley indicated "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 Joe Barton (R-TX). 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..." *(See* Hearing of the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, December 7, 2004, opening statement of Chairman Joe Barton).

When new Federal Upper Limits (FULs) are phased in this spring, most 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."[1] (*See* 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.[2]

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. This amount varies by state. (*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. 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 BLS pharmacist wage index – because pharmacy labor costs, which account for about 75 to 80 percent of the average pharmacy's cost of dispensing, are increasing each year.

Increasing dispensing fees will not threaten the budget savings forecasted by the Congressional Budget Office (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 (*See* 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 SPAs that simply decrease payment for the reimbursement paid to pharmacies for the ingredient cost component without making increases to the dispensing fee.

With respect to the definition of "dispensing fee, found at proposed §447.502, NACDS believes that the definition of "dispensing fee" in the proposed regulation is overly restrictive. To accommodate any future costs that pharmacies might incur in dispensing prescriptions to Medicaid recipients, we agree that the terminology "includes, are not limited to" should remain in the final definition. However, it should be made clear to states that they can provide a reasonable margin or profit to pharmacies when determining a reasonable dispensing fee. Pharmacies can not 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 the state 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 MTM services. States should not be discouraged from paying for these services because of an overly restrictive definition of dispensing fee as proposed in the regulation.

d. Eliminate Ability for States to Promote Brands rather than Generics

We are concerned that some states are promoting the use of brand name versions of generically-available drugs because they are receiving rebates from branded manufacturers that lower the net cost of the brand to that of the generic. While this may be viewed by some as "pro competitive", the growth of this practice has potential negative implications for generic drug use in Medicaid. We encourage CMS to prohibit states from engaging in this practice because it can discourage the overall availability of generic drugs in the marketplace.

If generic manufacturers cannot gain access to the Medicaid market in states because of these brand name manufacturers' practices, it could discourage generic manufacturers from legally challenging the patents on brand name drugs. This could reduce the availability of generics in the marketplace in general, and for the Medicaid market in particular. Whatever short term gain this might bring to states, it could end up increasing long term Medicaid prescription drug costs.

V. Section 447.514 – Upper Limits for Multiple Source Drugs

Proposed §447.514 would specify the procedures by which CMS would establish and issue a list of FULs for multiple source drugs, specify the upper limits, and assure that a drug is available for sale nationally when determining such FULs.

a. Identify Reference Product Used to Set FUL

Proposed §447.514(a) describes the criteria by which CMS would determine whether a multiple source drug product should have a FUL. The DRA changed 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 FDA *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 an 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 an 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 an FUL should be set.

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 an 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.

b. Establish FULs Based on Weighted Average AMPs

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 percent of the average manufacturers' price..."for the least costly therapeutic agent." However, DRA does not specify that the FUL must be set at 250 percent of the lowest AMP, as the rule would propose. DRA merely changes a section of the current regulation found at section 447.332(b) which indicates that "250 percent of the average manufacturers price (as computed without regard to customary prompt pay discounts extended to wholesalers)" shall be substituted for "150 percent 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 percent 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 would require that manufacturers report sales volume of their generics, as is done in the calculation of the ASP under Medicare Part B.

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 percent. Even when GAO calculated AMP-based FUL rates using 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 percent of the weighted average AMPs (based on 11-digit NDCs) for the 100's package sizes or the package sizes most frequently dispensed by community retail pharmacies.

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 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 didn't intend that the AMPs be calculated at the 11-digit level for generic drugs in order to determine the FULs.

We believe that CMS should use an 11-digit weighted average 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 amended 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 which may be bought 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 the FUL. In order to encourage continued generic drug dispensing in Medicaid, it is critical that the FUL be based on prices for products that are currently nationally and widely available in the marketplace.

For example, 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 reference AMP.

Unit dose products, larger bulk package sizes (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 nationally available and in consistent supply, by contacting the manufacturers of these products on a regular basis, or the national wholesalers that stock them.

We 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. That is because 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 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 percent 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 percent 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 an 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.

Moreover, 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. This will result in the same inconsistencies in the calculation of AMP that exist today. 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 and states 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 an 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.

VI. State Plan Amendment Requirements: Findings and Assurances

Proposed §447.518 describes state plan requirements relating to the payment of prescription drugs. We believe that the state plan amendment process must be more deliberative and transparent than the process that has been used to date by states to make changes in their payment methodology. States need to be more diligent and transparent in providing public notice about reimbursement methodologies, and substantiating the impact that the changes could have on Medicaid beneficiaries' access to retail pharmacies.

We agree that states should report to CMS annually on their spending for multiple source drugs and triennially for other drugs. However, the state plan and any amendments should also be accompanied by important justification of why changes are being made and how such changes will impact utilization of generic drugs and affect Medicaid beneficiaries' access to pharmacies.

Each state plan should describe in detail how the state will set payment rates for multiple source drugs. While many states use the FULs as their payment limits, other states adopt other methodologies, such as maximum allowable cost (MAC) programs. States often set these MACs without any public review of the process, or adequate notice to providers of the drugs that will have MACs, how the MACs will change, or the data sources used.

In the interest of transparency in pricing, this information should be required by CMS to be part of the state plan. Because generic payment policies are critical to assuring the maximum use of generics, CMS should require that states provide this information relating to these MAC programs within three months of the final regulation's effective date, and that providers have a chance to review these MAC program details through a public comment process. Any time that changes are made, CMS should review the changes to assure that they are consistent with the objective of promoting the use of multiple source drugs.

With respect to the recordkeeping requirements at proposed §447.518(c), CMS should also require that states justify their dispensing fee changes – whether increases or decreases – by providing credible dispensing fee studies based on data from a representative sample of retail pharmacies that operate in the state. States should not be able to change fees based solely on dispensing fee amounts paid by other neighboring states or amounts that pharmacies might accept from other third party plans. Each state has its own unique cost of doing business, and each third party plan has its own unique cost of doing business. For these reasons, state Medicaid dispensing fees should be based on the pharmacies' costs of dispensing Medicaid prescriptions.

VII. Regulatory Impact Analysis

The regulatory impact analysis of the proposed rule suggests that the proposed generic drug payment reductions will have a small impact on the "great majority" of retail pharmacies. The main conclusion is that the anticipated effect on retail pharmacies will be less than one percent of revenue, on average, and that this impact is potentially even smaller when potential increases in non-prescription sales are considered.

The analysis also concludes that the proposed rule may have a significant impact on "small" pharmacies, particularly those in low-income areas, but fails to quantify the impact on pharmacies. This analysis demonstrates a lack of understanding of the pharmaceutical and pharmacy marketplace on many different levels, and the likely reaction of the entities that comprise the pharmacy supply chain.

a. Analysis Substantially Underestimates Financial Impact to All Retail Pharmacies

We believe this analysis seriously understates the potential financial impact on retail pharmacies. Fully $8 billion out of the $8.4 billion in the proposed regulation's budgeted Medicaid savings (2007-2011), or 95 percent, comes from cuts in generic drug reimbursement to retail pharmacies. While CMS measures the economic impact to retail pharmacies in terms of a reduction in gross revenues, it is more appropriate to measure the impact in terms of a reduction in margins or profits.

As CMS points out, the analysis also does not take into account the additional impact to pharmacies from a decrease in state payments for drugs which are not on the FUL list, and the impact on pharmacies if states start to use AMP as a reimbursement mechanism for brand name drugs. The regulatory impact analysis section admits, "States may use AMP and Retail survey prices in their payment methodologies. The savings for section 6001 of the DRA do not reflect decreases to State payments for drugs not on the FUL list." (See 71 *Fed Reg* 77191.)

Because of the time lag in the calculation and reporting of AMP, brand name drug prices will likely always be higher than AMP, meaning that pharmacies will be underpaid if AMP is used. Moreover, the analysis fails to account for the fact that CMS proposed definition of AMP, if adopted, would not even approximate retail pharmacy acquisition costs. The proposed definition includes prices and discounts that are not available to retail pharmacies.

We are concerned that these inaccuracies and omissions in doing this regulatory analysis have led CMS to the erroneous conclusion that the impact on retail pharmacies will generally be insignificant. For these reasons, we believe that CMS must substantially revise the Impact Analysis to reflect: (i) the projected impact of the use of AMP as a reimbursement benchmark instead of AWP in the Medicaid and commercial marketplace for brand name and generic drugs other than those subject to the FUL; (ii) the projected impact of the lack of currency of the AMP benchmark and the fact that AMP as proposed would understate pharmacy purchasing costs; and, (iii) the distinction between the impact on pharmacy profits versus pharmacy revenue, so that the impact on the latter is not understated.

In conducting its analysis, CMS cites NACDS statistics estimating that there were sales of $230 billion in pharmaceuticals at retail pharmacies in 2005. It then trends forward this amount to over $300 billion in sales by 2011 by assuming five percent annual growth. Comparing this amount to the estimated $2.1 billion savings in 2011 arising from the planned cuts in retail pharmacy reimbursement for multiple source drugs, CMS concludes that the economic impact on pharmacies of the proposed rule is "less than one percent of total revenues".

One problem with this measure is that $230 billion in 2005 is not the appropriate baseline for these calculations. This amount includes mail order sales, but there is almost no mail order use in Medicaid. The baseline should reflect only sales at *community-based* retail pharmacies. The NACDS data cited by CMS indicate that mail order sales were 19.1 percent of the $230.3 billion in total retail sales in 2005. Community-based retail sales were $186.3 billion in 2005. Projecting to 2011 using five percent annual growth, total community-based retail pharmacy sales would be about $250 billion in 2011.

In addition, while CMS measures the impact in terms of a loss of pharmacy revenue, the actual impact on pharmacies falls directly to the bottom line – that is, margins or profits. Cuts to reimbursement paid to pharmacies do not change the prices that pharmacies must pay to wholesalers or manufacturers to acquire products, nor do they change the costs that pharmacies incur to staff and operate stores convenient to patients. A significant percentage of a pharmacy's revenue is needed to cover these costs of purchasing, maintaining, and dispensing its pharmaceutical inventory. As a result, the $800 million decrease in 2007 and $2 billion decrease annually by 2011 will be decreases in profits, not revenues.

The 2005 NCPA-Pfizer Digest reports that independent pharmacy owner's discretionary profit was 7.4 percent in 2004. Taking out owner compensation, net profits were about 3.6 percent. Similarly, NACDS estimates that the average retail pharmacy net profit per prescription is about 2.8 percent. Assuming a net profit margin of 5 percent, a $2.1 billion decrease in annual profits in 2011 actually translates to a $42 billion decrease in revenue. Considering that total pharmaceutical sales are estimated to be $250 billion, this would equate to a nearly 17 percent decrease in revenues – by no means an insignificant change.

A key shortcoming of the proposed rule is that it fails to account for additional changes to pharmacy reimbursement by states and other payers once AMP data are published on a public website. Such changes are clearly the government's intent in providing AMP data to states on a monthly basis, posting it on a public website, and producing reports that will compare pricing among states. Therefore, the impact analysis omits what may be a far more significant and profound financial impact on pharmacies due to this proposed rule, rendering the impact analysis misleading at best.

If new AMP-based pricing were to decrease reimbursement to pharmacies by 1 percent overall, that would be a loss of over $3 billion in 2011 alone based on CMS projection of more than $300 billion in total drug sales at retail pharmacies. Using the lower NACDS-estimated figure of $250 billion in total drug sales at community-based retail pharmacies (i.e., excluding mail order), the impact would be $2.5 billion in 2011 and more than $9.2 billion from 2008-2011.

CMS also fails to estimate the impact of lost rebate revenues to states as a result of the proposed definition of AMP. The proposed definition of AMP – which would make it a standard practice for manufacturers to include PBM rebates in their AMP calculations – will invariably lower AMP for many drugs. This will reduce the rebates paid by manufacturers for these drugs to the extent that other changes in the "best price" calculation do not affect these manufacturer rebate liabilities.

b. Analysis Fails to Estimate Impact on Generic Drug Use

The economic impact analysis indicates that the $8.4 billion in savings from Medicaid's pharmacy benefit represents 5.6 percent of projected drug spending. Based on these data, it can be derived that CMS projects roughly $150 billion in total Medicaid pharmacy expenditures over the 2007-2011 budget period before these cuts.

However, the $8 billion in savings comes from cuts in reimbursement for multiple-source (generic) drugs. Dispensing of off-patent brands is relatively rare in Medicaid programs. When these products are dispensed to Medicaid beneficiaries, they are likely to be paid above the FUL due to a "dispense as written" designation. Therefore, the $8 billion in savings is likely to be taken entirely from reimbursements for generic drugs.

In 2006, generics accounted for about 18 percent of Medicaid spending for prescription drugs. Carrying this percentage forward, Medicaid would spend about $27 billion for generics over the entire 2007-2011 budget period (18 percent of $150 million). Savings of $8 billion out of $27 billion in spending for generic drugs equates to a 30 percent reduction in reimbursement for generic drugs.

A reduction of this proportion will have a considerable impact on incentives to dispense generic medications where pharmacies have a choice. Rather than a system where pharmacies gain equal or greater revenue from dispensing a generic instead of a brand-name drug, the pharmacy will receive far less revenue from a generic. CMS cannot ignore the perverse incentives that it is establishing in this program that could discourage the dispensing of generic drugs.

c. Rule Will Adversely Affect Many Retail Pharmacies

Requirements for federal rulemaking stipulate that agencies report on the potential effects on "small business." For the purposes of the rule, a small pharmacy is defined as one that receives less than $6.5 million in average annual receipts. The rule indicates that roughly 18,000 pharmacies meet this definition. CMS concludes that the proposed rule may have a significant impact on some small, independent pharmacies.

The proposed rule will have a significant impact on many more pharmacies than this statement suggests. A large number of pharmacies – even those that are part of retail chains – operate much like small businesses. Like an independent pharmacy, each pharmacy in a multiple-location company must generate enough revenue to cover its costs of purchasing, maintaining, and dispensing its pharmaceutical inventory. A chain pharmacy that does not cover its own costs is not likely to remain open for long. The average total sales in traditional pharmacies are about $4.5 million per year. Chain-operated stores have a higher average per store ($6.2 million) compared to independent stores ($2.4 million), but overall many small chain-operated stores are not significantly different at an individual store level than independent pharmacies.

