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February 20, 2007

VIA ELECTRONIC SUBMISSION AND HAND-DELIVERED
(http://www.cms.hhs.gov/eRulemaking)

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 Administrator Norwalk:

Abbott is pleased to submit comments regarding several specific provisions of the Centers for Medicare & Medicaid Services' (CMS) proposed rule to implement the Medicaid prescription drug provisions of the Deficit Reduction Act of 2005 (DRA). Abbott is a broad-based health care company that discovers, develops, manufactures and markets products that span the continuum of care – from prevention to treatment and cure. Our product portfolio includes pharmaceuticals and medical devices as well as nutritional products for children and adults. Abbott is headquartered in north suburban Chicago, Illinois and employs 65,000 people worldwide.

We commend CMS for the thoughtful approach taken in the proposed rule. Abbott understands the difficulties faced by CMS in drafting a regulation that addresses the complexities and realities of today's pharmaceutical marketplace.

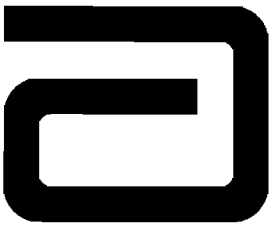
Our specific comments follow.

Determination of AMP (Section 447.504)

CMS has advanced a proposed rule that provides the much-needed clarity that has been recommended and requested by Congress, the GAO, OIG and stakeholders. In defining AMP with respect to the "retail pharmacy class of trade" we agree with CMS' interpretation that Congress intended to include multiple entities beyond the traditional walk-in retail pharmacy. Therefore, to reflect the reality of today's retail pharmaceutical marketplace, it is appropriate that CMS defines "retail class of trade" to include entities such as independent pharmacies, chain pharmacies, mail order pharmacies, and other arrangements that utilize retail class of trade for the dispensing of pharmaceuticals such as PBMs. Abbott also supports the inclusion of SCHIP, Medicare Part D, and SPAP sales, units and rebates in the calculation of AMP.

- PBM Payments – Abbott commends CMS' recognition that PBMs have assumed a significant role in retail drug distribution since the enactment of the Medicaid rebate law. We fully support CMS' proposal that AMP should be calculated to reflect the net price realized by the manufacturer inclusive of any "discounts, rebates, or other price concessions to PBMs associated with sales for drugs to the retail pharmacy class of trade." Abbott agrees that other arrangements with third party intermediaries, such as PBMs, which impact the amount realized by the manufacturer on drugs distributed to the retail class of trade should be included in the calculation of AMP.

  In the proposed rule, CMS seeks comment as to whether the inclusion of PBM rebates, discounts, and other price concessions in the AMP calculation is operationally feasible. As a manufacturer, Abbott would not have difficulty tracking rebates, discounts and other price concessions, as we are knowledgeable of such payments to the PBMs. Contracts with these entities generally provide that rebates, discounts, and other price concessions are payable to a PBM for prescriptions dispensed at retail and mail order pharmacies. Therefore, Abbott believes that manufacturers should be able to include all such rebates and other price concessions in the AMP calculation.



Abbott, however, is concerned about any approach that would impose on manufacturers an obligation to determine whether such price concessions are passed on to others, because we do not have access to that information. We ask that CMS clarify that there is no automatic requirement that manufacturers affirmatively obtain information concerning such downstream transactions.

- Coupons - The proposed rule would require manufacturers to include in their AMP and Best Price calculations the value of any patient coupons except those redeemed by a patient directly to the manufacturer. We ask CMS to reconsider this proposal for two reasons. First, patient coupons provide a benefit only to the individual and do not provide a benefit or truly impact any third party. And second, differential treatment of coupons based on method of redemption could have unintended consequences for patients who rely on coupons to help lower their drug prices. For example, patients could experience a delay in receiving the benefit of the coupon at point of purchase or some may never realize the offered benefit due to the additional steps that would be required to redeem the coupon directly with the manufacturer. We ask that CMS reconsider and permit manufacturers to exclude patient coupons from AMP and Best Price calculations.

- Single AMP- CMS should be aware that the Office of Pharmacy Affairs (OPA), within the Healthcare Systems Bureau of the Health Resources and Services Administration issued a letter dated January 30, 2007 advising pharmaceutical manufacturers that the DRA's statutory and regulatory changes to AMP will not impact the AMP used by the 340B program. If OPA's deterrnination stands, pharmaceutical manufacturers will be required to calculate and maintain two separate AMPs.

  We believe that a single AMP is intended for use by both the Medicaid Rebate Program and the 340B program. We believe that Congress did not intend for two separate AMPs to be used – one for Medicaid rebates and the other for 340B pricing.

  We respectfully request that CMS work with OPA to ensure that pharmaceutical manufacturers are required to maintain only one AMP per 11-digit NDC.

Determination of Best Price (Section 447.505)

- Prompt Pay Discounts – While the DRA requires pharmaceutical manufacturers to exclude customary prompt pay discounts to wholesalers from AMP calculations, Congress was silent on the treatment of prompt pay discounts on Best Price determinations. A change in treatment of prompt pay discounts to exclude them from the calculation of AMP not only increases the basic rebate (15.1% of a now higher AMP) but also, in fact, establishes a new Best Price. We do not believe that it was Congress' intent to create a new level of Best Price and we urge CMS to reconsider its position. A more equitable treatment is to exclude the prompt pay discount not only from AMP but also from a manufacturer's Best Price determination.

- Bundled Sales – We recommend that CMS refrain from expanding the definition of bundled sales and instead adopt in the final rule the current definition contained in the Medicaid Rebate Agreement. 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." We ask CMS to confirm that it is only in arrangements where a discount/rebate is offered on one drug contingent on the actual purchase of a separate drug, that a bundled sale exists. Also, in recognition of the fact that a given contract may describe multiple discounts, only some of which are bundled discounts, we ask CMS to confirm that the allocation required by the proposed rule need only be performed in connection with bundled discounts and the products whose sales create the bundle.

Authorized Generic Drugs (Section 447.506)

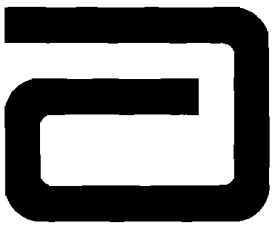
The DRA requires a manufacturer holding title to an original NDA of an authorized generic drug to include in the branded drug's Best Price calculation the sales of the authorized generic drug.

Abbott interprets the statute and proposed rule as imposing a new requirement on an NDA holder to include in its Best Price determination sales of the authorized generic drug by the authorized generic company/secondary manufacturer. The statute and proposed rule do not appear to require the NDA holder to include in its Best Price determination the transfer price from the NDA holder to the authorized generic company/secondary manufacturer. The proposed rule's preamble language reads in pertinent part, "We propose to require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and Best Price." This language indicates that it is the downstream sales of the authorized generic company or secondary manufacturer that the statute requires to be included in the brand manufacturer's Best Price determination. This interpretation is consistent with the manner in which CMS has historically treated Best Price, intending to capture in the calculation all downstream sales into the commercial marketplace. Although the proposed rule provides some guidance, Abbott encourages CMS to explicitly confirm in the final rule that the statute does not require an NDA holder to include in its AMP and Best Price calculations the transfer price of the authorized generic drug from the NDA holder to the secondary manufacturer.

Also, CMS should provide assurances that the primary manufacturer is permitted to rely on the accuracy of the pricing information provided by the authorized generic company.

Requirements for Manufacturers (Section 447.510)

- 12-month Rolling Average Methodology – We appreciate CMS' willingness to entertain comments from manufacturers about applying a 12-month rolling average methodology to the calculation of monthly and quarterly AMPs. This methodology is particularly helpful for the monthly calculation,



because the DRA does not permit manufacturers to restate monthly AMPs. In general, a rolling average methodology benefits virtually all stakeholders by providing stability in pricing and avoiding significant fluctuations in monthly and quarterly AMPs caused by lagged sales and rebate data.

- Recalculation of Base Date AMP - Abbott applauds CMS for recognizing that manufacturers should have the opportunity to adjust base date AMP to account for the changes set forth in the DRA and the final rule. However, we request that pharmaceutical manufacturers be given the opportunity to restate earlier 2007 AMPs to account for the CPI impact caused by implementation of the DRA's Prompt Pay and authorized generic provisions and also be able to re-establish the base date AMP for the new calculation metric created by the CMS final rule. Senator Grassley stated in his May 12, 2006 letter to CMS in pertinent part, "... your recommendations should suggest a means for adjusting rebate computations so that no manufacturer is subject to increased inflation adjustment rebates by function of the changing definition." The Senator's statement is consistent with the two-step approach advocated by Abbott above.

- Certification of Pricing Reports - CMS proposes to adopt the certification requirements established by the Medicare Part B Program for average sales price (ASP). While we applaud the goal of consistency with ASP procedures, we respectfully remind the agency that ASP is calculated on a quarterly basis, not every month. The timeliness of our monthly AMP reports will be undermined if we are required to provide certification as outlined in the proposed rule. The Medicaid Rebate statute contains a civil monetary penalty provision for knowingly submitting false information. As there is no statutory requirement in the DRA for such a certification we ask that CMS eliminate the certification process for the monthly AMP reports.

Physician-Administered Drugs (Section 447.520)

Concerning rebates for physician-administered drugs, we respectfully request that CMS provide clarification in the final rule that the states should collect a Medicaid rebate only for that portion of the payment made by a state Medicaid program. If CMS does not clarify this provision, manufacturers could be required to remit full rebate payments to states where Medicare is the primary

payer for a drug for which the Medicaid program pays only a small co-payment.