All pharmacies have some percentage of Medicaid business, averaging about 8 to 9 percent. Many in urban and rural areas have a much higher percentage of Medicaid, some with half of their prescriptions paid for by Medicaid. The use of AMP, however, by payers other than Medicaid could have a significant negative economic impact on all retail pharmacies, given that third party prescription sales represent over 90 percent of the average retail pharmacy's business. If these payers use a government-sponsored benchmark that is inaccurate and outdated, it could cause irreparable economic harm to many pharmacies, maybe forcing many to close.

Rural pharmacies may be particularly hard hit by this rulemaking. Data from a recent nationwide survey found that Medicaid accounted for approximately 12 percent of all prescriptions filled by rural pharmacies. (*See* Grant Thornton LLP, "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies" (January 2007). A reduction in beneficiary access to prescriptions in rural areas could result in higher costs for other Medicaid services, such as hospitalizations, physician office visits and emergency room visits.

d. Limited Ability to Compensate for Lost Revenues with Non-Prescription Sales

With regards to the impact of the proposed regulation on pharmacy revenues, CMS claims that "actual revenue losses would be even smaller" than their projections. One reason cited is that sales of other merchandise ("front end" sales) help offset these losses. CMS states that, "almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as pharmacy sales." This statement is incorrect. The data cited by CMS and posted on the NACDS Web site (www.nacds.org) show that pharmacy sales are, on average, 78 percent of total retail sales in traditional chain and independent drug stores.

In 2005, total pharmacy sales in these stores were $136.3 billion, including $94.4 billion for traditional chain drug stores and $41.8 billion for independent pharmacies, while their combined total retail sales were $174.2 billion. For traditional chain drug stores alone (that is, excluding independent pharmacies) pharmacy sales average 72 percent of total retail sales ($94.4 billion in pharmacy sales divided by $131.7 billion total retail sales). Clearly, front-end sales are a *minority* of total sales in most retail pharmacies, not "twice as much" as pharmacy sales as CMS claims.

Although not shown on that Web page, NACDS has also determined that:

- Pharmacy sales average 62 percent of total retail sales across all types of pharmacies when weighted by the number of pharmacies of each type. This measurement is the only credible way to compare pharmacy sales to retail sales regardless of the type of store.
- For independent drug stores, pharmacy sales average 98 percent of total retail sales.
- Pharmacy sales are a smaller percentage of sales at grocery (13 percent) and mass merchandise stores (7 percent), but these types of stores account for less than one-quarter of all community-based retail pharmacies in the United States.

It is unlikely that most retail pharmacies can make up pharmacy sales losses with front end sales. The marketplace for the products sold in pharmacy front ends is much more competitive and margins on these can be particularly small. Pharmacies cannot simply force consumers to purchase more front end items. *Fortune Magazine* reports that profits as a share of total revenues average less than 2 percent among the largest food and drug stores in the country, reflecting these smaller margins.

The report measures costs including prescription department salaries and benefits, other prescription department costs (e.g., containers and pharmacy supplies), and facilities and other costs (e.g., rent, utilities, computer systems). State-specific averages range from $8.50 in Rhode Island to $13.08 in California.

All of these averages give more weight to higher volume pharmacies that fill larger numbers of prescriptions and which tend to have lower costs per prescription as a result of that volume. The nationwide average increases to more than $12 per prescription when all pharmacies are given equal weight in computing the average. Nevertheless, CMS does not require nor even suggest in the proposed rule that states should consider increasing their dispensing fees. Medicaid dispensing fees are, on average, about $4.50 nationally, far below pharmacies' actual costs of providing services.

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PhRMA

February 20, 2007

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

FEB 20 2007

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

Re: **Comments on Proposed Rule Related to the Medicaid Drug Rebate Program, CMS-2238-P**

Dear Acting Administrator Norwalk:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit the following comments regarding the proposed rule to implement provisions of the Deficit Reduction Act of 2005 (DRA) that was published by the Centers for Medicare and Medicaid Services (CMS) in the *Federal Register* on December 22, 2006.[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

PhRMA appreciates the efforts of CMS to clarify terms and concepts that are essential to the smooth and efficient operation of the Medicaid Drug Rebate program, and to manufacturers' ability to calculate Average Manufacturer Price (AMP) and Best Price accurately. The specific guidance set forth in the rule will be helpful to manufacturers' important pricing calculations. While some issues require additional clarification and some issues should be revised to more appropriately reflect statutory intent, we appreciate CMS' rulemaking. To assist the Agency with this endeavor, PhRMA respectfully offers the following comments.

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

I. Determination of AMP - Section 447.504

A. Retail pharmacy class of trade generally

AMP is defined by statute 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."[2] While CMS has issued guidance previously regarding the definition of AMP in the Medicaid Rebate Agreement, certain Medicaid Rebate Releases, and proposed rules, it has not defined the term "retail pharmacy class of trade" or provided a comprehensive listing of which entities fall inside and outside the retail pharmacy class. In the DRA, Congress recognized the need for clear and consistent guidance concerning the definition and calculation of AMP, by directing CMS to "promulgate a regulation that clarifies the requirements for, and manner in which, [AMPs] are determined under Section 1927 of the Social Security Act," taking into consideration the recommendations of the HHS Office of Inspector General (OIG).[3]

We applaud CMS' efforts to define the term AMP, the phrase "retail class of trade" and to provide guidance on what sales are included in and excluded from AMP. While we will discuss certain specific issues below, CMS has gone a long way in providing the much needed clarity that has been recommended and requested by the Government Accountability Office (GAO), OIG and stakeholders. In particular, PhRMA believes that the definition of retail class of trade which includes a specific list of entities and also a broader "catch all" to include any "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*" is appropriately detailed and will give manufacturers greater clarity in the future. At the same time, including the broader "catch all" gives the rule sufficient flexibility that will appropriately accommodate changes that may emerge in the pharmaceutical distribution marketplace in the future.

Retail is generally defined as "the sale of small quantities directly to the ultimate consumer."[4] In defining AMP with respect to the "retail pharmacy class of trade," PhRMA believes that Congress intended for multiple entities beyond the traditional walk- in retail pharmacy to be included. Therefore, it is appropriate that CMS defines the "retail class of trade" to include specifically those entities that fall into such category today (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, and PBMs that provide drugs to the general public[5]) as well as a broader approach that is function-based. A function-based

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[2] Social Security Act (SSA) § 1927(k)(1).

[3] DRA § 6001(c)(3)(B).

[4] Merriam-Webster Online Dictionary.

[5] CMS should confirm that closed mail order pharmacies that do not serve the general public, such as the TRICARE Mail Order Pharmacy are not included in the definition of retail class of trade.

definition can take into account other entities that fit the category but also serve other functions in other instances, or that have not yet emerged in the pharmaceutical distribution chain.

Except as specifically discussed below, we agree with CMS's classifications of various sales to retail entities as included in AMP irrespective of whether the payor is a government payor or a commercial payor but where those sales would be treated differently for Best Price purposes, i.e., Part D, State Children's Health Insurance Program (SCHIP), and state pharmaceutical assistance programs (SPAPs). Other items listed reflect or clarify previous guidance, such as PBMs, and sales to outpatient clinics, and we appreciate the specificity and clarity. However, we note that a number of other entities to which manufacturers have direct or indirect sales are not expressly listed and it would be helpful to have CMS clarify the status of these entities as in or out of the retail class of trade: prisons, physician offices and hospices.[6]

B. Sales, rebates, discounts, or other price concessions included in AMP

PhRMA appreciates the specific listing of sales, rebates, and discounts that are included and excluded in AMP. In response to CMS' invitation to comment on a number of issues and in order to clarify a number of other issues, we offer the following recommendations.

1. Outpatient pharmacy

In the rule CMS has proposed that sales of drugs to hospital outpatient pharmacies be included in AMP calculations. PhRMA requests that CMS clarify its rationale for finding that hospital outpatient pharmacies dispense drugs to the general public. In addition, PhRMA notes that manufacturers may not know whether the drugs sold to hospitals will be used in the inpatient setting, which is outside of the retail pharmacy class of trade, or dispensed through the hospital's outpatient pharmacy. PhRMA recommends that CMS confirm that manufacturers are permitted to exclude from their AMP calculations sales to hospitals where the manufacturer does not know in which setting the drug will be dispensed.

2. Bundled sale

The proposed rule would define a "bundled sale" as an arrangement "under which the rebate, discount or other price concession is conditioned upon the purchase of the same drug or drugs of different types [at the 9-digit NDC level] or some other performance requirement (e.g., the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been

[6] There are a variety of different arrangements in the pharmaceutical distribution chain and it may be necessary for a manufacturer to document that a particular sale should be included or excluded from the retail class of trade or AMP in a manner different from the manner in which CMS has suggested in the proposed rule. CMS should provide in the final rule for such documentation.

available had the bundled drugs been purchased separately or outside the bundled arrangement."[7] This definition appears to encompass a broad range of contracting practices, which under the existing Medicaid Rebate Agreement are not considered bundled sales. Currently, the Medicaid Rebate Agreement defines a bundled sale as "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately."[8]

The definition under the proposed rule introduces several modifications to the definition of a bundled sale under the Rebate Agreement and the purpose for these changes is unclear. For example, the definition in the proposed rule could encompass an arrangement involving "the purchase of the same drug," whereas the current definition requires "the packaging of drugs of different types." (Emphasis added.) In addition, the current definition of a bundled sale is limited to arrangements where multiple drugs must be purchased to achieve a greater discount. However, the new proposed definition arguably would extend to arrangements where the only condition for the discount is including drugs on a formulary (or placement on a certain formulary tier), even if there is no requirement to purchase any or all of the formulary drugs. This definition is overbroad and could implicate as a "bundled sale" any contract covering more than one product. This interpretation could create absurd results and thus, PhRMA strongly disagrees that a single contract that covers multiple products where there is no purchase requirement should be deemed a bundled sale. Such a broad definition would create confusion and substantially increase the complexity of AMP and Best Price calculations. It could well distort the economic reality of a particular transaction in such a way that the reported AMP and Best Price for the affected products would not reflect the economic reality of the underlying transactions. In a given instance this could greatly understate, or overstate, the price of a particular drug.

Similarly the proposed rule appears to sweep into the definition of a bundle any arrangement involving a "market share" requirement, even though such requirements could take a variety of forms and would not necessarily require the purchase of different types of drugs. The proposed definition also might encompass any arrangement, either involving the same drug or different drugs, that included any "performance requirement" - an undefined term with the potential to create confusion and interpretive difficulties. Moreover, under the proposed rule's definition, a bundle apparently could include an arrangement in which the "same drug" is sold under circumstances where "the resulting discount . . . [is] greater than [that] which would have

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[7] 71 Fed. Reg. at 77176. PhRMA notes that the arrangements described in this discussion are included for illustrative purposes, and are not intended to suggest that price reporting requirements are the only standards against which marketing arrangements are evaluated. PhRMA and its members recognize that, in addition to the implications that a marketing arrangement may have in a price reporting context, marketing arrangements must also comply with the applicable laws governing health care fraud and abuse.

[8] Medicaid Rebate Agreement, § 1(e).

been available had the bundled drugs been purchased . . . outside the bundled arrangement."[9] Under this language, it is difficult to understand what arrangements would not represent a "bundled sale," since almost any contract would presumably offer a discount greater than what would have been available to the purchaser outside the contract.

Given these considerations, we are concerned that the seemingly all-encompassing definition of a "bundled sale" in the proposed rule could cause confusion and substantially increase the complexity of manufacturers' AMP and Best Price calculations. The consequence of characterizing a particular arrangement as a "bundled sale" is that special discount-apportionment rules become applicable, which often call for interpretation in particular cases and add an extra layer of complexity to a manufacturer's pricing calculations. The proposed rule's broad definition of bundling, by complicating manufacturers' AMP and Best Price calculations and introducing new interpretive problems, could thus increase the risk of error in pricing calculations. The breadth of the proposed definition could also discourage manufacturers from adopting innovative discounting arrangements, in order to avoid the difficulties associated with calculating AMP and Best Price for products sold under arrangements that could be deemed bundled sales.

Moreover, we are not aware of any considerations that would warrant creating the problems associated with an expanded definition of "bundling." Despite the fact that the proposed rule's definition of a bundled sale sweeps in a broad variety of contracting practices that fall outside the Medicaid Rebate Agreement's definition of bundling, the proposed rule does not explain any rationale for this radical proposed change.

In these circumstances, the prudent course is to refrain from expanding the definition of bundled sales and PhRMA therefore recommends that CMS adopt the current definition in the Medicaid Rebate Agreement in its final rule. In addition, CMS should clarify the current definition by specifying in the final rule the types of arrangements that do not fall within the definition; for example, the final rule should provide explicitly that "different types of drugs" do not include different strengths or dosage forms of the same drug, and that bundled sales do not include any arrangements where the actual purchase of different types of drugs is not necessary to achieve the discounts available under the agreement. Provisions that clarify and simplify the existing definition of bundled sales and reduce confusion will be particularly important in the current period of transition and turbulence: a period in which (1) manufacturers will face increased disruption due to the need to adjust their systems to incorporate a number of significant changes in their AMP and Best Price calculations (including computing monthly AMPs for the first time and refining their procedures for calculating this new pricing metric, as well as adjusting to a new regime for calculating AMP and Best Price for drugs with authorized generic versions); (2) AMPs will begin to serve a new function as a reimbursement metric for certain multiple-source drugs, thus enhancing the need to minimize potentially destabilizing changes;

[9] 71 Fed. Reg. at 77176.

and (3) manufacturers will be expected to certify the accuracy of their AMP and Best Price calculations.

Where, however, a marketing arrangement includes a bundled sale, PhRMA understands the need to apportion the value of the transaction across the products in the bundle. With respect to the methodology to be employed in such situations, PhRMA notes that currently the Medicaid Rebate Agreement calls for the allocation of the discount provided in a bundled sales transaction to be "made proportionately to the dollar value of the units of each drug sold under the bundled arrangement."[10] The proposed rule would require that for bundled sales, "the discounts are allocated proportionately to the dollar value of the units of each drug sold under the bundled arrangement" and "[f]or bundled sales where multiple drugs are discounted, the aggregate value of all the discounts should be proportionately allocated across all of the drugs in the bundle."[11] To avoid any suggestion that CMS is changing its approach to allocation of discounts on bundled sales, PhRMA suggests that in the final rule CMS adopt the apportionment language set forth in the current Medicaid Rebate Agreement.

3. PBM payments

The proposed rule states that "discounts, rebates, or other price concessions to PBM associated with sales for drugs provided to the retail pharmacy class of trade" are to be included in AMP. In addition, CMS invites comments as to whether the inclusion of PBM rebates in the AMP calculation is feasible. The appropriate treatment of fees paid to purchasers or PBMs in AMP calculations is a critical issue, and we appreciate CMS efforts to clarify the proper treatment of these fees. PhRMA agrees with the concept that PBM and other price concessions associated with drugs that are distributed to the retail pharmacy class of trade should be included in AMP. Indeed, PhRMA believes that there should be a presumption that AMP calculations should include all PBM price concessions. Manufacturers can track what price concessions are provided to PBMs, but it is neither realistic nor appropriate to track which price concessions are provided by the PBM to the retail pharmacy class of trade. This would conform to the statutory framework of the Medicaid drug rebate provisions and ensure that AMP reflects the average price paid by wholesalers to the manufacturer for drugs distributed to the retail pharmacy class of trade.

PhRMA has critical concerns about any approach that would impose on manufacturers an obligation to determine whether such price concessions are passed on to others by PBMs. In the proposed rule, CMS proposes a standard that could be interpreted to require manufacturer to base inclusion or exclusion of PBM price concessions on whether the payment is passed through by its recipient to another party. However, this analysis may not adequately capture the fluid nature of certain transactions with and among downstream entities or the role of different entities in the distribution chain. Accordingly, PhRMA believes that CMS should clarify that there is no

[10] Medicaid Rebate Agreement, §§ I(a), I(d).

[11] 71 Fed. Reg. at 77176.

automatic requirement that manufacturers affirmatively obtain information concerning transactions between downstream entities. We believe that such a requirement would create serious administrative difficulties. As noted previously in PhRMA's submission to the OIG concerning the AMP provisions, which were included as an attachment to the OIG's recommendations to CMS, manufacturers have no authority to demand that payment recipients disclose to the manufacturer whether they have shared the payment in question with their own customers or clients, and there is no guarantee that payment recipients would agree voluntarily to such disclosures. The payment recipient might reject such disclosure provisions due to, for example, concerns about its ability to preserve the confidentiality of this competitively sensitive information once it was routinely disclosed to manufacturers; concerns about the administrative burdens associated with such reporting obligations; or concerns about the potential liability risks associated with furnishing manufacturers with information that would be used in the manufacturer's AMP calculations, and that could thus result in incorrect rebate payments and Medicaid reimbursement rates if the information turned out to be inaccurate in some respect. Consequently, manufacturers simply might be unsuccessful in negotiating contractual provisions requiring disclosure of pass-through information, or they could experience prolonged delays in negotiating contracts important to their ability to sell products or to acquire needed services.

Moreover, even if manufacturers could negotiate and enforce pass-through reporting provisions, the resulting information could be difficult to incorporate into a manufacturer's systems for calculating and reporting AMP. In our submission to the OIG in response to its request for input as it developed its recommendations required by the DRA, we included an appendix that provides an overview of the pharmaceutical payment system. The appendix (attached to these comments) describes how PBM contracts take a variety of different forms and the difficulty of tracking the extent to which payments are passed on by PBMs.

Given the problems with requiring that manufacturers contract with customers to obtain information on pass-through issues and then incorporate that information into their AMP calculations, we urge CMS not to adopt such an approach.

4. Direct patient sales

The Medicaid rebate statute defines AMP 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". Because sales made to patients through direct programs fail to satisfy two requirements of this statutory definition, they should be excluded from AMP calculations. As discussed below, direct sales to patients are neither sales to the retail pharmacy class of class, nor does any party in such a transaction act as a wholesaler.

a. Retail Pharmacy Class of Trade

In the proposed rule, CMS has taken the sound position that the retail pharmacy class of trade means the sector of the drug marketplace that "dispens[es drugs] to the general public."[12] As an individual patient is distinctly different from the "general public," direct sales to patients are not sales to the general public, and thus not sales to the retail pharmacy class of trade.

b. Definition of Wholesaler

In describing its rationale for proposing to include direct sales to patients in the determination of AMP, CMS states that a direct patient sales arrangement exists "where the manufacturer retains ownership of the drug and pays either an administrative or service fee to a third party for functions such as storage, delivery, and billing of the drug."[13] The proposed rule defines the term wholesaler as "any entity . . . 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."[14] When one compares the direct patient sales scenario described in the proposed rule to its definition of wholesaler, it is clear that no wholesaler is part of this scenario. The manufacturer arranges for the sale of the product, and sells the products to the patient (who clearly is not a "wholesaler"). The distributor is simply performing storage, delivery, and billing services, and these actions do not constitute "arrang[ing] for the sale of the covered outpatient drug." The manufacturer retains ownership of the drug" (presumably until its sale to the patient) and neither sells the drug to the distributor nor arranges for its sale to the distributor.

As a result of these two observations, PhRMA requests that in the final rule CMS exclude direct sales to patients from the determination of AMP.

5. Coupons

The proposed rule states that AMP shall include "[m]anufacturer coupons redeemed by any entity other than the consumer that are associated with sales of drugs provided to the retail pharmacy class of trade;" and exclude "[m]anufacturer coupons redeemed by a consumer." There is similar language in connection with the determination of best price. As support, in the preamble CMS states, "[w]e believe that the redemption of coupons by any entity other than the consumer to the manufacturer ultimately affects the price paid by the entity (e.g., retail pharmacy)." The proposed rule erroneously makes a distinction between the type of coupons or vouchers that the consumer directly redeems and coupons that others in the distribution chain, e.g., pharmacies, redeem that also reduce the price for the consumer. In fact, regardless of whether the consumer or an entity redeems the coupon or voucher[15], there is no impact on the

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[12] Id. at 77179.

[13] Id. at 77180.

[14] Id. at 77196.

[15] This section discusses coupon and voucher programs generally, but is not intended to suggest that these are the only types of programs covered by the proposed rule's treatment of coupons. This discussion should be read to

Footnote continued on next page

price paid by the entity. When the financial benefit is only to the patient, there is no statutory basis for inclusion of the arrangement in AMP or Best Price. As discussed in the previous section, "sales" to patients do not meet the definition of retail class of trade for purposes of the AMP calculation. In addition, Best Price is the lowest price available from the manufacturer "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity" with specific exemptions. Patients are not included in that list.

Despite this fact, under the proposed rule, it could be interpreted that the only way a coupon that lowers a patient's cost would be excluded from AMP and Best Price determinations would be if the coupon program were structured as a mail-in rebate. Typically with such coupons the consumer submits the mail-in coupon directly to the manufacturer, along with proof of purchase, to receive a rebate. Because the consumer redeems mail-in rebates directly to the manufacturer this type of coupon would be excluded from AMP and Best Price under the proposed rule.[16] However, if such coupons were redeemed at the pharmacy or through a third-party vendor that administers the program on behalf of a manufacturer (but does not itself purchase the product), there would be the same result for the pharmacy and patient, but there would be a different result with respect to AMP and Best Price under the proposed rule. In such a case, the consumer would receive the same benefit as if the coupon were mailed directly to the manufacturer, and no financial benefit would be realized within the retail pharmacy class of trade.

Similarly, a coupon offering a consumer, for example, a set dollar amount reduction on the price or co-payment of a drug or a voucher that provides the consumer with a limited supply of a drug for free where the pharmacy redeems the voucher to the manufacturer, also does not result in a discount to an entity in the retail pharmacy class of trade. Although such coupons or vouchers[17] are generally redeemed at the point of sale, the retail pharmacy does not itself realize a price discount. Instead, the pharmacy will submit the coupon or voucher to the manufacturer or a third party vendor and will seek appropriate reimbursement (the allowed amount plus a processing fee at fair market value) for honoring the coupon or voucher presented by the consumer. Rather than providing a discount to the pharmacy, this reimbursement simply "makes the pharmacy whole" for the actual expense it incurs in honoring the coupon or voucher. The same is true of vouchers that entitle the consumer to a certain amount of free goods. Here, too, the retail pharmacy provides the consumer the product in accordance with the terms set forth in the voucher. Again, the pharmacy then seeks appropriate reimbursement from the manufacturer to cover the value of the outlay of the product and a fair market value processing fee. Previous

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encompass all manufacturer programs that provide a direct financial benefit to the patient without any direct financial benefit to a third party such as the pharmacy.

[16] See id. at 77197-98 (proposed 42 C.F.R. pts. 447.504(h)(9), .505(d)(8)).

[17] This might include, but not be limited to, vouchers for trial scripts (e.g., the pharmacy provides a limited supply of the drug to the patient for free and "redeems" the voucher to the manufacturer and receives reimbursement that reflects the voucher's value) and discount card programs.

CMS guidance indicated that in such circumstances, manufacturers could reimburse the pharmacy in kind or, alternatively, manufacturers could employ a set formula to estimate the pharmacy's acquisition price. Once again, in employing either method the pharmacy does not realize a discount; it merely is made whole following the transaction.

Thus, the real question should be whether the patient coupon or voucher provides a direct benefit to the patient without an additional financial benefit to a third party, not who physically redeems the coupon or voucher. While there are a variety of patient coupon or voucher programs, all of the programs are designed to provide a benefit to the consumer by covering a portion of the consumer's prescription drug cost or co-payment. In cases where a pharmacy accepts a coupon or voucher in lieu of some or all of the cash payment due from the customer and then redeems that coupon or voucher with the manufacturer, the manufacturer is only reimbursing the pharmacy for its out of pocket expense (plus a fair market value processing fee).[18] This reimbursement does not impact the price paid by the pharmacy and is, in fact, revenue neutral with respect to the pharmacy regardless of whether the patient redeems the coupon or the pharmacy itself sends the coupon in for redemption.

As mentioned above, CMS has provided previous guidance on this issue in the context of a discount card program and Best Price. In connection with the Together Rx savings program, former CMS Administrator Scully set forth a fact based analysis on whether a program would be considered a "direct to patient coupon." [19] The key factors identified were:

- "The manufacturer establishes an amount of the benefit to be given to individual patients, without any negotiation between the manufacturers and a third party (such as an insurer or PBM) as to that amount."

- "The entire amount of that benefit is made available to an individual patient, without any opportunity for the retail pharmacy or any other third party (such as an insurer or PBM) to reduce that benefit, or take a portion of it, for its own purposes."

- "The pharmacy reimbursement formula provides that the pharmacy will be reimbursed based upon the lower of (a) a formulaic 'ceiling price' equal to [ ] or (b) the pharmacy's usual and customary price for the drug."

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[18] Any processing or other fee should be evaluated under the bona fide service fee exemption and should not alter the treatment of the entire patient coupon for purposes of AMP and Best Price. [See section I.C.1.]

[19] Letter from Thomas A Scully to Thomas McKenna, October 22, 2002. [See attached.]

- "The pharmacy collects no additional payment[20], other than the benefit amount, from the [ ] program."

Based on the above, CMS should revise its treatment of patient coupons to exclude patient coupons and other similar arrangements from AMP and Best Price where the coupons and similar arrangements provide a financial benefit only to the consumer, regardless of how they are actually redeemed.

In the absence of a change, the treatment of patient coupons may have unintended consequences on coupons currently used to help patients lower their drug prices, but that are distributed in different ways. For example, as a result of this approach, a manufacturer might choose to require patients to redeem all coupons directly. Patients would then have to pay the full amount of the prescription and then submit the amount for reimbursement which could take some time to process. This might be particularly burdensome for low-income patients.

Finally, to the extent these types of coupons are already in the stream of commerce and have expiration dates beyond July 1, 2007, manufacturers would have to account for them in their AMPs and Best Price calculations once redeemed when that was not the original intent or state of guidance. Thus there would be retroactive application of the rule which is not intended or permitted. At a minimum, even if CMS does not change the treatment of patient coupons in the final rule, CMS should have a later effective date for inclusion of those sales that takes into account later expiration dates.

C. Sales, rebates, discounts, or other price concessions included in AMP

1. Bona Fide Service Fees

In the proposed rule, CMS proposes to include all fees that do not satisfy the definition of bona fide service fee in the calculations of AMP and Best Price, even if the entity that receives the fee does not take title to the product.[21] Bona fide service fees are defined as "a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturers that a manufacturers would otherwise perform (or contract for) in the advance of the service arrangement, and that is not passed on in whole or in part to a client or customer of the entity, whether or not that entity takes title to the drug."

PhRMA supports adopting a uniform definition of bona fide service fee that will apply to ASP, AMP, and Best Price calculations. CMS has announced its interpretation of certain key

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[20] Consistent with CMS' previous guidance and as noted above, reimbursement of costs to the pharmacy to make the pharmacy whole, including payment of fair market value dispensing fee and adjudication cost should not be considered an additional payment.

[21] 71 Fed. Reg. at 77195.

elements in the bona fide service fee definition in the ASP context.[22] In the final rule, CMS should specify that these interpretations, as set forth below, also apply in the Medicaid rebate context.[23]

In particular, CMS clarified that bona fide service fees must not be "passed in whole or in part to a client or customer of an entity [that receives the fee]." Because manufacturers often do not know whether a fee is "passed on" by the recipient, CMS stated that if a fee otherwise qualifies as a bona fide service fee "then the manufacturer may presume, in the absence of any evidence or notice to the contrary, that the fee is not passed on to a client or customer of any entity."[24] PhRMA asks that CMS confirm explicitly that, as with ASP, a fee that otherwise qualifies as a bona fide service fee can be treated as a bona fide service fee for Medicaid rebate reporting purposes unless the manufacturer has specific knowledge that some or all of the particular fee in question has been passed through by the recipient.

CMS also announced additional principles of importance regarding the "fair market value" element of the bona fide service fee definition in the context of ASP. In order to address concerns that the fair market value criterion would not apply to fees for services "that can only be performed by the entity to which the fee is paid," CMS made clear that bona fide service fees mean expenses that a manufacturer "generally would have . . . paid for . . . at the same rate had these services been performed by other or similarly situated entities."[25] CMS also explained that manufacturers were not required to calculate a fair market value for each individual service purchased from an entity; rather, "it may be appropriate to calculate fair market value for a set of itemized bona fide services, rather than fair market value for each individual itemized service, when the nature of the itemized services warrants such treatment."[26] CMS then emphasized that the appropriate methods for determining whether a fee represents fair market value "may depend on the specifics of the contracting terms, such as the agreed-upon mechanism for establishing the payment (for example, percentage of goods purchased)," and noted that since "manufacturers are well-equipped to determine the most appropriate, industry-accepted method for determining fair market value" it would be inappropriate for CMS to "mandat[e] the specific method manufacturers must use to determine whether a fee represents fair market value."[27] Given the

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[22] These interpretations were announced in the Medicare final physician fee schedule rule for 2007, published in the Federal Register on December 1, 2006.