We believe this to be the intent of the statutory language, which is bolstered by then Senate Finance Chairman Grassley in his August 14, 2006 letter to CMS in which he advised that it was not Congress' intent to require manufacturers to pay rebates at a level above the percentage paid for the drug by a state Medicaid program. Applicable statutory language further supports this point. As a prerequisite to receiving federal Medicaid matching funds, Section 1927(a)(7)(A) of the Social Security Act, as amended by Section 6002 of the DRA requires states to collect and submit utilization and to secure Medicaid rebates for single source physician-administered drugs. The statutory language reads in pertinent part, "to secure rebates *under this section* for drugs administered for which payment is made *under this title*." This language clearly refers to payments under the Medicaid program. The statutory language does not give states the authority to collect rebates based on expenditures through the Medicare program.

Abbott appreciates the opportunity to comment on the proposed rule, as well as the effort that CMS has 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 hope our comments are helpful. Please feel free to contact us if we can be of further assistance.

Sincerely,

Virginia Tobiason

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February 12, 2007

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9:01 am

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Norwalk,

On behalf of Medicaid beneficiaries and retail pharmacies in our districts, we are writing to express our deep concern with the Centers for Medicare and Medicaid Services' (CMS) proposed changes in the payment for prescription drugs in the Medicaid program. These proposed changes, announced in December of 2006, would implement provisions of the Deficit Reduction Act of 2005 (DRA).

The current method that manufacturers use to define Average Manufacturer Price (AMP) has never been fully defined by CMS, which has resulted in variations in how these values are calculated. Government studies and reports have documented these inconsistencies, demonstrating significant differences between AMP and the actual prices at which retail pharmacies purchase drugs.

In the proposed rule, CMS defines AMP to address these problems. It was our expectation that this definition would approximate the prices at which retail pharmacies purchase medications from manufacturers and wholesalers. However, the proposed rule is flawed in that it allows manufacturers to include mail order sales and pharmacy benefit manager rebates in the calculation. This change will result in an AMP that does not reflect the prices paid by retail pharmacies.

In addition, the proposed rule released by CMS dictates that the Federal Upper Limit (FUL) for a generic drug will be based on 250% of the product that has the lowest AMP for all the versions of that generic medication. However, a December 22, 2006 Government Accountability Office (GAO) report that analyzed the impact of the new FUL formula found that retail pharmacies will be reimbursed on average 36 percent lower than their costs to purchase generic medications dispersed to Medicaid beneficiaries. This change would clearly fail to cover the pharmacy's costs of purchasing generic medications. In fact, the formula would create a disincentive to dispense generic drugs and would deny the Medicaid program and beneficiaries the savings gained from generic medications.

This proposed payment formula will be devastating to many community retail pharmacies, Medicaid beneficiaries, and the financing of the Medicaid program itself. We respectfully request that you delay the release of any AMP data until a final definition is adopted ensuring that AMP accurately reflects pharmacy acquisition costs.

Sincerely,

Randall Buchanan, RPh.
Vice President, Bartholomew's Pharmacy

[redacted]
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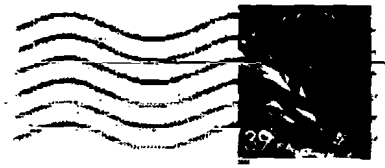

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February 19, 2007

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VIA ELECTRONIC and HAND DELIVERY

Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-2238-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 21244-1850

Re: Comments on CMS-2238-P: Medicaid Program; Prescription Drugs; Proposed Rule

Dear Ms. Norwalk:

AmerisourceBergen Corporation respectfully submits the following comments pertaining to CMS-2238-P, "Medicaid Program; Prescription Drugs; Proposed Rule," published in the *Federal Register* on December 22, 2006 (the "Proposed Rule").

Overview of AmerisourceBergen

AmerisourceBergen is one of the nation's largest pharmaceutical services companies. Servicing both pharmaceutical manufacturers and healthcare providers in the pharmaceutical supply channel, we provide drug distribution and related services designed to reduce costs and improve patient outcomes. AmerisourceBergen's service solutions range from pharmacy automation and pharmaceutical packaging to pharmacy services for skilled nursing and assisted living facilities, reimbursement and pharmaceutical consulting services and physician education. Through our Performance Plus Network, we represent approximately 5,000 community pharmacies in dealing with national third party payors. As a result of these relationships we are keenly aware of the business challenges faced by community pharmacy owners in the retail marketplace and some of our responses in this communication represent their interests as well as ours.

An integral aspect of AmerisourceBergen's business is the important role it plays in the distribution of specialty pharmaceuticals through AmerisourceBergen Specialty Group ("ABSG"). This specialty drug distribution component of AmerisourceBergen is responsible for safely and

efficiently ensuring the handling and delivery of critically needed complex pharmaceuticals, and providing other necessary services to manufacturers and healthcare providers.

AmerisourceBergen has been an industry leader in working to implement policies and procedures to ensure the safe delivery of pharmaceuticals by promoting a variety of innovative initiatives, including the development of a national pedigree. We are committed to finding ways to efficiently deliver necessary products to our customers; to enhancing the safety of the pharmaceutical supply chain; and ultimately to improving the quality of care received by patients who need the products that we distribute. Due to the comprehensive nature of its pharmaceutical distribution and pharmacy service business, AmerisourceBergen believes it is uniquely situated to provide Comments on the Proposed Rule, and we offer these Comments for your consideration and look forward to the opportunity to provide additional input as this rulemaking proceeds.

Bona Fide Service Fee

AmerisourceBergen agrees with CMS' decision to use the same definition of bona fide service fees for calculating AMP and determining Best Price that was established as part of the implementing regulations related to the calculation of Average Sales Price ("ASP"). We believe that this consistent definition will help ensure that manufacturers are able to efficiently calculate both AMP and ASP because they can use similar methodologies to account for fees paid to wholesale distributors.

AmerisourceBergen also supports and agrees with the extensive discussion related to bona fide service fees provided as part of the 2007 Physician Fee Schedule Final Rule ("PFS"), including the commentary related to determining fair market value.[1] Therefore, AmerisourceBergen suggests that CMS stipulate that the commentary explanations applicable to the definition of *bona fide* service fees when manufacturers are calculating ASP also applies when they are determining AMP and Best Price, and that CMS expressly reference the discussion of *bona fide* service fees in the preamble to the 2007 PFS Final Rule when it prepares the preamble for this Final Rule.

We also urge CMS to further clarify its guidance related to certain fees at 42 C.F.R. § 447.504(i)(1) related to the calculation of AMP. We are concerned because this provision again combines fees, discounts and other concessions offered to purchasers of drug products with payments made to third parties like PBMs and GPOs that do not purchase or take possession of drugs. This guidance is particularly problematic with regard to GPOs because they are in no way involved in the payment for drugs. We are concerned because this guidance implies that all concessions to non-purchasers should be deducted when AMP is calculated, which we believe is an overly broad approach. Therefore, we urge CMS to limit the provision clarifying AMP to price reductions and other payments that flow to purchasers, and expressly exclude payments that flow to third parties not involved in the purchase transaction.

Also, we believe that the provision further confuses the issue of the proper handling of *bona fide* service fees and appears to create unnecessary distinctions between administrative fees, service fees and distribution fees. In most instances, *bona fide* service fees paid to wholesalers and distributors include compensation for distribution services which are defined by

[1] 71 *Fed. Reg.* 69623, 69666-70 (Dec. 1, 2006).

the involved parties. Furthermore, administrative fees – a term typically used to describe fees manufacturers pay to GPOs and PBMs to support the contracting functions those entities perform on behalf of numerous buyers or health plans – meet the definition of a *bona fide* service fee under a variety of circumstances consistent with CMS' preamble guidance published with the 2007 Physician Fee Schedule Rule. Therefore, we recommend that CMS clarify, either in § 447.504(i)(1) itself or by adding a new paragraph to the subsection, that all fees that manufacturers pay to customers or third parties meeting the definition of a *bona fide* service fee are to be excluded from the calculation of AMP.

Customary Prompt Pay Discounts

AmerisourceBergen applauds CMS' decision to include language in the Proposed Rule expressly instructing manufacturers to exclude Customary Prompt Pay Discounts ("CPPDs") given to wholesalers when determining AMP. We also support the definition CMS provided for the term "customary prompt pay discount" in an effort to clarify the types of price concessions that should not be included in the AMP calculation. We are particularly pleased that the agency did not incorporate any specific payment amounts or time terms in the definition. Although we anticipate that some manufacturers may ask CMS to further define the various aspects of CPPDs, we encourage CMS to maintain the proposed definition in the Final Rule because this approach allows manufacturers and wholesalers the necessary flexibility to negotiate payment terms, including CPPDs, based on their particular situations and the commercial conditions at the time of the particular transaction. We believe that this flexibility also will promote competition in the healthcare distribution business, which ultimately will lower distribution costs.

Also, in order to avoid potential confusion, AmerisourceBergen requests that CMS clarify that its requirement that cash discounts be deducted from the calculation of AMP and Best Price ***does not*** include CPPDs.

Retail Pharmacy Class of Trade

AmerisourceBergen agrees with CMS that in order to qualify as a member of the retail pharmacy class of trade, an entity must provide public access. For that reason, we disagree with including certain entities listed in 42 CFR § 447.504(e) as part of the retail pharmacy class of trade. Specifically, mail-order pharmacies, PBMs, and hospital pharmacies should be excluded from the definition of retail class of trade. In addition to these entities, AmerisourceBergen also believes that CMS should clarify that sales of drugs to physicians for administration in their offices should not be included in the retail pharmacy class of trade for the purpose of calculating AMP.