[23] As discussed in greater detail in the section of this letter on patient coupon and voucher programs, CMS also should confirm in its Final Rule that fees to pharmacies or vendors for services associated with redeeming coupons or administering voucher programs should be evaluated under the bona fide service fee definition to determine their proper treatment.

[24] 71 Fed. Reg. 69624, 69669 (Dec. 1, 2006).

[25] Id.

[26] Id.

[27] Id.

importance of the principles quoted above, CMS should expressly confirm in the final rule that these principles apply equally to Medicaid rebate calculations.

a. GPO Fees

We also note that CMS' proposed approach fails adequately to address fees that are paid to GPOs. Fees to GPOs are not price concessions; they are bona fide service fees that reflect the value of the facilitated contracting. In this regard, PhRMA endorses the approach previously set out by the Health Industry Group Purchasing Association (HIGPA), a trade association representing GPOs. As noted in its comments, GPO's are entities that negotiate on behalf of their members (e.g., clinics, hospitals) with manufacturers for drugs and biologicals. As a general matter, they do not purchase these products. Rather they negotiate contracts that their members use to purchase drugs and biologicals. In light of these factors, HIGPA has taken the position that fees to GPOs should not be treated as price concessions "unless the fees (or any portion thereof) are passed on to the group purchasing organization's members or customers as part of an agreement between the manufacturer and the group purchasing organization."[28] PhRMA believes HIGPA's approach provides a clear standard that would readily allow manufacturers to identify which portions (if any) of GPO fees are appropriately considered a price concession, because they influence the price paid by customers, and which portions are not price concessions. Such an approach would be consistent with the OIG's GPO-specific exception and safe harbor[29] and recognition by Congress that such fees are an integral and legitimate part of certain providers' supply chain, if specific conditions are met.

While GPOs may distribute a portion of their <u>own</u> revenues to their members; it does not follow automatically that any portion of the GPO fees paid by manufacturers to the GPOs should be treated as price concessions from the manufacturer to the purchaser. In the event a GPO makes a distribution to its members of its own volition — and not under any agreement or other legal arrangement between the GPO and the manufacturer — CMS should not deem the distribution a "price concession" by the manufacturer, or otherwise attribute it to the manufacturer, for AMP purposes. However, PhRMA recognized that if a drug manufacturer enters into an agreement with a GPO pursuant to which the GPO will pay its members a certain percentage of the fees paid by the manufacturer to the GPO, then the percentage should be considered a price concession from the manufacturer to the purchaser and, thus be included in the calculation of the manufacturer's AMP.

2. <u>Other Federal Programs</u>

In the rule's treatment of included and excluded sales and prices for both AMP and Best Price purposes, CMS proposes to exclude "[a]ny depot prices (including TRICARE)." As CMS may be aware, the Department of Defense's (DoD) TRICARE health care program provides

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[28] January 2, 2007 Health Industry Group Purchasing Association letter to CMS, at 2.

[29] 42 U.S.C. §1320a-7b(b)(3)(C) and 42 C.F.R. §1001.952(j).

coverage for prescription drugs through three different delivery systems: the military treatment facility, mail order and retail pharmacy. Under the Veterans Health Care Act (VHCA), which prescribes price limits for direct sales of covered drugs to DoD, VA and other specified federal agencies, the term "depot contracting system" is defined as "a centralized commodity management system" through which covered drugs are "procured by" a federal agency. The price controls in the VHCA apply to drugs procured by DoD (and other specified agencies) through a depot contracting system.

In our view, with respect to TRICARE, drugs are procured only by the military treatment facility and mail order pharmacy and thus only those entities can be party to a depot contracting system under the VHCA. Distribution of drugs through the retail pharmacy network does not fall within the statutory definition of a depot contracting system, because drugs dispensed to DoD beneficiaries at retail pharmacies are not procured by DoD (or any other federal agency). Instead, the retail pharmacies acquire those drugs through commercial arrangements between the retail pharmacies and wholesalers. DoD never takes title to or possession of the drugs that are dispensed to its beneficiaries in retail pharmacies.

In October 2004, the VA issued a dear manufacturer letter that purported to interpret the VHCA to include DoD retail pharmacy sales as part of a depot contracting system. This interpretation, if accepted, would have extended federal price controls under the VHCA to sales to DoD beneficiaries in the DoD's retail pharmacy network. However, in September 2006, the United States Court of Appeals for the Federal Circuit invalidated the VA's October 2004 dear manufacturer letter on the ground that the VA had failed to publish the letter for notice and comment rulemaking as required under the Administrative Procedure Act. Following the Court's decision, the DoD has suspended its rebate program and has not sought to treat retail pharmacy sales as sales under a depot contracting system.

The DOD has announced that it welcomes voluntary rebate agreements with manufacturers covering retail pharmacy sales.[30] Under those agreements, manufacturers would pay negotiated rebates to DoD for drugs sold by retail pharmacies to DoD beneficiaries. The sales and associated rebates under the TRICARE retail pharmacy program thus would be analogous to the sales and associated rebates in government programs, such as the Medicare Part D program and state pharmaceutical programs, under which the government acts as a third party payer for drugs dispensed by an entity in the retail pharmacy class of trade. Consistent with CMS's proposed approach for dealing with Part D and SPAP rebates, therefore, the TRICARE retail pharmacy program sales and rebates should be included in AMP.

With respect to Best Price, our view is that the prices and any voluntary rebates offered under the TRICARE retail pharmacy program should be excluded from the calculation. However, this exclusion should not be based on the statutory exemption for depot prices (because, as noted, there is no procurement by DoD of the drugs that are sold through its retail

[30] See, www.tricare.mil/pharm_mfg/default.cfm

pharmacy network), but rather should be based on the statutory exemption for "any price charged on or after October 1, 1992, to . . . the Department of Defense."[31] Any rebates offered to DoD under its voluntary rebate program would be a price concession paid to the DoD relating to covered drugs. Accordingly, we believe this exemption is an appropriate basis for excluding rebates paid to DoD for drugs sold to DoD beneficiaries through the retail pharmacy network. CMS should make this distinction clear in the final rule.[32]

3. Sales to health maintenance organizations

CMS proposes to exclude from AMP "sales to health maintenance organizations (HMOs), including managed care organizations." As CMS is aware, there are many forms of managed care organizations. Staff model HMOs typically have their own pharmacies that only serve the HMO's enrollees. It is appropriate to exclude sales to those staff model HMOs from AMP as they do not sell or provide drugs to the general public. However, for the vast majority of other managed care organizations, those HMOs and MCOs typically contract directly or indirectly with retail pharmacies to provide drugs to the MCO's enrollees. Those arrangements are no different than the arrangements under Part D and the Medicare Advantage Prescription Drug Program that are included in AMP under proposed rule § 447.504(g)(12). It would be incongruous to include the sales and associated rebates in the government sponsored Medicare Part D and Medicare managed care programs which use private managed care plans but not include those sales and associated rebates and price concessions when those plans are acting in a private commercial capacity. In addition, those HMOs frequently contract with the PBMs whose rebate arrangements are being included in AMP. As CMS appears to recognize that sales to PBMs that flow to the retail class of trade are included in AMP, certainly CMS must intend that sales to health plans whether they contract with PBMs or not, are included in AMP as long as those health plans do not operate a closed pharmacy. Any other result would be inconsistent. Consequently, we recommend that CMS clarify that excluded sales include only those to HMO models that have closed pharmacies.

D. Relationship between AMP and pharmacy acquisition costs

Under the DRA, the federal upper limit (FUL) for multiple source drugs generally is 250% of the AMP for the least costly drug in that multiple-source group.[33] In the proposed rule, CMS also proposed to establish safeguards to "ensure that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally as presently provided in our regulations."[34] Specifically, CMS proposed: (1) to disregard the AMP of an NDC that has been

[31] SSA § 1927 (c)(1)(C)(I).

[32] To the extent CMS considers the TRICARE retail pharmacy program in a "depot" category, it should make clear that it is interpreting its Medicaid rebate statute and not interpreting the VHCA, which CMS lacks the authority to interpret.

[33] SSA § 1927(e)(5).

[34] 71 Fed. Reg. at 77187.

terminated when setting FULs; and (2) to set the FUL "based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug"[35] (meaning that, the lowest AMP would be disregarded in setting the FUL if it was 70% or more below the next-lowest AMP in the multiple-source group). CMS solicited comments on whether 30% was the appropriate percentage to use and on "how best to accomplish the goal of ensuring that the use of AMP in calculating the FUL will ensure that a drug is available nationally at the FUL price."[36]

We agree with CMS that the new AMP-based FUL system requires safeguards to help ensure Medicaid beneficiaries' access to multiple-source drugs. However, we are also concerned that the safeguards in the proposed do not go far enough to ensure adequate access to particularly critical medications. For example, patients who have had organ transplants must take immunosuppressive drugs to prevent the rejection of their transplanted organs. Unimpaired access to these medications is essential; missing even a few days of medication can cause the patient's body to reject the transplanted organs. In these circumstances, heightened safeguards are warranted to reduce the risk of life-threatening medical problems and ensure that the FUL will at least make critical multiple-source drugs widely available to Medicaid beneficiaries who need these medications. Consequently, CMS should adopt special criteria for setting the FULs for critical medications that will provide more adequate safeguards. This policy should apply to all FULs for critical medications, including FULs for multiple-source drug groups that only include the innovator drug and the first generic competitor.

A policy incorporating heightened safeguards would comport with special policies for immunosuppressives and five other classes of clinical concern that CMS has adopted in the Medicare Part D context, finding that special safeguards for these classes were necessary "to mitigate the risks and complications associated with an interruption in therapy for these vulnerable populations."[37] Vulnerable Medicaid beneficiaries who need these critical medications deserve similar consideration.

A special FUL policy to make critical multiple-source medications widely available to Medicaid beneficiaries is particularly important given a recent report by the Government Accountability Office (GAO) comparing AMP-based FULs with retail pharmacy acquisition costs.[38] GAO compared AMP-based FULs for 77 multiple-source drug groups (some representing the most frequently-used multiple-source drugs, some representing the multiple-source drugs with the highest Medicaid expenditures, and some

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[35] Id. at 77188. However, CMS proposed not to apply this "30% carve-out policy" if the multiple-source drug group only included the innovator drug and the first generic to enter the market. Id.

[36] Id.

[37] Medicare Modernization Act, 2007 Final Guidelines—Formularies, at 7. In addition to immunosuppressants, the other classes of clinical concern are antidepressants, antipsychotics, anticonvulsants, HIV/AIDS drugs, and antineoplastics.

[38] GAO, Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared With Retail Pharmacy Acquisition Costs (Dec. 22, 2006).

falling within both categories) with retail pharmacy acquisition costs for those drug groups, and found that the AMP-based FULs generally were well below retail pharmacy acquisition costs.

We recognize that the data available to GAO had some limitations, as CMS pointed out in its comments on GAO's draft report.[39] Nevertheless, GAO's findings clearly suggest a serious risk of access problems that could result from the new FULs. These findings underscore the importance of CMS' proposal to build certain safeguards into the new FULs, and of adopting extra safeguards to help ensure that the FULs for especially critical medications will make them widely available to Medicaid patients.

II. Determination of Best Price - Section 447.505

A. Price concessions generally

In the proposed rule, CMS states that "best price should be adjusted by the manufacturer if other arrangements subsequently adjust the prices actually realized."[40] CMS further proposes "to consider any price adjustment which ultimately affects those prices which are actually realized by the manufacturer as 'other arrangements'. . . that . . . should be included in the calculation of Best Price . . we propose that best price be calculated to include all sales, discounts, and other price concessions provided by the manufacturers for covered outpatient drugs to any entity."[41] By statute, Best Price is the lowest price available from the manufacturer "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity" (with specified exemptions).[42] Therefore, the preamble language must be read to mean that Best Price is the lowest price realized by the manufacturer net of all price concessions to a specific Best Price-eligible customer. Best price is not calculated as a price derived by aggregating price concessions to different customers. And nothing in the statute, the Medicaid Rebate Agreement, or other guidance issued by CMS would support such an interpretation. Moreover, the DRA does not expressly authorize any changes to the calculation of Best Price other than in connection with Section 6003. Thus, any other changes to the definition of Best Price are not authorized by law.

B. PBM price concessions

See discussion above in Section I.B.3.

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[39] In particular, GAO used 2006 AMPs (which did not reflect the exclusion of prompt pay discounts from AMP starting in 2007), and its data on pharmacy acquisition costs (which came from IMS Health) did not reflect any rebates that may have been available to pharmacies.

[40] 71 Fed. Reg. at 77182.

[41] Id.

[42] SSA § 1927(c)(1)(C)(i).

C. Returns

Best Price is defined by statute as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity within the United States."[43] Because returns involve the reversal of a sale, rather than a price available from the manufacturer for purchase of a drug, they should not be taken into account in the determination of Best Price. Consistent with this position, CMS did not include returns as part of the list of transactions for which manufacturers must account in ascertaining Best Price in its discussion of Best Price in the preamble to the proposed rule. The preamble also notes that with this proposed regulation CMS intends to codify the policy embodied in the Medicaid Rebate Agreement with respect to the definition of Best Price. Under that definition, returns are notably absent. However, in section 447.505(e)(1) of the proposed regulation, "returns" is included as a consideration in the determination of Best Price. This provision appears inconsistent with both the statutory definition of Best Price and CMS' expressed intent to codify the Best Price definition in the Medicaid Rebate Agreement. Consequently, PhRMA suggests that returns be stricken from this section in the final regulation. At a minimum, CMS should exclude returns from Best Price determinations when products are returned in "good faith" (i.e., pursuant to a manufacturer policy that is "not designed to manipulate or artificially inflate or deflate" pricing calculations), as CMS has proposed in the AMP context.

D. Coupons

See discussion above in Section I.B.5.

E. Nominal price exclusion

The DRA clarified that the scope of the "nominal price" exclusion from Best Price extends only to sales at nominal prices to 340B covered entities, intermediate care facilities for the mentally retarded (ICF/MR), State-owned or operated nursing facilities, or any additional safety-net providers identified by CMS. To facilitate the proper application of this exclusion, PhRMA recommends that CMS maintain a current listing on its website of entities that qualify as ICF/MRs or State-owned or operated nursing facilities. Manufacturers will not necessarily be able to determine with certainty whether a particular entity falls within one of those categories, and should be able to rely on an authoritative list established by CMS instead of having to speculate about an entity's status.