We object to the inclusion of PBMs in the retail pharmacy class of trade because PBMs contract with retail pharmacies to offer pharmacy services at prearranged prices to enrollees in the health plans the PBMs represent. They negotiate insurance payment terms, which is significantly different from arranging for the purchases of drugs that pharmacies make from their manufacturer and wholesaler vendors. PBMs do not affect the net prices manufacturers are paid by wholesalers and retail pharmacies for drugs dispensed to the general public. Therefore, under the controlling statutory definition of AMP, the contract terms between manufacturers and PBMs, and any related rebate payments provided to PBMs, should not be factored into the determination of AMP.

AmerisourceBergen supports CMS' decision to exclude sales to Long-Term Care facilities ("LTC") and urges CMS to exclude sales to other entities that do not satisfy the threshold public access criterion from manufacturers' AMP calculation, including sales to mail-order pharmacies. The reason CMS gave for excluding sales to LTC pharmacies from the calculation of AMP was that those pharmacies are closed operations that serve only the residents of specific LTC facilities, not pharmacies that are open to the general public. The same is true for mail-order pharmacies, the vast majority of which are affiliated with PBMs or with health plans that administer pharmacy benefits internally. These mail-order pharmacies are not open to the general public and the services provided are more limited than those provided by community pharmacies. Access to any particular mail-order pharmacy is limited to individuals enrolled in a health plan with a mail-order option that is sponsored by the organization that operates the pharmacy or that contracts with the PBM that operates the pharmacy. In other words, mail-order pharmacies are closed operations in the same way that LTC pharmacies are closed operations.

PBM Rebates

AmerisourceBergen objects to CMS' proposal for deducting PBM rebates from the AMP calculation. CMS' proposal for deducting PBM rebates when AMP is calculated is contrary to the statutory definition of AMP at Social Security Act § 1927(k)(1) (as amended by the DRA) and to the definition of AMP in the Rebate Agreement. Both definitions say AMP is "the average price *paid to* the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade (emphasis added)." Rebates *paid by* the manufacturer to a PBM that does not buy or take possession of drugs simply do not qualify. They are not part of the price paid to the manufacturer by the pharmacies in the PBM's retail pharmacy network because those pharmacies do not share in the PBM rebates. CMS does not have the statutory authority to reinterpret the definition of AMP to focus on the net revenues realized by manufacturers instead of the net costs incurred by retail pharmacies for the drugs they dispense.

Additionally, although PBMs only collect rebates on single source drugs,[2] CMS' position on the handling of these rebates will have a negative impact on State Medicaid budgets. The OIG found that some manufacturers do not currently view transactions with PBMs as sales and, therefore, do not net PBM rebates out when they calculate AMP.[3] It also observed that other manufacturers only include a portion of their PBM rebates in AMP.[4] As a result, the Proposed Rule's treatment of PBM rebates will lead to lower AMPs and lower rebate payments on some single-source products. We do not have access to the data needed to estimate the total revenue reduction, but we are confident the losses will be significant since the CBO recently reported State Medicaid programs received rebates in 2003 on single source drugs that averaged 31.4% of AMP.[5] Further, the CBO observed that the percentage of State Medicaid revenues tied to rebates on single source drugs has been trending upward.

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[2] *Prescription Drug Pricing in the Private Sector* at p 12; *Pharmacy Benefit Managers* at 50-55.

[3] *Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of* 2005, OIG (A-06-06-00063) (May 30, 2006).

[4] *Id.*

[5] *Payment for Prescription Drugs under Medicaid* at Table 2.

Dispensing Fee

AmerisourceBergen applauds CMS' decision to recommend that State Medicaid programs "reexamine and reevaluate the reasonableness of the dispensing fees paid as part of a pharmacy claim"[6] if they elect to adopt AMP-driven pharmacy reimbursement formulas. We urge CMS to consider the results of a recently completed national survey of dispensing costs when it reviews proposed State Plan Amendments revising Medicaid pharmacy reimbursement formulas. Grant Thornton LLP obtained cost data from nearly half the retail pharmacy outlets in the United States for the 6-month period from March through August 2006 and determined that the mean cost of dispensing per prescription was $10.50 and the mean cost of dispensing per pharmacy was $12.10.[7] For the 65 million Medicaid prescriptions included in the sample, the mean cost per prescription was $10.51 and the mean cost per pharmacy was $12.81. Given these cost data, it will no longer be acceptable for States to skimp on payments for dispensing services to Medicaid recipients once they take steps to trim the margins on ingredient costs that have been subsidizing Medicaid dispensing for years.

We also recommend including a few additional elements in the list of services detailed in proposed 42 CFR § 447.502 that must be considered when a dispensing fee representative of fully loaded costs is developed. We are hesitant to rely on the "[p]harmacy costs include, but are not limited to" language currently used to preface the list because of the inadequacy of dispensing fees paid by State Medicaid programs over the years. The revised definition also needs to include the time pharmacists spend entering billing information into their computer systems and communicating by telephone, fax and email with State Medicaid agencies and PBMs about coverage and billing questions. As with other third party drug programs, the Medicaid program creates an additional cost due to accounts receivables, which can have a substantial impact on a community pharmacy. More importantly, the Proposed Rule must include as an element of pharmacy costs the important health, safety and counseling services community pharmacists routinely provide – typically based on an individualized understanding of the customers' medical needs and personal preferences – to ensure that each physician's prescription leads to the best drug regimen for the patient.

Innovator Multiple Source, Multiple Source, and Single Source Drugs

The Proposed Rule also does not define "covered outpatient drug" but rather lets stand without elaboration the definition of covered outpatient drug in the Medicaid Drug Rebate Statute at Social Security Act § 1927(k)(2). That statutory definition reaches beyond drugs approved by the FDA under NDAs, BLAs, antibiotic approvals or ANDAs to over-the-counter (OTC) products that have been prescribed by a physician. To capture the full breadth of the Medicaid drug benefit, we recommend including a definition of covered outpatient drug in the Final Rule that addresses both OTC and prescription drug products. The statutory definition of covered outpatient drug also incorporates grandfathered products and drugs still undergoing the DESI review process. The Proposed Rule's definitions of single source, innovator multiple source and multiple source drugs do not, however, reach all of the products that came to market

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[6] Medicaid Drug Rebate Program Release for State Medicaid Directors No. 144 (December 2006).

[7] *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies,* prepared for The Coalition for Community Pharmacy Action by Grant Thornton, LLP (January 2007), available at http://www.rxaction.org/publications/COD_Study.cfm. The cost of dispensing per pharmacy treats every pharmacy equally, regardless of prescription volume. It is higher than the cost of dispensing per prescription because high-volume, lower-cost stores are weighted more heavily in this statistic.

before 1962 and remain commercially available today. To avoid any ambiguities, AmerisourceBergen suggests CMS revise the definitions of multiple source, innovator multiple source and single source drugs to address these gaps.

Lagged Methodology

AmerisourceBergen also is concerned that the Proposed Rule does not set forth a methodology for dealing with lagged unit data or lagged discounts when monthly or quarterly AMPs are calculated. This lack of guidance is problematic because the Proposed Rule requires manufacturers to consider sales and associated price concessions extended to State Children's Health Insurance Programs ("SCHIPs") and State Pharmaceutical Assistance Programs ("SPAPs") when they determine AMP. This requirement is virtually impossible to achieve because manufacturers have no way of knowing how many units of drug were dispensed to enrollees in these programs or what their program rebate liabilities will be until they receive quarterly rebate invoices from the States. Unfortunately, our experience shows that these invoices rarely arrive prior to the stipulated deadline for filing quarterly AMP reports under the Proposed Rule. Depending on the plan, Part D rebate demands and PBM rebate demands also may arrive too late to be properly included in quarterly calculations.

Therefore, we believe that the best approach to address the inevitable delays in the receipt of data critical to AMP calculations is to include instructions for processing lagged data into the Final Rule. We strongly recommend using a 12-month rolling percentage methodology similar to that required in the ASP rule.

Because upfront discounts on large purchases meant to be sold out of inventory over an extended period of time also can distort pricing available to retail pharmacies in the market when they are factored into the AMP calculation on an as-paid basis, AmerisourceBergen encourages CMS to build a well-defined smoothing methodology for handling all price concessions – not just lagged concessions – and for handling lagged unit data that must be considered when AMP is determined. We believe that the methodology would operate much like the 12-month rolling percentage methodology specified for quantifying lagged discounts under the ASP rule. However, for AMP purposes, we suggest instructing manufacturers to look to the four (4) full calendar quarters before the reporting period to calculate the rolling 12-month percentage. That percentage could then be used to determine all three monthly AMPs and the quarterly AMP.

If CMS is not inclined to include upfront discounts in a smoothing methodology for AMP, it is imperative, particularly for multiple source products, that chargebacks be singled out for lagged treatment on a routine basis along with rebates because chargebacks often relate back to sales from previous quarters. Because of the complexities involved, we request that CMS provide examples showing how the methodology should be applied in both the monthly and the quarterly context. Those examples also should take into account the proper treatment of the various types of bundled sales.

AMPs and FULs Set at 11-Digit NDC Level

AmerisourceBergen strongly disagrees with the Proposed Rule's instruction to calculate and set Federal Upper Limit ("FUL") reimbursement at the 9-digit NDC level for purposes of calculating AMP. We are concerned with the utilization of the 9-digit AMPs because this methodology would exclude tying FULs to the package sizes most frequently purchased by pharmacies.