Additionally, the DRA authorized CMS to identify additional facilities or entities as "safety net providers," to which sales at nominal prices could be excluded from Best Price. Although PhRMA understands that CMS has declined to use this authority at this time, PhRMA requests that CMS develop and publish the procedures the Agency intends to follow to determine

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[43] Id.

whether additional safety net providers will be eligible for inclusion in the nominal price exemption at some point in the future. CMS should then publish a list of those entities on which manufacturers may rely.

F. "SPAPs" Exempt From Best Price

Under the Medicaid rebate statute, prices used by SPAPs are exempt from Best Price.[44] CMS has periodically provided guidance (most recently, in Medicaid Rebate Release No. 68, issued on April 1, 2005) concerning the criteria that a State program must meet in order to qualify as an "SPAP" for purposes of the Best Price exemption. The CMS website also provides a list of "State Pharmaceutical Assistance Programs Excluded from Medicaid Best Price,"[45] which represents "a list of programs that meet the criteria to be considered SPAPs." The list provides that it only includes State programs that qualify as SPAPs (under the criteria in Release 68) for those States that submitted a description of their programs for review under those criteria. However, the list also states that "[t]he qualification of State-only programs as SPAPs is based on the information provided by the State and may be subject to further review if changes occur within the program."

Because CMS is in a better position than manufacturers to determine whether a particular State program meets the criteria CMS has established to qualify as an SPAP, CMS should specify in the final rule that manufacturers may rely on the CMS list in determining whether a particular State program is an "SPAP" for Best Price exemption purposes. If CMS determines that any new "SPAP" criteria it issues, or additional or revised information from a State, raise questions about a program's status as a Best Price-exempt SPAP, then CMS should delete the program in question from the list and provide that (as of a specified future date, which should be at least one quarter after a program's deletion from the CMS list), a manufacturer may not rely on the program's previous listing as conclusive evidence that the program qualifies as a Best Price-exempt SPAP. This approach would help to give manufacturers the certainty needed to extend rebates that might otherwise set a Best Price to listed SPAPs.

G. Other Federal Programs

See discussion above in Section I.C.2.

III. Authorized Generic Drugs - Section 447.506

Under Section 6003 of the DRA starting in 2007 manufacturers of innovator drugs that have authorized versions marketed under the New Drug Application (NDA) must take account of the AMP and Best Price for these versions in determining the AMP and Best Price for the innovator drug. With respect to AMP, the DRA requires that "[i]n the case of a manufacturer

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[44] SSA § 1927(c)(1)(C)(i)(III).

[45] http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_Overview.asp.

that approves, allows, or otherwise permits any drug of the manufacturer to be sold under [an NDA] approved under section 505(c) of the Federal Food, Drug, and Cosmetics Act", the innovator manufacturer's AMP "shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade."[46] With respect to Best Price, the DRA requires that the innovator drug's Best Price "shall be inclusive of the lowest price for such authorized (generic) drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, providers, [HMO], nonprofit or governmental entity" (with specified exemptions).[47]

The proposed rule would describe those innovator drugs subject to DRA § 6003 as drugs with "authorized generic" versions, which would be defined as "any drug sold, licensed or marketed under an NDA approved by the FDA under Section 505(c) of the FFDCA; and marketed, sold or distributed ... under a different product code, labeler code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the listed drug."[48] This proposed language goes beyond the statutory language that Congress enacted and PhRMA is concerned that such language may unintentionally capture marketing arrangements that were never envisioned.

For example, Manufacturer A may acquire a license from Manufacturer B to sell a product originally approved under an NDA owned by Manufacturer B. In this scenario, Manufacturer A is selling the product as a branded product because the product is still protected under patent. In this scenario, Manufacturer B's product may remain in inventory at pharmacies, bearing its labeler code, for a period of time. Manufacturer A would obtain a new labeler code for the product. Depending on the structure of the license agreement, Manufacturer A may assume liability for any future sales of the product, including those with Manufacturer B's labeler code. Under current requirements, Manufacturer A would calculate separate AMPs and Best Prices for each of the labeler codes. Under the proposed rule, it appears that a combined AMP and Best Price would be required to be calculated, but the manufacturer that would be required to combine would be Manufacturer B, even though it is no longer in the market, as it holds title to the original NDA. Manufacturer A would report its stand-alone AMP and Best Price.

Likewise, a manufacturer may be required to change the labeler code assigned to a product, as might be the case under the proposed FDA rule on manufacturer establishments and drug listing.[49] Alternatively, a manufacturer might acquire rights to sell another manufacturer's product exclusively, meaning that for a period of time Manufacturer A is selling product bearing its own labeler code and product bearing the transferor's labeler code. This might continue until

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[46] SSA § 1927(k)(1)(C).

[47] SSA § 1927(k)(1)(C)(ii)(IV).

[48] 71 Fed. Reg. at 77198 (proposed 42 C.F.R. § 447.506).

[49] 71 Fed. Reg. 51276 (Aug. 29, 2006) (Proposed Rule: Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs).

the transferor's labeled product is extinguished from pharmacy inventories. In both of these scenarios, the same drug will bear two different labeler codes during the transition period. In this scenario, the drug is under patent protection. Under the current regime, AMP and Best Price would be required to be reported for both products separately until inventory of product with the original NDC is fully expired (plus for four quarters after the last batch expiration date). Under the proposed rule, the AMPs and Best Prices for products bearing both labeler codes would be combined, although neither would be considered a generic product in the marketplace.

Moreover, the proposed rule does not provide sufficient specificity regarding the calculation of AMP and Best Price for innovator drugs with authorized generic versions in three respects.

First, CMS should specify that the innovator manufacturer may rely on the AMP reported to it by the authorized generic manufacturer, plus the number of AMP-eligible units sold reported by the authorized generic manufacturer, to derive the "weighted" AMP that must be reported as the AMP for the innovator drug. That is, CMS should make clear that the innovator manufacturer is not required to calculate the AMP for the innovator drug by demanding raw sales data from the authorized generic manufacturer and then use the raw sales data to calculate for itself the AMP for the authorized generic drug and the number of AMP-eligible units of that drug sold during the relevant period. Similarly, CMS should specify in the final rule that the innovator manufacturer may rely on the Best Price for the authorized generic drug reported to it by the authorized generic manufacturer in determining the Best Price for the innovator drug.

It would be infeasible for innovator manufacturers to calculate the AMP and Best Price for the innovator drug within the 30-days reporting deadline if it could not rely on information from the authorized generic manufacturer regarding the AMP for the authorized generic, the number of AMP-relevant units sold of the authorized generic during the period in question, and the Best Price of the authorized generic during the relevant quarter, Moreover, an innovator manufacturer would have to have access to proprietary books and records of the authorized generic manufacturer, who may be a competitor, raising a variety of business and legal issues. Consequently, it is essential for CMS to clarify in the final rule that innovator manufacturers may rely on the AMP (and number of AMP-relevant units) and the Best Price for the authorized generic product reported to the innovator manufacturer by the manufacturer of the authorized generic product (including an authorized generic manufacturer that is a subsidiary of, or otherwise affiliated with, the innovator manufacturer) and not have liability for reasonable reliance on such information.

Second, CMS should confirm explicitly in the final rule that "transfer prices" and license fees for authorized generic drugs are irrelevant to Best Price calculations for the innovator drug. That is, CMS should provide explicitly that the Best Price for the innovator drug should not be based on the innovator manufacturer's price to the authorized generic manufacturer. While the following statements in the preamble and proposed rule would suggest that result, an explicit discussion of this point in the final rule will eliminate any uncertainty.

Section 447.506 of the proposed rule would define "authorized generic" and require manufacturers to include "the direct and indirect sales of [an authorized generic] drug in its AMP" and "the price of [an authorized generic] drug in the computation of Best Price for the single source or innovator multiple source drug . . . to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity within the United States." In the preamble to the proposed rule, CMS indicates that the only relevant price of the authorized generic for innovator Best Price purposes is the price from the authorized generic manufacturer to its own customers:

> we would require that sales of authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs be included by the primary manufacturer in the sales used to determine the Best Price for the single source or innovator multiple source drug approved under Section 505(c) of the FFDCA during the rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity or governmental entity within the United States. The primary manufacturer must include in its calculation of Best Price all sales of the authorized generic drug which have been sold or marketed by a secondary manufacturer or by a subsidiary of the brand manufacturer.[50]

Consistent with this statement in the proposed rule, the Best Price for a drug with an authorized generic version should be the lower of: (1) the lowest price charged by the innovator manufacturer in a Best Price-eligible sale; or (2) the lowest price charged by the authorized generic manufacturer in a Best Price-eligible sale. The transfer price -- i.e., the price at which the innovator manufacturer sells the drug to the authorized generic manufacturer -- should not be taken into account in Best Price, even if it would otherwise be the lowest price at which the drug is sold. Transfer prices could involve arrangements between affiliated companies (as where the authorized generic is marketed by a subsidiary of the innovator company) or could involve royalty or profit-sharing arrangements that would be difficult for the innovator manufacturer to translate into a set price. Consequently, the approach suggested by CMS in the proposed rule would simplify the Best Price calculation and should be expressly adopted and confirmed in the final rule.

Finally, CMS should clarify in the final rule the effect of authorized generic products that are introduced in the middle of a quarter on the AMP and Best Price for the innovator drug. CMS should require the innovator manufacturer to take the authorized generic into account in its pricing calculations in the first full quarter after the authorized generic product's launch (using the same principle used in determining the base date AMP). Similarly, CMS should provide that an authorized generic product will not be taken into account in monthly AMP calculations until the first month of the first full quarter following the launch of the authorized generic.

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[50] 71 Fed. Reg. at 77184.

IV. Requirements for Manufacturers - Section 447.510

A. 12- month rolling average methodology

In its discussion of the monthly AMP, CMS stated that "to maximize the usefulness of the monthly AMP and to minimize volatility in the prices, we propose allowing manufacturers to rely on estimates regarding the impact of their end-of-quarter rebates and other price concessions and allocate these . . . price concessions in the monthly AMPs."[51] CMS also invited comments on "allowing the use of 12-month rolling average estimates of all lagged discounts for both the monthly and quarterly AMP."[52] PhRMA supports allowing manufacturers to use reasonable estimates of lagged discounts or a 12-month rolling average methodology (or a similar smoothing methodology)[53] in their monthly and/or quarterly AMPs. Like allowing manufacturers to estimate end-of-quarter rebates, allowing the use of a 12-month rolling average methodology could help to reduce period-to-period volatility in AMPs. Mechanisms such as estimates and smoothing enhance stability and smooth out variations in reported AMPs. This could be useful because monthly AMPs will now be used to set federal upper limits for multiple-source drugs, and potentially some states might also use AMPs in other reimbursement formulas.

B. Recalculation of base date AMP

The "additional rebate" for innovator drugs is calculated by subtracting the drug's quarterly AMP from its inflation-adjusted base date AMP. PhRMA applauds CMS for recognizing that manufacturers must have the opportunity to adjust base date AMP to account for the changes set forth in the DRA and the final rule. However, PhRMA requests that CMS confirm that manufacturers may make reasonable adjustments to base date AMP to address the varying points in time during which AMP calculations will change due to both statutory and regulatory changes. As of January 1, 2007, the DRA excluded customary prompt payment discounts to wholesalers from AMP calculations. Further changes to AMP will occur once CMS' final regulation is promulgated.

We believe that manufacturers should have the ability to restate base date AMP for any changes in the AMP calculation recommended by CMS. Furthermore, CMS should explicitly state in the final rule that manufacturers may make reasonable assumptions in their recalculation of base date AMP. This would include the use of a reasonable methodology to approximate the impact of the new rule on their base date AMPs.

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[51] Id. at 77186.

[52] Id.

[53] For example, CMS should also allow manufacturers to use a four quarter rolling average methodology.

Moreover, PhRMA recommends that the recalculated base date AMPs should be applied retroactively to the first and second quarter of 2007 for the calculation of rebates. CMS itself recognized the inherent inequity created by the change in the AMP definition, and in the preamble on the recalculation issue, stated, "[w]e propose this amendment so that the additional rebate would not increase due to changes in the definition of AMP."[54] Further on, CMS states, "[h]owever, we decided that retaining the current base date AMP is unwarranted because it would create a financial burden on manufacturers that was not intended by Section 6001 of the DRA".[55] The only way to alleviate that additional financial burden is to apply the recalculated base date AMP retroactively to the first and second quarter of 2007 when provisions of the DRA that changed the AMP definition were effective. PhRMA understands that this may create additional workload due to restating prior periods; however we believe this is a necessary step to achieve the appropriate outcome.

CMS should therefore confirm that manufacturers may recalculate base date AMP for the first and second quarters of 2007, to account for the statutory change that has already come into effect, and then, once again when the final regulations come into effect. Alternatively, PhRMA requests that manufacturers be permitted to restate their base date AMPs retroactively for the first two quarters of 2007 after the regulations are finalized, so as to account for changes to base date AMP during those quarters that were not previously reflected in additional rebate calculations.

In addition, the section of the proposed regulation that addresses base date AMP includes an internal cross-reference that appears to be incorrect. Proposed Section 447.510(c)(2) states that recalculations of base date AMP "must only reflect the revisions to AMP as provided for in § 447.504(e) of this subpart."[56] While Section 447.504 as a whole sets forth the new regulations for determining AMP, paragraph (e) only addresses the retail pharmacy class of trade. Based on the discussion of base date AMP in the proposed rule's preamble, PhRMA believes that the cross-reference should not be restricted to paragraph (e) and instead should encompass all of Section 447.504. Accordingly, PhRMA requests that CMS correct this cross-reference.

V. Conditions Relating to Physician-Administered Drugs - Section 447.520

In connection with physician administered drugs where Medicaid is a secondary payor under the Medicaid Drug Rebate Program, CMS has taken the position that "if a state Medicaid agency pays any portion of a drug claim to the provider, for purposes of the drug rebate agreement, the manufacturer is liable for the payment of rebates for those units of the drug."

We understood it to be the agency's position that manufacturers are subject to full rebate liability in all instances because of the statutory language that the manufacturer pay the rebate as

[54] 71 Fed. Reg. at 77185.

[55] Id. at 77194.

[56] Id. at 77198.

defined in "subsection (c) of this section" for drugs paid under the State Medicaid plan. Subsection (c), however, provides only for the full rebate amount. PhRMA believes that this statutory language cannot be read alone, but must be interpreted in a manner consistent with the statutory language that rebates are to be considered "a reduction in the amount expended."[57] PhRMA believes it to be unreasonable and illogical for the manufacturer's rebate to the state to exceed the State's payment amount. It is our belief that the Congress, through the Medicaid rebate statute, did not intend for rebates to exceed a State Medicaid agency's expense.