In order to address this concern, and to ensure that the most accurate FUL reimbursement and AMP are calculated for a given product, we urge CMS to modify the Rule to require manufacturers to calculate and report AMPs at the 11-digit NDC level. The utilization of 11-digit level NDCs would permit FULs to be established based on the most commonly purchased package sizes, and this approach would be consistent with past FUL calculation practices.

AMPs and Outlier Methodology

We applaud CMS's recognition of the need to eliminate outlier AMPs from the determination of FUL. Eliminating the sale of product that is extremely short-dated or otherwise distressed avoids setting an artificially low FUL based upon prices that do not reflect true market conditions (comparable to CMS' decision to disregard AMPs for NDCs that have been terminated). To ensure that reimbursement is adequate to permit retail pharmacies to buy from reputable suppliers with sufficient supply to meet retail pharmacy demands, we would prefer to see FULs calculated using the weighted average AMP of the therapeutically equivalent products available in the market. However, if CMS decides it will not take that approach, we propose that the outlier test should incorporate market-share as a fundamental criteria in defining outliers. To that end, we support requiring manufacturers to report, along with monthly AMPs, data at the 11-digit level (as discussed above) on the volume of product sold during the period. CMS could then classify monthly AMPs associated with low market share as outliers that do not represent available prices.

Specifically, we recommend examining AMPs on a cumulative market share basis starting with the lowest reported AMP, then the next highest and so on, rejecting AMPs until a cumulative market share of 50% is reached. This approach will allow CMS to focus directly on whether a low-priced NDC is only available on a "limited basis"[8] (rather than the indirect price-based test CMS proposed). Doing so should "ensure that a drug is nationally available at the FUL price"[9] because it will disregard AMPs that, despite low price, were only able to capture less than half the market. If product, from one or more sources, is not available to at least 50 percent of the market, its price is not indicative of true market conditions and, being available in only limited quantity, it's not available for sale nationally. For example, if manufacturers reported monthly AMPs for five NDCs of a given drug/strength/dosage form of a multiple-source product of $0.30, $1.50, $4.50, $5, and $5.50 with corresponding sales volumes of 100 units, 400 units, 6000 units, 3500 units, and 500 units, the first two would be classified as outliers as they represent less than a 5% market share. The FUL would be set based on the $4.50 price because the 6,000 units added to the previous 500 units (100 + 400) would cross the 50% market share threshold. In other words, $4.50 is the lowest price for a product that is available

[8] 71 FR at 77188 (Dec. 22, 2006); see also proposed rule §447.514(c).
[9] *Id.*

for sale nationally. This contrasts with an FUL of $3.75 (250% x $1.50) under the price-based outlier methodology described in the proposed Rule – an FUL that would not be representative of prices for half the market (and would likely result in a local pharmacy losing money on most Medicaid sales).

Definition of Wholesaler

AmerisourceBergen is concerned that the Proposed Rule defines "wholesaler" in an overly expansive fashion, including within the reach of the definition not only traditional full-service wholesalers and specialty distributors but also pharmacy chains, pharmacies, and PBMs See 42 C.F.R. § 447.504(f). We request that this definition be revised so that it is consistent with the provisions of the Food Drug and Cosmetic Act incorporating the Prescription Drug Marketing Act (PDMA)[10] and with the definitions of "wholesale distributor,"[11] "wholesale distribution,"[12] and "distribute"[13] in the FDA regulations that govern prescription drug marketing. Although we believe these definitions are quite broad, they adequately and appropriately limit wholesalers to entities engaged in selling, offering to sell, delivering, or offering to deliver drugs to persons other than a consumer or patient.

We do, however, agree that warehousing pharmacy chains and warehousing mass merchant and supermarket pharmacy operations should be treated as wholesalers for purposes of calculating AMP and Best Price. They function virtually identical to traditional wholesalers and specialty distributors: they buy drugs directly from manufacturers and/or other wholesalers; consolidate orders for products from a variety of sources; and distribute the drugs to pharmacies within their chain, which resell the drugs at retail to consumers who present a prescription. Also, warehousing chains, warehousing mass merchants and supermarkets are licensed as wholesalers under State laws implementing the requirements of the PDMA.

Although we agree that the above entities should be treated as wholesalers under the Rule, we object to identifying other entities including mail-order pharmacies operated by PBMs, as wholesalers. These entities are quite different from wholesalers because they have a limited product inventory, routinely sell drugs to consumers and patients and they rarely function as or are licensed as wholesalers under applicable State laws.

We are particularly troubled by the inclusion of PBMs in the definition of wholesaler. Although many PBMs operate mail-order pharmacies, they typically function merely as an ancillary to the PBM's primary business operation. As discussed above, we do not believe these types of entities should be classified as wholesalers.

As discussed above, we urge CMS to align that definition with the definitions of wholesale distributor, wholesale distribution, and distribute in the FDA regulations implementing the PDMA. We also suggest including a statement in the preamble to the Final Rule saying CMS has adopted those FDA definitions which are well-recognized throughout the industry.

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[10] P.L. 100-293.
[11] 21 CFR § 203.2(dd).
[12] 21 CFR § 203.2(cc).
[13] 21CFR § 203.2(h).

Postponing the Posting of AMPs

AmerisourceBergen urges CMS to consider delaying postings of AMPs because there are valid reasons for delay and in consideration that the delay likely will be for a reasonably short period of time. We believe a delay is appropriate in this instance because many critical issues related to ensuring the accurate calculation of AMP remain unresolved and are unlikely to be completely resolved and understood throughout the industry prior to the scheduled posting of AMPs. In the past, CMS wisely has delayed implementing programs because too many problems remained unresolved, and the agency took additional time to resolve those outstanding issues related to the program. We believe that approach may be useful in regard to the public posting of AMPs, and that the posting should be delayed until all the regulatory changes have been finalized and manufacturers have been given sufficient time to update their systems to satisfy the final reporting requirements.

Therefore, we urge CMS to delay website postings until the new AMP rule becomes effective, or at a minimum to preface any web-postings of AMP values with an introductory discussion explaining the current shortcomings of AMP as a measure of retail prices and pharmacy acquisition costs and highlighting the potential for changes in the calculation methodology underlying AMP over the next year.

Retail Survey Price

We had hoped CMS would address implementation issues related to DRA § 6001(e) in the Proposed Rule. We were looking forward to the opportunity to comment on how and from what sources data underlying RSP should be collected and how the data should be used to determine "a nationwide average of consumer purchase prices, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available)"[14] since the DRA defines RSP but provides little other substantive guidance on RSP-related issues. For example, because RSP is supposed to be representative of "consumer purchase prices" at retail, we wanted to talk about how CMS and its vendor would ensure only pharmacies within the retail class of trade are surveyed. We wanted to speak to how CMS would ensure valid results by structuring surveys to include an appropriate sample size and geographic distribution. We also wanted to discuss other steps that could be taken to ensure that RSP data is true to the statutory requirement to capture the out-the-door prices pharmacies charge consumers.

We note Medicaid Drug Rebate Program Release No. 144 for State Medicaid Directors dated December 15, 2006 – a week before the Proposed Rule was published in the *Federal Register* – advises States that CMS will begin disseminating a monthly national survey of retail prices beginning in January 2007. We take that promise to mean CMS is moving forward with plans to implement DRA § 6001(e). That said, we strongly urge CMS to engage stakeholders, as soon as possible and in a meaningful way, in the development of the procedures the RSP contractor will be tasked with using when it collects, aggregates, and disseminates RSP data. Including stakeholders in the regulatory processes relating to the implementation of DRA § 6001(e) likely will allow the development of RSP policies and procedures that anticipate issues associated with data availability and adequacy, reflect a more nuanced approach to data collection and analysis, and, in the end, result in the dissemination of RSP data that is – as the

[14] DRA § 6001(e) adding Social Security Act § 1927(f)(1)(A).

DRA mandates – representative of consumer purchase prices at retail for outpatient prescription drugs.

* * * * *

In closing AmerisourceBergen appreciates the opportunity to provide you its comments on this important Proposed Rule. We are available at your convenience to address any concerns related to these Comments, the proposed Rule, or the pharmaceutical supply chain.

Sincerely,

R. David Yost

R. David Yost

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ALLSCRIPT PHARMACY, INC.
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BUFFALO, NEW YORK 14204
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Fax: 716-882-0214

February 12,2007

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P 500
P.O. Box 8015
Baltimore, MD 21244-8015

Ladies and Gentlemen:

I am writing to you to express my sincere concerns about the Center for Medicaid and Medicare Services(CMS) proposed changers in the payment for prescription Drugs. When the new AMP reimbursement rate takes affect, it will only be a matter of months before we are forced to close our doors. We have been in business for twenty-six years at the same location and cannot afford any more reimbursement cuts.

Last year our sales were $244,741.62 LESS than the year before because of Medicaid, Epic, and Medicare Part D reimbursement rate reductions.

We clearly cannot absorb another reimbursement cut at all, and a cut which amounts to 36% less than our actual cost of the drugs we purchase is unthinkable.

We are located in a very poor inner city neighborhood, known as the Fruit belt, in Buffalo, N.Y. The residents depend on us for all of their pharmaceutical needs which we also deliver free of charge. Almost all of them are either on Medicaid, Medicare Part D, or Epic.

Please note that the number of prescriptions we fill has not changed; only our reimbursement for filling these prescriptions has fallen sharply. We will not be able to remain in business with another cut.