The rationale behind enactment of the original Medicaid rebate program was to ensure that Medicaid could access the same prices as other purchasers in the market. It was not the intention, nor should it be allowed, to provide unmerited financial gain as is the case when States are able to obtain full rebates, regardless of actual prescription drug expenditures under their Medicaid program.

In a letter sent to CMS last fall, Senator Grassley, Former Chairman of the Senate Finance Committee confirmed the Congressional expectation that Medicaid rebates be proportional to Medicaid expenditures. Senator Grassley clarified that "[f]ederal law does not authorize States to collect rebates for the proportion of the payment made by the Medicare program" and that the DRA amended the Medicaid rebate statute to ensure that States are only entitled to rebates "for drugs administered for which payment is made under this title." This statutory language clearly means that "the Medicaid rebate is only available for the Medicaid portion of the payment."

For all of these reasons, PhRMA strongly urges CMS to adopt a position and guidance on Medicaid rebates in the final rule consistent with the statute as explained by Senator Grassley and require that the states receive rebates that are proportional to the dollars expended by the states.

VI. Further AMP Clarifications

CMS states in the preamble that plans "to address future clarifications of AMP through the issuance of program releases and by posting the clarifications on the CMS Web site as needed." [58] We recognize the importance of CMS being able to issue guidance to respond to changes in the marketplace. However, it is critical that stakeholders be permitted the opportunity to comment on such guidance to ensure that CMS fully appreciates the significance of any change. In addition, it is important that those entities that are impacted by the changes are notified of changes in a manner other than a posting to the CMS website. In Part D, CMS has issued a substantial amount of subregulatory guidance and has provided, in many instances, for public comment. In addition, under Part D as well all other areas of Medicare, CMS issues a

[57] SSA § 1927 (b)(1)(B).

[58] 71 Fed. Reg. at 77181.

Manual which is continually updated which provides for all of the guidance in one place. We encourage CMS to consider developing a Medicaid Prescription Drug Program Manual.

VII. Certification

The DRA and these implementing regulations, once finalized, create a number of new reporting requirements, including, but not limited to, more frequent reporting of AMP than has been required historically. As a result manufacturers must revamp existing price reporting processes and institute new reporting time frames. CMS has proposed to require CEO or CFO certification of all price reporting submissions related to this new rule, which adds another layer of complexity on an already complicated process. Such a certification requirement will create operational difficulties for manufacturers without serving any program integrity purpose for Medicaid. The timing required to: (1) obtain the previous month's information: (2) conduct calculations; (3) include an authorized generic's information, where applicable, and then (4) have the time to review the information with a CEO or CFO who may not be engaged in the daily activities necessary to produce the report makes meeting a monthly deadline difficult. Certification seems an unnecessary additional step in light of the statutory authority to impose civil monetary penalties for inaccurate price reporting submissions that already exists. Had Congress had felt that the existing civil monetary penalty provisions were insufficient to ensure accurate price reporting, then Congress would have included additional statutory provisions in the DRA to address such a concern.

If CMS retains the certification requirement, CMS should consider requiring it only for the quarterly reporting, which is the frequency of ASP, on which the certification requirement is based. Furthermore, it is the quarterly report on which the manufacturer's rebate is based.

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

VIII. Effective Date

Under the DRA, CMS is required to promulgate a final rule concerning AMP no later than July 1, 20007. PhRMA notes that the proposed rule includes many changes, clarifications, and in some cases, departures from past guidance. Thus, the magnitude of system and other operational changes that the final rule requires may be substantial and require significant adjustments. PhRMA therefore urges CMS to allow manufacturers at least 4 quarters from the publication date to come into compliance with the final rule. CMS should also specify that

manufacturers may make changes incrementally as long as they are fully compliant by the effective date of the final rule.

* * *

PhRMA appreciates the opportunity to comment on this proposed rule, as well as all of the effort that CMS put into the development of the proposed rule. We look forward to further dialogue with CMS on the many important topics addressed in this rulemaking and we hope that our comments will be useful to the Agency as it develops the final rule. We trust that CMS will not hesitate to contact us with any questions or requests for additional information.

Sincerely,

Ann Leopold Kaplan
Assistant General Counsel

Maya J. Bermingham
Assistant General Counsel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

October 22, 2002

VIA FIRST CLASS MAIL AND FACSIMILE: (609) 897-6095

Thomas McKenna
Senior Vice-President/Planning & Operations
Bristol-Myers Squibb Company
P.O. Box 4500
Princeton, NJ 08543-4500

Dear Mr. McKenna:

Thank you for presenting to us the methodology by which Together Rx operates. As we understand it, the Together Rx savings program operates as follows:

- The program is focused on extending pharmacy assistance to a limited subset of individual, low-income, Medicare-eligible patients.
- Each manufacturer establishes an amount of the benefit to be given to individual patients, without any negotiation between the manufacturer and a third party (such as an insurer or PBM) as to that amount.
- The entire amount of the benefit is made available to an individual patient, without any opportunity for the retail pharmacy or any other third party (such as an insurer or PBM) to reduce that benefit, or take a portion of it, for its own purposes.
- The pharmacy reimbursement formula provides that the pharmacy will be reimbursed based upon the lower of (a) a formulaic "ceiling price" equal to AWP - 6 2/3% + $2.50 or (b) the pharmacy's usual and customary price for the drug.
- The pharmacy collects no additional payment, other than the benefit amount, from the Together Rx program.

CMS does not believe that the specific facts described above would have implications for the determination of best price under section 1927(c)(1)(C) of the Social Security Act, since the fact pattern you have presented would be akin to a direct-to-patient coupon. As I stated in my June 24, 2002 letter to Mr. Alan Holmer, "direct-to-patient coupons" are not included in best price

The analysis in this letter is limited to the facts described in this letter and has no applicability to a different set of facts even if such facts appeared similar in nature or in scope. Also, as you know, this letter cannot be considered an advisory opinion under section 1128D(b) of the Social Security Act, since only the Department's Inspector General has been authorized to issue advisory opinions relating to health care fraud and abuse under that section.

Sincerely,

Thomas A. Scully

Appendix

Overview of the Pharmaceutical Payment System [24]

While there is variation in the way that prescription drugs are distributed, the payment and pricing system is much more complex than the distribution system, and continually is evolving. Partly this increased complexity is because payment and pricing arrangements involve additional parties that generally do not play a role in the physical distribution of pharmaceuticals: in particular, PBMs and payors. As summarized in one report, "while the flow of products through the pharmaceutical chain is relatively straightforward, the flow of money involves a wider range of players and complex financial relationships."[25] The discussion below begins with a general summary of the payment arrangements between the key entities involved in the distribution chain — manufacturers, wholesalers, and pharmacies —and then briefly describes some of the other participants in the payment system and the roles they play.

As noted earlier, manufacturers most commonly sell to wholesalers that resell to pharmacies. Manufacturers' list prices to wholesalers are known as wholesale acquisition cost (WAC).[26] Wholesalers typically purchase at a discount off of WAC[27]; examples of discounts for branded products include prompt pay discounts, volume discounts, and "short-dated" product discounts (where the wholesaler assumes the risk that the product will expire before it can be resold).[28] In recent years, the major wholesalers have sought to move to a "fee-for-service" model in which they negotiate fees with manufacturers for activities such as distribution and inventory management.[29]

Pharmacies that purchase from wholesalers pay an amount negotiated with the wholesaler. According to one report, pharmacies typically pay wholesalers WAC plus some negotiated percentage.[30] In some cases, pharmacies or other "end-user" customers that purchase through wholesalers may negotiate rebate agreements with manufacturers, or they may negotiate a contracted price with the manufacturer. When

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[24] As noted earlier, this appendix provides a brief general overview of the pharmaceutical distribution chain and payment system based on information in publicly available reports. Particularly given the complexity of the payment system, there may be arrangements or practices not captured in these reports.

[25] Navigating the Pharmacy Benefits Marketplace at 18.

[26] As defined in the Medicare Modernization Act, WAC represents "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price . . . as reported in wholesale price guides or other publications of drug and biological pricing data." Social Security Act §1847A(c)(6)(B).

[27] Follow the Pill at 18.

[28] Id.

[29] See, e.g., R. David Yost, New Economics of the Pharmaceutical Supply Chain, 62 Am. J. Health-System Pharm. 525 (March 2005).

[30] Follow the Pill at 18.

wholesalers sell to customers that have a contract price with a manufacturer, they charge the contract price and then bill the manufacturer for a "chargeback"; the chargeback equals the differential between WAC and the contract price.[31]

Smaller pharmacies also may use group purchasing organizations (GPOs) in some cases to negotiate prices with wholesalers or manufacturers.[32] GPOs are entities that negotiate discounted prices on behalf of their members (which primarily are hospitals and other healthcare providers) from manufacturers and distributors of pharmaceuticals and other healthcare products. Pharmaceutical manufacturers and other vendors pay administrative fees to GPOs, which (at least in the case of six GPOs that were studied by the OIG) distribute a portion of their administrative fee revenues to their members.[33]

PBMs play a number of roles in the pharmaceutical payment system. Normally PBMs are not directly involved in the product supply chain, since they do not take physical possession or control of pharmaceuticals as part of their core pharmacy benefit management functions.[34] However, many PBMs own and operate mail order pharmacies and (in their capacity as mail order pharmacies) buy drugs from wholesalers or manufacturers and dispense them to patients.[35]

PBM clients can generally be described as "payors." That is, a PBM's clients usually are entities that provide prescription drug insurance to their enrollees or members, such as self-insured employers, insurers, and HMOs and other managed care organizations.[36] The specific services a PBM performs will vary depending on its contract with particular clients, but PBM functions generally include forming pharmacy networks and negotiating discounted reimbursement rates with network pharmacies; developing and administering formularies and related features of the plan design (e.g., formulary tiering structures, utilization management tools such as prior authorization); negotiating rebates with manufacturers; and processing claims.[37]

Payments that PBMs negotiate with manufacturers of brand-name drugs include rebates, and administrative fees that compensate the PBM for formulary-related administrative activities.[38] The effect of manufacturer rebates to PBMs on

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31 Id. at 19.

32 Navigating the Pharmacy Benefits Marketplace at 25; Follow the Pill at 19-20.

33 See HHS OIG, Review of Revenue From Vendors at Three Group Purchasing Organization and Their Members, A-05-3-00074, Jan. 2005 (the GPOs studied collected $1.8 billion in administrative fee revenue during the audit period and distributed $898 million to members); HHS OIG, Review of Revenue From Vendors at Three Additional Group Purchasing Organizations and Their Members, A-05-04-00073, May 2005 (GPOs studied collected $513 million in administrative fee revenue during the audit period and distributed $217 million to members).

34 Follow the Pill at 14-15; FTC report at 7.

35 Follow the Pill at 14-15; FTC report at 5-6.

36 FTC report at v; PricewaterhouseCoopers report at 17. In some cases, these entities can be purchasers of drugs as well as payors; for example, some "staff model" HMOs operate on-site pharmacies at their facilities.

37 See, e.g., PricewaterhouseCoopers report at 50-58.

38 See, e.g., FTC report at 50-55. In some instances manufacturers also may pay PBMs fees for compliance, therapeutic interchange, and other programs related to particular drugs. Id. at 55. In addition to entering into

pharmaceutical prices has been described as follows: "This rebate does not affect the price paid by a wholesaler to a manufacturer for the drug, the price paid by a retail pharmacy to the wholesaler, or the price paid by the PBM to the pharmacy. It is a separate transaction between the PBM and the manufacturer and thus affects the total amount spent by the PBM. To the extent that a portion of the rebate is passed along, the insurer, employer, or beneficiary may realize a part of these savings."[39]

Both the FTC's recent study on PBMs and an earlier study by PricewaterhouseCoopers reported that PBMs commonly pass through a share of manufacturer rebates, but not administrative fees, to their clients.[40] In addition, both studies indicated that the share of rebates passed through to a PBM's clients varies considerably from contract to contract.[41] For example, the FTC examined the retention rates for all pharmaceutical manufacturer payments (including non-pass-through administrative fees) on 11 PBM contracts, and found that in 2003 the PBMs' retention rates on these contracts ranged from 25% to 91% (i.e., pass-through rates ranged from 75% to 9%).[42] The PricewaterhouseCoopers study reported that the percentage of rebates PBMs share with their clients can range from zero to 100%.[43]

The FTC also noted that the percentage of manufacturer rebates that a PBM passes through to a client cannot be viewed in isolation, because clients make payments to PBMs (e.g., administrative fees for claims processing and other services, and reimbursement for the drugs dispensed to plan beneficiaries) and a client could negotiate lower payments in exchange for receiving a lower percentage of manufacturer rebates. Thus, "PBMs could adjust any of a number of terms (e.g., dispensing fees, discounts off of ingredient costs) to make the contract more attractive to plan sponsors" and "in this way manufacturer payments to PBMs could be passed on to plan sponsor clients through a complex array of adjustments to contract provisions relating, for example, to the services that would be provided by the PBM and the prices and fees that would be paid by plan sponsor clients."[44]

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agreements with PBMs providing for rebates and administrative fees, manufacturers may enter into similar agreements with insurers or other health plan sponsors that manage their own drug benefits, as well as with public programs that provide drug coverage.

39 HHS report at 104.

40 PricewaterhouseCoopers report at 9, 16, 52; FTC report at 59.

41 The FTC found that PBMs and their clients have agreements with three different types of rebate sharing models. In addition to contracting for a certain percentage of manufacturer rebates, PBM clients may also negotiate arrangements in which they receive a specific dollar amount per brand-name drug prescription from the PBM rather than receiving a share of the actual rebates paid to the PBM, or arrangements in which they receive a specified share of rebates subject to a guaranteed minimum rebate payment. FTC report at 57-58.

42 FTC report at 59.

43 PricewaterhouseCoopers report at 88. See also HHS report at 105 (noting that industry sources report that PBM clients typically receive 70-90% of rebates).

44 FTC report at 60. CMS made a similar point in a recent "call letter" to Medicare Part D plans; CMS stated there that "[w]e must assume that if a PBM retains a portion of the manufacturer rebates it negotiates on behalf of a Part D sponsor, the direct payment the sponsor pays the PBM for its services will be less, i.e., the sponsor receives a price concession from the PBM." CMS PDP Call LetterApril 3, 2006, at 10.

As noted earlier, PBMs also establish networks of retail and mail-order pharmacies where patients with PBM-administered benefits can fill prescriptions, and negotiate the reimbursement rates network pharmacies receive (i.e., the total payment the pharmacy receives, including the PBM payment and the patient copayment or coinsurance amount). These negotiated reimbursement rates are lower than the rates that pharmacies charge to uninsured "cash-paying" patients, and usually vary depending on the restrictiveness of the pharmacy network (i.e., pharmacies can obtain more business by participating in a more exclusive network, and may thus be willing to accept lower reimbursement rates).[45] The drug ("ingredient cost") reimbursement rates negotiated between PBMs and network pharmacies reportedly are often based on a discount from Average Wholesale Price for brand-name drugs and a Maximum Allowable Cost limitation for generics;[46] pharmacies usually also receive a dispensing fee. The amount that the PBM itself is reimbursed by its clients may or may not equal the amount paid by the PBM to the pharmacy (i.e., ingredient cost plus dispensing fee minus patient copay/coinsurance); the PBM may be paid for pharmacy costs based on a contractually-specified pharmacy reimbursement rate, and could thus experience a profit or loss on pharmacy costs.[47]

The amount paid to the pharmacy by a patient depends on whether the patient is insured. Patients with insurance pay the copayment or coinsurance amount set by their insurer for the drug in question; uninsured patients usually would pay the "cash price."[48] By one estimate, the cash price is approximately 15% higher than the pharmacy's total payment (i.e., insurance payment plus patient copay) for an insured patient.[49] Of course, insured patients ordinarily pay a premium for their coverage as well as the payments they make on prescriptions.

Although this brief overview of the pharmaceutical payment system cannot catalogue all of the system's complexities, it suggests that the "price" of a pharmaceutical product is not easily captured and will depend on the perspective one wishes to examine. Rather than being a single number, the average "price" for a product at a particular time may vary depending on whether one examines the amount realized by the manufacturer; the amount paid by wholesalers; the amount paid by pharmacies; the amount paid by PBMs; the amount paid by PBM clients such as insurers or other health plan sponsors; or the amount paid by patients.

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45 FTC report at 5; PricewaterhouseCoopers report at 57, 70.

46 PricewaterhouseCoopers report at 86-87; FTC report at 4-5; Follow the Pill at 19.

47 PricewaterhouseCoopers report at 71; FTC report at 9-10.

48 Patients with traditional indemnity insurance also may pay the cash price at the pharmacy counter and then submit a claim for reimbursement to their insurer.

49 HHS report at 96.

State of New Jersey
DEPARTMENT OF HUMAN SERVICES
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JON S. CORZINE
Governor

JENNIFER VELEZ
Acting Commissioner

ANN CLEMENCY KOHLER
Director

February 20, 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, D.C. 20201

Attention: **CMS-2238-P**

Re: Proposed Rule: Medicaid Program; Prescription Drugs

Dear Ms. Norwalk:

The New Jersey Division of Medical Assistance and Health Services, Department of Human Services, respectfully submits this comment letter on the Medicaid prescription drug benefit. The comments are based on the proposed rule published in the December 22, 2006 Federal Register (71 FR 77174) for the Centers for Medicare and Medicaid Services (CMS). Please be assured that New Jersey is fully committed to implementing the prescription drug-related provisions of this Deficit Reduction Act of 2005 (DRA).

Among its requirements, the DRA included important provisions that could facilitate increased transparency in prescription drug pricing. New Jersey has already taken the initiative to create a website (which will be accessible to the public) as a result of a recent bill establishing the New Jersey Prescription Drug Retail Price Registry within the Division of Consumer Affairs.

We also share in your goal to make the proposed rule workable. Our comments are intended to highlight those areas where we have concerns about timely implementation in order to achieve compliance with the Congressional intent.

We offer these comments for your consideration:

Requirements for Manufacturers – Section 447.510

Dispensing Fee Adjustments
The rule states that ". . . savings reflect CBO's expectation that states would raise dispensing fees to mitigate the effects of the revised payment limit . . ."
We believe that the rule should not require states to raise its dispensing fees. We strongly recommend that the rule remain silent on this issue since it is not specifically addressed in the DRA.

Implementation Timeline
According to the proposed rule, the revised FUL would take effect on January 1, 2007 and that the Secretary of the Department of Health and Human Services (HHS) would disclose AMP data for all drugs to the states, starting July 1, 2006.

Thus far, no guidance has been provided to the states regarding the source of the revised FULs and the file parameters. Since no advance programming could take place, it will not be possible to accommodate the files when they become available. We recommend that the effective date be changed to 90 days subsequent to the first release of the new source file. Otherwise, savings will be underreported by the States; i.e., the denominator will be the number of months since January 1, 2007 to implementation of the new source file, vs. the actual number of months where savings could have accrued as a result of the implementation of AMP.

Transfer of AMP Files
The proposed rule states that CMS will distribute the monthly AMP file to states but it is not clear what information will be contained in the file. We recommend that, in addition to the descriptor, the **11 digit** NDC number be included as well so that States may appropriately price claims and invoice drug rebates. (The 9 digit NDC number is insufficient to identify the quantity of a dispensed drug.)

The sample files that have been sent to the States since July, 2006 include about 50% of the total number (approximately 50,000) of NDCs. According to the report of the Office of Inspector General *"Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices"*, dated June 2005, approximately 25,560 NDCs were represented in the data provided by CMS. The States need guidance regarding the appropriate FUL for those NDCs that have both an AMP value and at least one other price, but which are not included in the monthly file.

FFP: Conditions Relating to Physician Administered Drugs – Section 447.520

The proposed rule requires states to collect NDC codes from physicians along with the HCPCS (J-codes).

Provider Education

There is concern that the proposed rule does not take into account the extensive education required to ensure that providers can comply. Further, this change comes at the same time when providers are being asked to apply for an NPI number and to adhere to the May 23rd date for implementation. We recommend that CMS do more to educate Medicare participating providers. States are reaching out to their participating pharmacies to alert them to the changes in reimbursement, but without CMS guidance there is a tendency for providers to assume the change is specific to the State and they might not be inclined to initiate requisite software reconfiguration.

Thank you for the opportunity to comment on this very important proposed rule. If you have any questions or need additional information, please do not hesitate to contact Valerie Harr at 609-588-3062 or Kaye Morrow at 609-631-2396.

Sincerely,

Ann Clemency Kohler
Director

c: Valerie Harr
Kaye Morrow

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WATSON Pharma, Inc.
A Subsidiary of Watson Pharmaceuticals, Inc.

February 20, 2007

Per Veronica in Leslie Norwalk office
Time 4:55
FEB 2 0 2007

VIA HAND DELIVERY
The Honorable Leslie V. Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201
Attn: CMS-2238-P

Re: CMS-2238-P – Deficit Reduction Act of 2005 Medicaid Prescription Drug Proposed Rule

Dear Ms. Norwalk:

On behalf of Watson Pharma, Inc. ("Watson"), thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") Deficit Reduction Act of 2005 proposed rule. Watson is a leading specialty pharmaceutical company dedicated to developing, manufacturing, marketing and distributing branded and generic pharmaceutical products in a cost-effective manner. Watson ranks third amongst U.S. based generic manufacturers in terms of prescriptions dispensed according to recent IMS data.

Based on Watson's review, Watson would like to provide CMS with a detailed response and recommendation to the authorized generics and best price reporting requirements provisions (Section 447.506) of the CMS proposed rule. In addition, Watson would like to recommend AMP reporting at the nine-digit level for computation of Federal Upper Limits (FUL) for multiple source drugs (Section 447.514).

Authorized Generic Drugs – Section 447.506

"Best Price" is defined as the lowest price at which drug manufacturers sell drugs to any purchaser. In the case of authorized generics, there are two selling prices – that of the primary manufacturer and that of the secondary manufacturer. Since Section 447.506 is not clear as to which manufacturer's selling price is to be reported to CMS as the best price for the authorized generic product, Watson's recommendation is that CMS should preserve its current policy of exempting from inclusion in best price reporting those entities, including manufacturers, who sell products for "repackaging" and, therefore, classify the secondary manufacturer of authorized generics as a repackager.

While the law is largely silent as to the definition of "repackaging", the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") inquiry "Medicaid Drug

Rebates – Sales to Repackagers Excluded From Best Price Determinations (A-06-00-00056) March 27, 2001" into sales to HMO's, provides a framework that points to a practical understanding of what an entity must do to be considered a repackager. The OIG inquiry notes that in order to qualify for the repackaging exemption, an entity is expected to vend the product using its own labeler code.

The next point to consider is the definition of "manufacturer".

As referenced in the proposed rule, Section 1927(k)(5) of the Deficit Reduction Act of 2005 defines manufacturer as follows:

> Manufacturer would be defined based on the definition in section 1927(k)(5) of the Act and the national rebate agreement. It would also mirror the current definition of manufacturer used by Medicare in the regulations regarding manufacturer's average sales price (ASP) data. For purposes of the Medicaid program, manufacturer would be defined as any entity that possesses legal title to the NDC for a covered drug or biological product and -
> (a) is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or
> (b) is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesaler of drugs or a retail pharmacy licensed under State law.
> (c) With respect to authorized generic products, the term "manufacturer" will also include the original holder of the NDA.
> (d) With respect to drugs subject to private labeling arrangements, the term "manufacturer" will also include those entities that do not possess legal title to the NDC.

Consistent with this definition is the well understood characterization of entities that repackage drugs as secondary manufacturers.

Therefore, Watson believes that, consistent with current OIG guidance, and Section 1927(k)(5) of the Act, CMS should agree that the sale to the secondary manufacturers, defined as repackagers in accordance with the Act, is exempt from best price reporting.

CMS's current definition of "best price" requires the calculation to include all sales, discounts and other price concessions provided by the manufacturer for covered outpatient drugs to "any entity". Watson's recommendation to CMS is to define "any entity" and to specifically exclude the sale price of the authorized generic from the primary manufacturer to the secondary manufacturer/repackager in the definition of "any entity". Lack of defining "any entity" by excluding the sale from primary manufacturer to secondary manufacturer in this policy could result in inadvertently using that first sale as the best price. This could result in increased cost to the pharmaceutical supply chain and result in an unnecessary shift in cost ultimately to payors

and consumers as both the primary and secondary manufacturers will raise their own sell out prices to recoup expected reduced margins because of an inaccurately calculated "best price". The present practice of requiring repackagers to calculate their best price using their sell out price to their customers, distributors and retailers in the supply chain, would preserve the present price relationships and protect payors and consumers from higher prices.

Watson would like to reiterate that we believe CMS intends to preserve the historical relationship between the primary manufacturer and repackager in calculating best price, and classifying the secondary manufacturer as a repackager, therefore exempting the first sale from best price reporting. To that end, Watson looks forward to clarification on this vital issue in the final rule.

Reporting of AMPs at the NDC Nine-Digit Level – Section 447.514

The currently reported AMP is based on the nine-digit NDC, combining all package sizes of the drug into the same computation. CMS proposed to continue this policy and solicited comments on the alternative approach of using 11-digit NDC to calculate AMP as well as comments on the merits of using both approaches in calculating AMP for the FUL calculation (71 *Fed. Reg.* 77187). Watson does not find a compelling reason to move away from the nine-digit NDC calculation, and we are concerned that significant system changes would be required to support 11-digit reporting. Therefore, Watson favors the proposed AMP reporting at the nine-digit level for FUL computation as well as rebate purposes.

Watson appreciates the opportunity to comment on this proposed rule. If there are additional questions regarding authorized generics and best price reporting requirements, or reporting of AMPs at the NDC nine-digit level, we encourage CMS to contact us. We look forward to CMS's response.

Sincerely,

Steve L. Goodman, R.Ph.
Vice President, Marketing - Generics
Watson Pharma, Inc.

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American Society of
Health-System Pharmacists®

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February 20, 2007

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

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

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & 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. ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems.

ASHP would like to specifically comment on the provision in the proposed rule that requires hospitals to include the 11-digit National Drug Code (NDC) on claims submitted for physician-administered drugs. Fundamentally, ASHP believes that "physician administered drugs" under the DRA is limited to drugs administered to patients in physician offices, not hospital outpatient departments. The DRA references "certain" physician administered drugs as determined by the Secretary. Moreover, the DRA makes no reference to Section 1927 (j) of the Act, which exempts drugs used in certain types of settings from rebate requirements. Therefore, hospital outpatient departments should be exempted from this requirement.

ASHP also believes that this requirement would create an undue financial hardship since the vast majority of affected facilities have no other option but to provide NDC information through a labor intensive process. The requirement is also likely to compromise patient safety because of changes in hospital workflows and the necessity of diverting staff (already in short supply) to the NDC – reporting requirement.

ASHP conducted a survey of pharmacy directors in February 2007 to estimate the impact of this new requirement on hospitals and health systems' current systems and processes. Over 700 surveys were returned and were received from hospitals in every state except Alaska. Respondents were from facilities with an average daily census from less than 50 to greater than 500 and outpatient visits ranged from 12,000 to 180,000 a year. A copy of the results is enclosed.

There are several key areas of concern that ASHP has identified through our own analysis of the survey results. Primary issues include:

- **Negative Impact on Patient Safety.** Current workflow and systems for dispensing and administration of medications were designed to be safe and efficient. Adding a requirement for tracking and reporting NDC numbers would require that systems be redesigned for accurate tracking of billing information, diverting limited staff from accurate dispensing and administration.

  A respondent from Minnesota told us: "*This would be a huge requirement. Even if we had a system for tracking the NDC, it would still add time to each order. This added time would also cause further confusion in an already busy pharmacy. Added confusion increases the risk for mistakes. With the constant changes to contracts and supply, managing to the NDC level would be very challenging.*"

- **Significant Costs Per Claim.** The proposed rule estimated a cost of 9 cents per claim based on a manual entry taking 15 seconds each. This estimate is inaccurate because it does not take into account the costs associated with making various changes that would be required throughout the institution with respect to the entire medication-use process. There is a range of steps required before filing a claim, including recording and tracking the NDC number from order entry to preparation and administration, as well as finance and patient billing. In our survey, the full estimated cost to comply with this proposal was $10.80 per claim, taking an average of 24 minutes if this requirement were implemented today.