Please do not initiate the new AMP until a fair study has been performed to see how devastating this cut will be to community pharmacies, that are not privy to special volume discounts and rebates that large institutions receive.

Sincerely,

Thomas J. Caldwell, Pharm. D.

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BARBARA ANN
KARMANOS
CANCER INSTITUTE

19 February, 2007

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

To Whom It May Concern:

On behalf of Karmanos Cancer Center, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Karmanos Cancer Center is a 123 bed hospital located in downtown Detroit, Michigan, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are threefold.

First, the proposed regulations would create enormous administrative and financial burdens for Karmanos Cancer Center by requiring the reporting of NDC information on drugs administered in hospital outpatient settings.

- Electronic billing systems are not configured to substitute NDC numbers for identifiers for clinic administered drugs. Software modifications to facilitate compliance to this proposed rule will encompass significant time and expense.
- In the interim, the manual impact is neither "small" nor "insignificant" in terms of personnel time and effort. Oncology clinical practice often dictates multiple NDCs are used to deliver one dose of medication as opposed to one product used in a retail setting. Group Purchasing Organization (GPO) contract most often allow auto-substitution among NDC numbers to maximize cost savings based on availability and price. The mandate of NDC reporting would be very problematic causing additional overhead and loss of any cost savings to assure accurate reporting of NDCs.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements.

- In our six years of participation (2001 – 2006), the 340B program has saved our institution over $33 million dollars (over $ 9 million in 2006 alone) in the provision of cancer care to our indigent urban population. Removal of this benefit would adversely affect several DSH hospitals in Southeastern Michigan and cause disasterous results for our highly vulnerable patients in Detroit and throughout Southeastern Michigan.

4100 John R
Detroit, Michigan 48201
(800) KARMANOS (1-800-527-6266)
info@karmanos.org | www.karmanos.org

NATIONAL CANCER INSTITUTE

Third, the rules relating to the treatment of prompt pay discounts in computing Average Manufacturer Price ("AMP"), as currently drafted, could drive up the prices our hospital pays for outpatient drugs by adversely affecting the formula for calculating 340B prices and by not expanding the list of safety net providers eligible for nominal pricing.

- The proposed regulations reflect a decision by the HHS secretary to decline to exercise his statutory discretion to identify additional "safety net" providers that may receive nominal pricing on drugs without those prices being included in calculations of "best price". This change would increase the price for 340B outpatient drugs and seems to be counter-productive to the important goal of supporting the nation's health care "safety net" for highly vulnerable patient populations

We hope that you will give serious consideration to the problems addressed in this letter, and that the proposed regulations published on December 22 will be clarified and revised as a result.

Sincerely,

Stephen T. Smith RPh MS FASHP

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Director, Pharmacy Services
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Detroit, Michigan 48201

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Oklahoma Pharmacists Association

February 12, 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 **OKLAHOMA PHARMACISTS ASSOCIATION** (OPhA) is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) regarding CMS' December 20, 2006 proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal upper limit (FUL) program for generic drugs.

Summary

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

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§447.504 Determination of AMP

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

Defining Retail Pharmacy Class of Trade

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

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

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

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

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

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

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

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

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

likely need to redress the impact or perceived impact inherent to the conflicts of these relationships, increasing regulatory oversight burdens to ensure true market pricing data.

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

Inclusion of Medicaid Sales

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

Discounts, Rebates and Price Concessions

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

AMP should reflect the prices paid by retail pharmacies. However, the proposed regulation in Sections 447.504(a), (g) and (i) indicates types of discounts and price concessions that manufacturers should deduct from the calculation of the AMP. While discounts, rebates, chargebacks and other forms of price concessions may reduce the amount received by the manufacturer for drugs, they are not realized by retail pharmacies and do not reduce prices paid by retail pharmacies. The proposal incorrectly bases AMP, not on amounts paid by wholesalers – the predominant supply source for retail pharmacies - but instead includes amounts that manufacturers pay to other entities, which in turn reduces the amount that manufacturers receive. Manufacturers contractually agree to discounts and rebates, not because wholesalers pay them these discounts or rebates. Retail pharmacies should not bear the financial burden and risk of manufacturers' contractual decisions with such third parties. On the other hand, discounts and rebates paid by manufacturers that are actually passed through to community retail pharmacies should be deducted from manufacturers' sales to retail pharmacies when calculating the AMP. On balance, we are concerned that, including discounts, rebates and other price concessions that may reduce manufacturers' prices received, but not the retail pharmacies' prices paid, would have the perverse effect of reducing AMP, drastically below the actual acquisition price to the retail pharmacy. Including PBMs' sales and discounts makes AMP unreflective of sales to retail pharmacies. This concern was confirmed by a recent CBO report which said that "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies."[1] Pharmacies are thus positioned to execute the dispensing requirements of PBMs, yet receive no benefit from their actions. Of greater concern, however, is the very real risk that, by including these rebates and lowering AMP, the traditional retail pharmacies may be reimbursed below their acquisition costs. This concern is highlighted in a recent study, which discovered, based on historical data, that "AMP-based FULs were, on average, 36 percent lower than average retail pharmacy acquisition costs."[2] The impact of these findings cannot be ignored. When factoring in information from numerous other studies on access to healthcare in rural areas and the results demonstrating the consistent trend of loss of retail pharmacies in these areas, CMS will need to develop yet another pricing structure or other system to ensure access to medication. These new structures will ultimately cost more to administer and reduce the actual savings realized under the proposed regulation.

§447.510 Requirements for Manufacturers.

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

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

Market Manipulation

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

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

'Claw-back'

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

Pricing Lag

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

Severe Price Shifts

The inherent market volatility, associated with pharmaceutical manufacturing, occasionally results in dramatic shifts in price structure. The proposed regulation is noticeably

[3] §447.510(d)(2)

silent in offering any mechanism to account for this fact. Severe price shifts and the significant issues associated with pricing lag can be effectively addressed with the implementation of trigger mechanisms. CMS should identify a reasonable and appropriate percentage shift in real time price that would trigger a review and recommendation by the Office of the Inspector General (IG). It is recommended that CMS clearly define the stakeholders empowered to alert CMS of significant price shifts. Once alerted the IG would research and then recommended an updated AMP figure to CMS. Following abbreviated review and comment by defined stakeholders, CMS would then pass the revised AMP figure on to the states and other users of AMP by the most efficient electronic means.

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

Record Keeping

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

Additional Comments

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

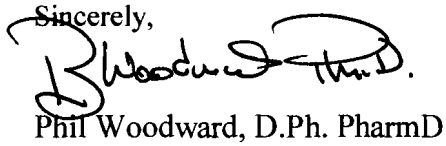
CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, yet then states that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the

legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." However, there is also no compelling evidence that Congressional intent was to have AMP calculated at the 9-digit level versus the 11-didgit level for generic drugs in determining FULs.

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

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

Sincerely,



Phil Woodward, D.Ph. PharmD

cc. Honorable U.S. Senator Tom Coburn
Honorable U.S. Senator James Inhofe
Honorable U.S. Representative Tom Cole
Honorable U.S. Representative John Sullivan
Honorable U.S. Representative Dan Boren
Honorable U.S. Representative Mary Fallin
Honorable U.S. Representative Frank Lucas

Dinsmore&Shohl LLP
ATTORNEYS

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February 20, 2007

Leslie V. Norwalk, Administrator (Acting)
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

SENT BY EMAIL: www.cms.hhs.gov/eRulemaking

Re: Comments on Proposed Rule
42 C.F.R. Part 447
File Code CMS-2238-P

Dear Ms. Norwalk:

I am writing to comment on the rule proposed by the Centers for Medicare & Medicaid Services ("CMS") implementing certain provisions of the Deficit Reduction Act of 2005 ("DRA"), published in the Federal Register on December 22, 2006 ("Proposed Rule"). Specifically, my comments relate to:

(1) Proposed Reg. §447.504 "Determination of AMP" and §447.505 "Determination of Best Price" as such provisions relate to manufacturer coupons and other point-of-sale discounts;

(2) The effect of Proposed Reg. §§447.504 and 447.505 (and the statutory provisions of the Deficit Reduction Act of 2005 ("DRA") upon which such proposed regulations are based) on drug manufacturers' obligations under §1927(a)(5) of the Social Security Act (42 USC § 1396r-8(a)(5)) to provide discount prices to "covered entities" under §340B of the Public Health Service Act (42 USC §256b) and certain children's hospitals in light of the position of the Office of Pharmacy Affairs ("OPA") that the 340B discount price is based upon the definition of AMP determined under the Medicaid rebate statute **prior to the changes under DRA** (and, presumably, without regard to guidance under the Final Rule)[1] and

[1] As expressed in the "Dear Pharmaceutical Manufacturer" letter issued by the Director of Office of Pharmacy Affairs on January 30, 2007, available at: http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm.

(3) The absence in the Collection of Information Requirements under the Paperwork Reduction Act and Impact Analysis required under the Regulatory Flexibility Act of an analysis of the impact of the Proposed Rule upon manufacturer information collection requirements under the 340B Discount Pricing Program.

First, CMS should be commended for attempting to set forth clearly in regulatory form agency interpretations of the statute involving inclusions and exclusions from AMP and best price. Introducing elements of certainty into the application of highly ambiguous statutory language that for years has been the subject of limited formal guidance can be expected to have the salutary effect of both leveling the competitive playing field and introducing greater price reporting consistency among manufacturers. Our comments follow in Sections I - IV.