  A respondent from South Dakota said: "*I coordinate services of nearly 20 rural Critical Access Hospital pharmacy departments, many of them with less than one full time staff person and little automation. In my opinion, this would have an enormous impact. Not only would it be almost impossible to be in compliance, it would certainly divert the limited resources we have away from patient care and medication safety, to a tracking exercise. It's likely that the time reduction from patient care and safety activities would tend to increase overall costs.*"

- **Unrealistic Tracking Requirements.** Of major concern is a survey finding that 60% of respondent facilities did not have information systems that could 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 that a therapeutic equivalent generic entity was administered. This is because hospitals have integrated inpatient and outpatient pharmacy billing systems, and both rely on the same drug product inventories that may include multiple generic suppliers (each with a separate NDC number) of the same medication.

  As one respondent said: *"We recently completed a review of all pharmacy software vendors for cancer care in the outpatient setting and concluded there is no vendor in the marketplace that could provide this tracking."*

  Another respondent indicated that *"the cost to modify computer systems could cost $1 to $1.5 million, if the modifications could even be developed and purchased."*

- **Minimal Bar Coding Capability.** Utilization of bar codes at the point of administration is considered by many to be the only feasible way of implementing the NDC requirement. Existing systems will not offer this as a viable solution for some time since only 6% of the survey respondents indicated they used bar-coding for outpatient medication doses. For bar coding to serve as a solution to providing the unique NDC number, it must be fully implemented throughout all the institution's information systems, including point of administration.

  A respondent from Oklahoma told us: *The health care industry is not currently positioned for this transition. With the future implementation of point-of-care/bedside medication verification scanning technology, hospitals may be better equipped to implement this edict. We are not currently positioned to meet this requirement in our rural health care setting.*

In order to meet the requirements in the proposed rule, institutions would face significant operational and financial hardship that is unrealistic and not justifiable given current workforce and fiscal constraints. Substantial expenditure of human and financial

resources would be required. We urge the agency to reconsider this requirement and exempt hospital outpatient departments, not only because of this significant burden, but also since there is no specific reference to their inclusion in the DRA.

Sincerely,

Brian M. Meyer
Director, Government Affairs Division

Enclosure

ASHP Survey Results:

Provision of NDC Numbers on Outpatient Medicaid Claims

February 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 36% 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 <u>out</u>patients (hospital clinic, emergency department services, and outpatient infusion centers). **Approximately how much time per <u>order</u> 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	1%	3%	14%	78%	4%
Provision of NDC information to finance/patient accounts	2%	2%	18%	70%	9%
Total Responses: 637					

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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

2007 FEB 14 PM 12:

NCPA NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

GPhA GENERIC PHARMACEUTICAL ASSOCIATION

HDMA Healthcare Distribution Management Association

February 12, 2007

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

Dear Ms. Norwalk:

We are writing to ask that the Centers for Medicare and Medicaid Services (CMS) provide our associations with important data that will assist us in assessing the economic impact of a proposed regulation on our industries. The regulation, **Medicaid Program: Prescription Drugs (RIN 0938-AO20)**, was published on December 22, 2006 in the Federal Register (71 Fed. Reg. 77174). Our associations represent independently-operated and chain-operated community pharmacies, generic pharmaceutical manufacturers and entities that distribute health care products, including pharmaceuticals.

In the proposed regulation, CMS' regulatory impact analysis estimates that the new Federal Upper Limits (FULs) for multiple-source drugs will reduce pharmacy payments by about $8 billion over the 2007-2011 federal fiscal years. Reductions of this magnitude can have a significant economic impact on the ability of the pharmaceutical supply chain to be able to provide critical prescription drugs, pharmacy services, and distribution services in the marketplace.

To be able to better provide comments on the regulation and the regulatory impact, we ask that the CMS provide our organizations with its best estimation of the actual Federal Upper Limit (FUL) for multiple-source drugs as they would be calculated under the proposed rule. Only CMS has access to the data necessary to make these calculations. As you are aware, FULs reflect an aggregation of AMP data across manufacturers and therefore are not protected by the Medicaid Rebate Statute's confidentiality provisions. Our organizations and our members need the FUL estimates in order to make a thorough and accurate analysis of the impact of the proposed rule on the pharmaceutical supply chain before completing our comments.

For example, CMS indicates that it is "unable to quantitatively estimate effects on small retail pharmacies, particularly in low income areas." If our organizations were provided with estimated FULs from CMS, we could better analyze the impact of the proposed regulation on all pharmacies, especially those in low income areas that serve a large percentage of Medicaid beneficiaries.

Second, we ask that CMS extend the comment period in order to allow our organizations and our membership adequate time to review and analyze the FUL data that we have requested above. We believe an extension by a minimum of 60 days (from the date that the requested FUL data are provided) would be appropriate to allow sufficient time for such a review.

We want to provide CMS with helpful comments so the agency can better understand the impact of this proposed regulation. It is difficult for us to do that without having critical data. We appreciate your consideration of this request and look forward to working with CMS on the proposed rule.

Sincerely,

Generic Pharmaceutical Association
Healthcare Distribution Management Association
National Association of Chain Drug Stores
National Community Pharmacists Association

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RICHARD SHELBY
ALABAMA

CHAIRMAN—COMMITTEE ON BANKING, HOUSING AND URBAN AFFAIRS
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February 16, 2007

Acting Administrator Leslie Norwalk
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Acting Administrator Norwalk:

I am writing to request your immediate action on an issue of concern to many of my constituents who are independent pharmacists. The Medicaid safety net has preserved the health and well-being of millions of Americans since its creation nearly a half century ago. I am concerned that actions by CMS, in an attempt to comply with the Deficit Reduction Act of 2005 (DRA), could severely jeopardize patient access to prescription drugs in the future.

Pursuant to the DRA, CMS is currently receiving comments on the proposed rule implementing Average Manufacturers Price (AMP) as the new basis for the Upper Federal Limit (FUL) on multiple-source generic medications.

In a report released on January 20, 2007, the GAO found that an AMP-based FUL will fall an average of 36% below pharmacy acquisition costs. This method will result in a shift of the cost share toward states, which will inevitably require the states to reduce reimbursement below pharmacy costs. As proposed, this rule may force many rural and family-owned pharmacies to remove themselves from the Medicaid program and effectively eliminate important access to needed cost-savings medications for participants- particularly those in rural Alabama.

I am also troubled by reports that CMS has demanded data to support suggested changes to the AMP definition, but refused to make the same data available for public review. In addition, it appears that CMS has summarily rejected the findings of a recent GAO study on the issue. It seems reasonable that if CMS is going to dismiss the GAO report it should make, at a minimum, a sampling of AMP data available for the public to review and use in their comments on the proposed rule.

To that end, I ask that CMS provide the AMP data for the numerous drugs covered in the GAO study for review by me and my constituents as well as others wishing to submit thorough, fact-driven comments. Given that such data is likely voluminous, I ask you to extend the comment period by no less than 60 days, so that those wishing to comment will have sufficient time to review the data and appropriately respond.

Thank you for your prompt response to this request.

Sincerely,

Richard Shelby

Richard Shelby

Richard Shelby

United States Senator * Alabama

Committees:
Chairman - Committee on Banking, Housing, & Urban Affairs
Committee on Appropriations
Chairman - Subcommittee on Commerce, Justice and Science
Special Committee on Aging

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FAX TRANSMISSION SHEET

Date: 2/16/07 Page 1 of 3

To: Acting Administrator Leslie Nonwalk

Fax Number: (202) 690-6262

From: Mary Margaret Carroll
Phone: (202) 224-5744
Fax: (202) 224-3416

Message:

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American Hospital Association

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February 20, 2007

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

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

Dear Ms. Norwalk:

The American Hospital Association (AHA), on behalf of our approximately 5,000 member hospitals, health care systems and other health care organizations, and our 37,000 individual members, appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule implementing provisions of the *Deficit Reduction Act of 2005* (DRA) that pertain to the Medicaid prescription drug program. Our comments address CMS' interpretation of Section 6002 of the DRA and the new requirement that hospitals report physician-administered drugs using the National Drug Code (NDC). We will focus on two issues:

- the legal premise upon which CMS has based its interpretation of Section 6002, and
- the significant administrative burden these new reporting requirements impose upon hospitals.

We urge CMS to revise its interpretation of Section 6002 of the DRA and not require the reporting of physician-administered drugs to hospital outpatient clinics and departments.

FFP: CONDITIONS RELATING TO PHYSICIAN-ADMINISTERED DRUGS – SECTION 447.420

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

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

Section 6002 does not apply to outpatient drugs administered in hospital outpatient clinics and departments.
Section 6002 requires only the collection of utilization and coding data for drugs that are subject to a rebate requirement under Medicaid statute provisions that predate the DRA – a position that CMS acknowledges in the proposed rule. Under Section 6002, state Medicaid programs are expressly directed to provide for the submission and collection of drug utilization and coding data "as necessary to identify [manufacturers of drugs] in order to secure rebates" under the Medicaid rebate law. In other words, the data collection requirement applies only if the state Medicaid agency finds it necessary to obtain a drug's NDC number in order to identify the responsible manufacturer and enforce a Medicaid rebate payment obligation. On the other hand, for outpatient drugs that are not subject to a rebate payment requirement – like those dispensed in hospital outpatient clinics and departments – the collection of NDC information with respect to that drug plainly is not necessary to securing a rebate, and the law does not require submission or collection of NDC data on the drug.

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

Further, the Secretary is authorized to delay applying the data reporting requirement in order to prevent hardship to any states that require additional time to implement the reporting system. Such hardship is not expressly limited in the statute and may encompass the state's consideration of difficulties in obtaining data from reporting hospitals and the time needed to reconfigure the systems of reporting hospitals.

Section 6002 was enacted to address a problem with rebate collection on drugs administered in physicians' offices – not hospital outpatient clinics and departments.
In the proposed rule, CMS seeks to give a much broader application to physician-administered drugs. By including all covered outpatient drugs that "are typically furnished incident to a physician's service," the agency expands the scope of Section 6002 well beyond the problem it

was designed to address. Precise congressional impetus for enactment of Section 6002 appears to be the April 2004 report "Medicaid Rebates for Physician-administered Drugs" from the Department of Health and Human Services Office of the Inspector General (OIG). In that report, the OIG projected that the states were losing millions of dollars in Medicaid rebate payments due to their failure to collect rebates on physician-administered drugs. The OIG report expressly defines the physician-administered drugs of concern as "drugs that a medical professional administers to a patient in a physician's office."

In the proposed rule, CMS acknowledges the relationship between this OIG report and enactment of Section 6002. The preamble makes numerous references to the "physician-administered drugs" covered by the OIG report, including a statement that current estimates of Medicaid savings from implementing Section 6002 are based on the 2004 OIG report. CMS' discussion appears to directly equate the physician-administered drugs that were the subject of the OIG report with those that are subject to Section 6002 and its proposed regulation.

Thus, the intent of Congress in enacting Section 6002 will be faithfully executed, and CMS' projected savings fully realized, if the proposed new NDC submission and collection requirements are construed as applicable only to drugs administered in physician's offices, and inapplicable to drugs administered in hospital outpatient clinics and departments.

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

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

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

Notwithstanding this clear legislative intent, CMS' proposed rule to implement Section 6002 makes no mention of the statutory exemptions from rebate requirements for either hospital outpatient clinic drugs or outpatient drugs dispensed by managed care organizations. The fact that neither exemption is addressed in the proposed rule is, at best, confusing, but clearly evidence that CMS overlooked the entire matter of these statutorily exempt physician-

administered drugs in construing how Section 6002 should be properly applied, as opposed to having simply construed Section 1927(j)(2) to have severely limited application to hospital outpatient clinic drugs.

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

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

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

ADMINISTRATIVE BURDEN FOR HOSPITALS

Many state Medicaid programs have moved forward with implementing this new NDC reporting requirement. Hospitals in these states have been instructed to bill outpatient drugs using the drug manufacturer's 11-digit NDC number. The AHA is concerned because these instructions fail to recognize the significant difficulty, burden and cost imposed upon the hospital community in order to meet these new billing requirements. Most, if not all, hospital patient accounting systems are not designed to handle the routine reporting of a drug manufacturer's NDC. Today, hospital patient accounting systems rely on the Healthcare Common Procedure Coding System (HCPCS), in particular, the HCPCS J-codes to report a particular drug or biologic rendered to a patient. The J-code is not exclusive to a particular drug manufacturer but rather used to describe the general ingredient and dosage of a drug. Patient accounting systems can easily report HCPCS codes, but not the NDC.

To be able to report the NDC, hospitals must make major revisions to their charge description master (CDM), including significant increases to the CDM in order to include multiple manufacturers of a particular type or category of drug. Additionally, any manufacturer changes in the packaging, dosage and/or ingredients would require adding another NDC to the CDM and thereby increase the frequency of updating the CDM.

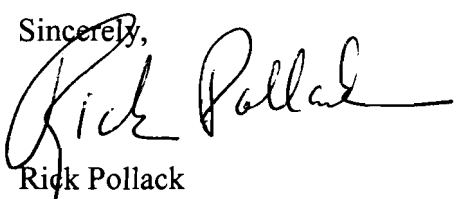
It should be noted that the language in the DRA conference report specifically indicates that the state Medicaid programs must "provide for the collection and submission of utilization and coding information for each Medicaid multiple source drug that is physician administered." The DRA further states that the "reporting would include J-codes and NDCs." As such, the AHA believes that state Medicaid agencies must provide for the collection process and bear the cost for hospitals to meet these new NDC reporting requirements. State Medicaid programs should pay hospitals to handle the system changes and new work routines required to collect and submit this coding information.

Preliminary estimates, which focus on rudimentary changes to hospital systems, indicate that it will take roughly 500 to 1,500 work hours to design, build and test a short-term work around. Even with these changes, there are no assurances that the NDC indicated on the claim reflects the manufacturer of the drug that was given to the patient. Many hospital pharmacy acquisition systems have limited record keeping ability and can assign only a primary NDC for a particular drug. The primary NDC reflects the manufacturer of a particular type of drug. When a drug needs to be replenished, the pharmacy goes to the primary manufacturer; however, often the primary manufacturer cannot supply or meet the hospital's need. In such instances, the hospital pharmacy seeks a secondary drug from another manufacturer with a different NDC. This is a common occurrence. Consequently, the hospital pharmacy's record keeping systems will need the ability to include multiple secondary sources for similar drugs. These changes also require massive system modifications and additional work routines.

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

We are willing to work with you to ensure the appropriate implementation of Section 6002 of the DRA. If you have questions about our comments, please contact me or Molly Collins Offner, senior associate director for policy, at (202) 626-2326 or mcollins@aha.org.

Sincerely,



Rick Pollack
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