I. Provisions of the Proposed Regulations
Determination of Best Price – Proposed Reg. §447.505(c) and (d)
Determination of AMP -- Proposed Reg. §447.504(g) and (h)
Manufacturer Coupons

The Final Rule should clarify that manufacturer coupons redeemed by consumers, either directly to the manufacturer or at point of sale though pharmacies, are excludable from the computation of AMP and from best price consideration as long as (1) manufacturer payments to pharmacies are limited to administrative fees, charged at fair market rates, to compensate the pharmacies for their services and (2) the prices paid by such pharmacies for the drugs are not affected by the coupon. No distinction should be made between manufacturer coupons and other manufacturer-sponsored point-of-sale discounts.

Proposed Reg. §447.505(d) states, in pertinent part:

> "Best price excludes ... [p]rices negotiated under a manufacturer's sponsored Drug Discount Card Program ...[and]... [m]anufacturer coupons redeemed by a consumer."

CMS has enunciated in the commentary accompanying the Proposed Rule the informal position CMS staff members have previously expressed -- *i.e.*, that manufacturer coupons not affecting the drug prices paid by a pharmacy should not be included in the manufacturer's determination of the drug's best price.[2] But, consistent with this policy, redemption by the consumer "directly" to the manufacturer also may be achieved by means of a point-of-sale redemption, with the pharmacy acting on the consumer's behalf in administering his or her redemption to the

[2] In the preamble to the Proposed Rule, CMS states:

> "In this proposed rule, we propose to clarify how manufacturer coupons should be treated for the purpose of establishing best price. We 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). In this rule, we propose to include coupons redeemed by any entity other than the consumer in the calculation of best price. We believe that the redemption of coupons by the consumer directly to the manufacturer does not affect the price paid by any entity whose sales are included in best price. In this proposed rule, we propose to exclude coupons redeemed by the consumer directly to the manufacturer from the calculation of best price. CMS invites comments from the public on this proposed policy."

manufacturer, as long as payment to the pharmacy is limited to "bona fide service fees" as defined in the Proposed Rule. In this way, consumers may realize the benefit of manufacturer discounts by the preferred method of redemption -- at point-of-sale. Because the reasonable compensation paid by a manufacturer to a pharmacy for administrative services does not affect the prices of drugs paid by the pharmacy, this interpretation of the Medicaid rebate statute is consistent with CMS' traditional position, as alluded to in the preamble.

Under the alternative "rebate" redemption method, the discount buyer is far less likely to follow through to completion the steps necessary to receive the rebate than is the case for the point-of-sale discount. Further, under a rebate system, the consumer must effectively advance the retailer the amount of the discount for an indeterminate amount of time -- a fact that may discourage the more needy consumers from making the purchase at all. It is unlikely that Congress, in enacting the Medicaid rebate statute, intended to penalize drug manufacturers for discounting their products to consumers or to force drug consumers, already confused by the complexities of the drug distribution and reimbursement system, to deal directly with distant manufacturers in order to obtain discounts on drugs purchased at their neighborhood pharmacies.

Proposed Reg. §§447.504(g)(11) and (h)(9) also should be revised to provide similar AMP treatment of manufacturer coupons and other point-of-sale discounts. A point-of-sale discount as described above does not affect the price received by the manufacturer for drugs distributed in the retail pharmacy class of trade. If a discount is excluded from best price consideration, it should also be excluded in the calculation of AMP unless there is a statutory basis for different treatment.

II. Provisions of the Proposed Regulations
Determination of Best Price – Proposed Reg. §447.505(d)
Determination of AMP -- Proposed Reg. §447.504(h)

Drug Discount Card Programs

The drug discount card program exclusion from best price (Proposed Reg. §447.50(d)(7)) should be clarified or eliminated in favor of an expansion of the manufacturer coupon exclusion in subparagraph (d)(8).

The language of Proposed Reg. §447.505(d)(7), which excludes from best price "[p]rices negotiated under a manufacturer's sponsored Drug Discount Card Program," is confusing and overly narrow. The only definition of "drug discount card program" in existing regulations refers to the Medicare-endorsed discount card program, which was discontinued when Medicare Part D took effect on January 1, 2006. The form a consumer drug discount takes (*e.g.*, discount card, voucher, coupon, etc.), and whether the "sponsorship" resides in the retailer or manufacturer, should not dictate whether it is includable or excludable for purposes of determining best price. The relevant inquiry under the statute is whether the price concession affects the pharmacy price from the manufacturer. A consumer drug discount card program would not affect the pharmacy price if the discount is passed through 100% to the consumer. Accordingly, the best price exclusion under Proposed Reg. §447.505(d)(7) should include prices under any manufacturer-sponsored discount program where 100% of the manufacturer's discount is passed through to the consumer. Alternatively, CMS should consider eliminating this

exclusion and expanding the coupon exclusion in subparagraph (d)(8) to include all point-of-sale discounts.

If the drug discount card program exclusion from best price is retained in the Final Rule, the Final Rule should also provide a similar exclusion from AMP. A drug discount card program involving the pass-through of a manufacturer discount 100% to the consumer does not affect the price received by the manufacturer for drugs distributed in the retail pharmacy class of trade.

III. Provisions of the Proposed Regulations

Determination of AMP -- Proposed Reg. §447.504

Additional Guidance on AMP for Determination of 340B Discount Program Prices

The Final Rule, or a separate regulatory provision, should clarify that the inclusions and exclusions from AMP enumerated in Proposed Reg. §447.504 and the statutory changes enacted in the DRA and other legislation since the enactment of the Veterans Health Care Act of 1992 that affect the determination of Medicaid rebates and the covered outpatient drugs with respect to which such rebates are payable apply with equal force in the manufacturer's computation of the 340B "ceiling prices" and the Federal ceiling prices for such drugs.

Background -- Need for Guidance

On January 30, 2007, the Director of the Office of Pharmacy Affairs ("OPA"), the office within the Health Care Resources Administration ("HCRA") that administers the 340B Discount Pricing Program, issued a "Dear Pharmaceutical Manufacturer" letter setting forth OPA's position on the determination of 340B ceiling prices in light of the changes to the definition of AMP under the DRA. According to the OPA, the following provision in Section 340B(1)(c) of the Public Health Service Act mandates that manufacturers use **the definition of AMP in effect on the date of enactment of legislation that established the 340B Discount Pricing Program** ("340B Enactment Date") in calculating the 340B ceiling price:

> "Any reference in [Section 340B] to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of enactment of this section [enacted Nov. 4, 1992]."

A virtually identical provision can be found in Section 603 of the Veterans Health Care Act of 1992 (38 U.S.C. §8126(g)(1)), which applies to the determination of Federal ceiling prices available to or through other federal agencies.[3]

Section 340B(b) of the Public Health Service Act defines AMP as follows:

> "In this section, the terms 'average manufacturer price', 'covered outpatient drug', and 'manufacturer' have the meaning given such terms in section 1927(k) of the Social Security Act."

[3] This section applies to the Department of Veterans Affairs, the Department of Defense, the Coast Guard and the Public Health Service with respect to drugs purchased under a depot contracting system or the Federal Supply Schedule.

Since inception, the 340B Discount Pricing Program and the Medicaid Rebate Program have been linked.[4] All of the components of the 340B pricing formula are taken from pricing and rebate information reported by manufacturers under the Medicaid Rebate Program and collected by CMS.[5] Under the AMP formula in effect at the enactment of Section 340B, the 340B ceiling price and net price to Medicaid would be exactly the same, although the 340B ceiling price lags the Medicaid rebate by a quarter. Indeed, as recently as August 5, 2005, in an audioconference overview of the 340B Discount Pricing Program, a Powerpoint presentation by a staff member of the HRSA Pharmacy Services Support Center explained how the 340B price is determined as follows:

> "Brand name drugs: 340B price for each unit of the drug cannot exceed AMP (***as reported to CMS under Medicaid rebate program***) minus 'rebate percentage.'"[6]

Similarly, the standard 340B Pharmaceutical Pricing Agreement executed by manufacturers states that it is the manufacturer's responsibility to charge covered entities a drug price not to exceed:

> "the **AMP** for the covered outpatient drug **reported** (or which would have been reported had the [m]anufacturer participated in the Medicaid rebate program) **to the Secretary in accordance with the [m]anufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage.**"

In 2005 testimony before the Congress on the 340B program, a Deputy Inspector General of HHS told Representatives that "[b]oth the Government and the manufacturers calculate 340B ceiling prices using **the same statutorily-defined formula and the drug pricing data** that manufacturers report to [CMS] for the purposes of the Medicaid drug rebate program."[7] Within weeks thereafter, DRA was enacted. Among the amendments to the Medicaid rebate statute included in DRA are:

- a new definition of AMP that ends the deduction of customary prompt pay discounts from gross sales and requires manufacturers to combine sales and price data for brand drugs and their authorized generics into a single AMP;
- a new definition of best price that includes prices for authorized generic drugs approved under the same NDA as a brand drug in the determination of the brand drug's best price;
- a limitation on which sales at nominal prices may be excluded in the determination of best price and

---

[4] Exchange among Senators Bentsen, Cranston, Kennedy and Rockefeller on joint committee responsibility for legislative matters pertaining to the 340B Discount Pricing Program and Medicaid Rebate Program, *Congressional Record*. 102nd Cong., 2nd Sess., 1992, 138, no. 144, daily edition (8 October, 1992): S17903.

[5] The use by OPA of CMS Medicaid Rebate Program pricing data is explained by the Inspector General of the U.S. Department of Health and Human Services in *Review of 340B Prices, July, 2006*, OIE-05-02-0073 on page 3.

[6] NGA/NCSL Web-assisted Audioconference, August 5, 2005, available at http://www.nga.org/Files/ppt/0508340BGOYETTE.PPT.

[7] Testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, U.S. Department of Health and Human Services before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, December 15, 2005.

- the addition of certain children's hospitals to 340B covered entities in the section requiring manufacturers to extend 340B discounts to safety-net providers.

The effect of the definition of AMP amended by DRA is that the same dollar discount extended by manufacturers results is a higher 340B ceiling price than Medicaid best price for a given drug. Nothing found in the legislative history of DRA indicates that Congress focused on the effect of the AMP definition amendment on 340B ceiling prices or the Federal ceiling price under §603 of the Veterans Health Care Act of 1992 (38 U.S.C. §8126). However, the commentary accompanying the Proposed Rule indicates that CMS believed the amendments to the Medicaid rebate provisions and the Final Rule would apply to 340B pricing.[8]

Support for a Single AMP for Medicaid and 340B Programs

There are two possible interpretations of **paragraph (c) of §340B** of the Public Health Service Act (the "340B Statute) as it relates to the **paragraph (b)** definition of AMP:

> (1) AMP is computed as provided under the Medicaid rebate statute that is current on the date of calculation, but to find what section that is in, you refer to Section 1927(c) of the Social Security Act (42 USC 1396r-8(c)) in 340B Enactment Date form, even if later legislative changes mean that the formula is in a different section of the Social Security Act currently.
>
> (2) Some, but not all, elements of the 340B Enactment Date substantive provisions of the Medicaid rebate pricing scheme are frozen in time for purposes of 340B pricing, so, even though the Medicaid and 340B prices were the same in 1992, any future change in the AMP formula under the Medicaid rebate statute has the effect of creating two different pricing schemes, **without any Congressional expression of an intent to do so.**

We believe that under the coordinated Medicaid/340B pricing scheme as intended by Congress, where prices and rebates reported under the Medicaid rebate statute are used to calculate 340B discounts, the only logical and expedient interpretation of the statutory interpretation provision in the 340B Statute is the first one. The following are some, but by no means all, of the issues and problems engendered if the second interpretation is applied, as the OPA Director has proposed in the "Dear Pharmaceutical Manufacturer" letter:

- Manufacturers who have overhauled their Medicaid price reporting systems to accommodate the new AMP definition and CMS's new DDR software system must retrieve their discarded pre-existing price reporting systems for use under 340B and make additional changes to disregard amendments to the Medicaid rebate statute since the 340B Enactment Date.
- The pricing provisions of existing 340B Pharmaceutical Pricing Agreements will be inconsistent with 340B program requirements.

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[8] CMS states that it believed that a change in the reporting of a drug's NDC number under the Medicaid rebate statute reporting provisions to require eleven digits rather than nine would assist 340B entities in the pricing of different package sizes (Medicaid Program; Prescription Drugs; Proposed Rule, 71 Fed. Reg. 77186 (December 22, 2006)).

- OPA and HRSA will be unable to calculate the 340B ceiling prices by using publicly-available AMP data and, as a result, must either forgo the calculation or institute a whole new data collection program, file Paperwork Reduction Act forms that estimate the burden upon manufacturers of the new data collection and obtain approval from the Office of Management and Budget.
- The 340B pricing scheme, unlinked from the AMP reported to Medicaid, will be based upon one of the following two formulas, depending upon the interpretation given to the phrase "average total rebate required under section 1927(c) of the Social Security Act ... during the preceding calendar quarter"[9]:

  Alternative Formula 1:

  340B price <= AMP calculated as defined on the 340B Enactment Date - (Medicaid rebate actually paid / AMP calculated as defined on the 340B Enactment Date)

  Alternative Formula 2:

  340B price <= AMP calculated as defined on the 340B Enactment Date - (rebate that would have been required under pre-340B Enactment Date Medicaid rebate provisions / AMP on the 340B Enactment Date)

  (a) Alternative Formula 1 uses the following:

  - the AMP definition in effect on the 340B Enactment Date;
  - the DRA best price definition, which, unlike the definition on the 340B Enactment Date, excludes inpatient prices charged to disproportionate share hospitals, prices negotiated with Medicare Part D plans and retiree drug plans receiving the retiree drug subsidy and only those nominal prices charged to enumerated safety-net entities; and
  - a revised baseline AMP derived from historic AMP data "grossed up" to include customary prompt pay discounts previously deducted.

  The AMP in effect on the 340B Enactment Date, which may or may not need to be adjusted by manufacturers to incorporate regulatory guidance included in the Final Rule (for inclusions and exclusions like manufacturer coupon discounts, mail order pharmacy prices, PBM prices and LTC pharmacy prices), differs from the current Medicaid AMP in that it:

  - includes customary prompt pay discounts;
  - includes returned goods;
  - does not include, for brand drugs, data on sales of authorized generic drugs approved under the same NDA; and
  - does not exclude discounts to Medicare Part D enrollees and employee plans receiving the retiree drug subsidy.

[9] One interpretation is that the average total rebate is the rebate required as provided in the Medicaid statute at the 340B Enactment Date but as actually calculated and reported to Medicaid the previous quarter (Alternative Formula 1). The other interpretation is that it is the rebate that would have been paid during the preceding quarter if the Medicaid rebate statute had been unchanged since the 340B Enactment Date (Alternative Formula 2).

(b) Alternative Formula 2 would, in addition to using the AMP in effect on the 340B Enactment Date (as described above), force manufacturers to compute the Medicaid rebate as if no changes had been made to the Medicaid rebate statute since November 4, 1992. The complexities of such an undertaking would be great.

- Certain drugs used for the treatment of sexual or erectile dysfunction will be covered under the Medicaid Rebate Program but not the 340B Discount Pricing Program. Drug manufacturers will have to assure that future changes to the Medicaid rebate statute involving definitions of "covered outpatient drug," "manufacturer" and "AMP" do not enter into 340B ceiling price computations.
- Any future changes to the definitions of "AMP," "manufacturer" or "covered outpatient drug" that Congress desires to incorporate into pricing under both the Medicaid Rebate Program and the 340B Discount Pricing Program must be coordinated with both CMS and OPA and incorporated into amendments to both the Social Security Act and the Public Health Service Act. If the agencies having responsibility for administering the Federal ceiling price program take the same position as OPA, similar amendments to the Federal ceiling price program statute may require coordination with additional agencies and amendments to additional statutes.
- If agencies that administer the Federal ceiling price program do not agree with OPA's position, an irreconcilable conflict will exist in the construction of two virtually identical provisions adopted as part of the same legislation (*i.e.*, the Veterans Health Care Act of 1992).
- Post-340B Enactment Date changes to the definition of "federally qualified health care center" and to the requirements for disproportionate share hospitals to qualify as 340B "covered entities" will not be given effect under the 340B Discount Pricing Program unless Section 340B of the Public Health Service Act is amended.

For the reasons outlined above, to the extent that it is not possible to discern the original Congressional intent in adopting the 340B Statute provision at issue, CMS and OPA should issue guidance on an emergency basis that gives effect to the integrity of the joint statutory scheme, requires as few changes as possible to newly-established Medicaid price reporting systems and avoids needless systemic complexity that could have the unintended effect of exposing manufacturers to sanctions for inadvertent errors. Consultation with agencies having responsibility for the Federal ceiling price program also may be appropriate.

IV. Collection of Information Requirements
Paperwork Reduction Act Notice
Requirements for Manufacturers (§447.510)
Regulatory Impact Analysis
Anticipated Effects
Effects on Manufacturers

The Paperwork Reduction Act Notice and Regulatory Impact Analysis accompanying the Proposed Rule should incorporate the additional burden on manufacturers in making the

calculations necessary to compute both the Medicaid AMP, best price and rebate and the 340B ceiling price if the OPA's interpretation of the 340B statute is given effect.

Since the 340B Discount Drug Program in the past has used information collected under the Medicaid Rebate Program, if the OPA interpretation of §340B(c) of the Public Health Service Act is given effect, any change to the information collection requirements under the Medicaid rebate statute, including any change in formulas for computing the reported data, after the 340B Enactment Date will require manufacturers to duplicate their efforts in providing price information, because they will have to make separate computations for use by CMS and OPA. We question the accuracy of the additional manufacturer data collection burden of 31 hours per quarter for additional data gathering and pricing and $50,000 (208 hours annually) for systems upgrades in light of the initial and ongoing investment that would be required for manufacturers to establish and maintain two price reporting systems, one for Medicaid rebates and another for 340B ceiling prices.

* * * * * * *

Please accept my thanks in advance to your anticipated consideration of these comments. If you wish to discuss them further, please do not hesitate to contact me at 513-977-8344 or lydon@dinslaw.com.

Sincerely,

Deborah R. Lydon

Deborah R. Lydon

cc: Centers for Medicare & Medicaid Services,
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Division of Regulations Development,
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katherine_astrich@omb.eop.gov. Fax (202) 395-6974.

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Foothill Pharmacy

From: "Hall, Robert" <rohall@amerisourcebergen.com>
To: <undisclosed-recipients:>
Sent: Friday, February 02, 2007 9:03 AM
Subject: FW: NACDS "Model" Comments to Proposed AMP Rule: Feb 20 Deadline

-----Original Message-----
From: Saunders, George
Sent: Friday, February 02, 2007 6:43 AM
To: Strategic Accounts; Retail Group; Neu Lead Team; Alternate Care Regional Vice Presidents
Cc: Norton, Rita; Bolen, Michael
Subject: NACDS "Model" Comments to Proposed AMP Rule: Feb 20 Deadline

ATTACHMENT A

MODEL COMMENTS TO CMS
SUBMIT COMMENTS TO:

COMMENTS DUE FEBRUARY 20th

February XX, 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 Foothill Corporation is writing to provide our views on CMS' December 20th proposed regulation that would provide a regulatory definition of AMP as well as implement the new Medicaid Federal Upper Limit (FUL) program for generic drugs.

Our Corporation operates 1 pharmacies in 1 states. We are a major provider of pharmacy services in the communities in which our stores are located.

This proposed regulation, if adopted, would have a significant negative economic impact on my pharmacies. It could jeopardize my ability to provide pharmacy services to Medicaid beneficiaries and the general public. This regulation should not move forward unless substantial revisions are made. Incentives need to be retained for pharmacies to dispense low-cost generic medications. I ask that CMS please do the following:

- **Delay Public Release of AMP Data**: The Centers for Medicare and Medicaid Services (CMS) should not make Average Manufacturers Price (AMP) data public until a final regulatory definition of AMP is released. This definition should reflect the prices at which traditional retail pharmacies purchase medications. CMS indicates that it will start putting these data on a public website this spring. However, release of flawed AMP data could adversely affect community retail pharmacies if used for reimbursement purposes. CMS has already delayed release of these data, and we urge that release of these data be delayed again.

- **Define AMP 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 prices at which retail pharmacies purchase medications. Only manufacturers' sales to wholesalers for drugs sold to traditional community retail pharmacies should be included in the AMP definition. This is what the law requires.

  Mail order pharmacy and nursing home pharmacy sales should be excluded because these are not 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. Retail pharmacies do not benefit from these rebates and discounts, so the resulting AMP would be lower than the prices paid by retail pharmacies for medications. This proposed definition needs to be significantly modified.

- **Delay New Generic Rates that Would Significantly Underpay Pharmacies:** The new Federal Upper Limits (FULs) for generic drugs would be calculated as 250% of the lowest average AMP for all versions of a generic drug. This 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 it is now documented that these new generic reimbursement rates will be well below pharmacy's acquisition costs. A recent report from the Government Accountability Office 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.

- **Require that States Increase Pharmacy Dispensing Fees**: CMS should direct states to make appropriate adjustments to pharmacy dispensing fees to offset potential 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.

I support the more extensive comments that are being filed by the National Association of Chain Drug Stores (NACDS) regarding this proposed regulation. We appreciate your consideration of these

comments and ask that you please contact us with any questions. Thank you.

Sincerely, Boya Davis RPH 29951

PCMA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

1514

February 20, 2007

FEB 20 2007

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

File Code: CMS-2238-P

Dear Ms. Norwalk,

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the Notice of Proposed Rulemaking (NPRM) implementing provisions of the Deficit Reduction Act of 2005 (DRA). Our specific comments pertain to provisions of the Act relating to prescription drug reimbursement.

Introduction

PCMA believes that an overly broad definition of Average Manufacturer Price (AMP) has the potential to threaten drug price competition throughout the marketplace. PCMA is concerned that the proposed changes to the definition and calculation of AMP will have implications beyond AMPs intended purpose to serve as a benchmark for Medicaid manufacturer rebates and Federal Upper Limits (FULs.) AMPs availability on a public website and to state Medicaid programs may lead to adoption of AMP as a reimbursement benchmark by government payers and perhaps others. As such, the elements that shape AMP are critical and consideration must be given to the two distinct, and we would argue, conflicting purposes AMP and its disclosure would now serve.

PCMA's specific recommendations are summarized as follows:

- CMS should narrowly define AMP to be consistent with Congressional intent that AMP reflects the costs incurred by retail pharmacies for purchasing prescription drugs.

- CMS should define AMP to ensure that AMP-based reimbursement to retail pharmacies will cover their acquisition costs and not cause a cost-shift to commercial payers.

- CMS should explicitly exclude PBM rebates from the calculation of AMP, irrespective of whether they are associated with contracts negotiated for drugs distributed to the retail class of trade.

- CMS should not require reporting of PBM rebates, fees or other price concessions for inclusion in AMP.

- CMS should not include mail service pharmacy in the definition of "retail class of trade."

- CMS should explicitly exclude specialty pharmacy from the definition of "retail class of trade."

- CMS should explicitly exclude PBMs from the proposed definition of "wholesaler."

Background

AMP was created as part of the Medicaid Drug Rebate Program instituted in the Omnibus Budget Reconciliation Act of 1990 to serve as a benchmark from which to measure rebates that drug manufacturers must pay to the Medicaid program. Therefore, the original statutory definition of AMP and the additional guidance provided by CMS in the national rebate agreement and program transmittals has focused on price concessions made by drug manufacturers that reflect the net drug price paid to the wholesaler. This ensured that rebates were based on manufacturer actual prices as oppose to reported retail acquisition costs.

AMP's purpose as a benchmark for measuring manufacturer rebates has historically provided an incentive for manufacturer to be more inclusive of price concessions and discounts at the time of purchase or included in purchasing agreements. CMS acknowledges this in the NPRM when it says "manufacturers would generally benefit from a broad definition of retail pharmacy class of trade which would include entities that purchase drugs at lower prices and which would lower rebate liability."[1] This incentive, combined with a lack of clarity regarding key terms, has caused inconsistencies in reporting AMP over the years and calls into question AMPs reliability as both a benchmark for rebates, but more importantly, as a benchmark for reimbursement.

PCMA believes AMP's dual purpose requires careful consideration of the elements that make up AMP, the incentives different actors in the drug distribution chain have in shaping AMP, and the impact that AMP disclosure will have on the competitiveness of drug pricing overall.

Drug Reimbursement Benchmarks: Issues to Consider

[1] NPRM, Federal Register / Vol. 71, No. 246 / Friday, December 22, 2006 / Proposed Rules. p. 77178.

Competitive pricing in the pharmaceutical marketplace is highly dependent on the ability of buyers and sellers to customize contracts to meet differing needs. PCMA is concerned that a broadly defined, publicly available AMP may lead to more standardization in PBM-manufacturer contracts. The specific concern is that AMP is likely to establish a price floor below which manufacturers have little incentive to negotiate because these discounts will only reduce reimbursement to pharmacies that purchase their drugs. This concern is more than theoretical. Recently, a bill was introduced in the Colorado State Legislature to create a generic drug discount card for uninsured and underinsured residents. The bill proposes using AMP as the price floor for generic drugs distributed in this program.[2] While this outcome may seem desirable due to potential savings in the short run, it creates incentives over time for manufacturers to increase prices in order to maximize pharmacy reimbursement for their products. To this end, CMS should evaluate net cost to the program, not just the price paid to the pharmacy. If the price paid to the pharmacy based on AMP is inadequate then one of two things is likely to occur: the pharmacies will drop out of the program; or AMPs will increase.

Pricing/Cost incentives should work in the opposite direction. Today, PBMs use formularies as the primary mechanism to foster competition between manufacturers by creating preferred and non-preferred categories of drugs. As CMS knows well from managing the Medicare Part D drug benefit, the key to PBMs ability to negotiate post provider payment discounts with drug manufacturers is their ability to customize their contracts based on the cost and access desires of a particular client or group of clients. If a PBM can place a particular drug in a preferred place on a formulary, thus increasing market share for that drug, they are likely to get preferential post provider payment discounts. Competition to get drugs in preferred formulary spots creates incentive to strike similar deals between manufacturers and PBMs.

In testimony before the House Energy and Commerce Subcommittee on Health, CBO Director Douglas Holtz-Eakin made the following observations about drug reimbursement benchmarking:

> *In moving to some other index, instead of AWP, which is convenient, because it is a list price and out there, easily accessible, there are probably three different things to consider.*
>
> *The first is the degree to which it is readily available. One of the advantages of AWP is it is always available. It is updated by the manufacturers. It is available in a timely fashion. So would the proxy be available in a regular fashion?*
>
> *The second is the degree to which that would be the correct comparison group for whomever you are trying to reimburse. Who are the correct comparisons for pharmacies, for example? Is it the VA? Is it hospitals? Or is it closer to the kinds of retail pharmacy transactions that you see in the private market?*

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[2] Section 25.5-2.5-103 (6) (a) (I), Senate Bill 07-001, "The Colorado Cares Rx Act," State of Colorado General Assembly, 66th Session.

And then the third would be the impact that going to a new index would have on private sector bargaining. If you went to a different index and manufacturers knew that that was going to affect reimbursements, it might change the way they cut the deal with their other customers. So those three things will come up regardless of whether you go to AMP or an average sales price or whatever it may be.[3]

PCMA echoes these comments regarding needed elements in a drug reimbursement benchmark and would note that the proposed AMP definition does not match-up with these criteria. The proposed AMP (1) would not be readily available as there would be at a minimum 30-day time lag between reported AMPs and their availability; (2) does not provide for the "correct comparison group" in that CMS proposes to include mail service and potentially specialty pharmacy in the definition of "retail class of trade," as well as PBM rebates which are not received by retail pharmacies; and (3) has the potential to impact private sector bargaining by undermining manufacturer incentives to negotiate discounts and rebates.

Section 447.504 - Determination of Average Manufacturer Price

Recommendation: CMS should narrowly define AMP to be consistent with Congressional intent that AMP reflect the costs incurred by retail pharmacies for purchasing prescription drugs.

CMS states, "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; however, in light of our understanding of congressional intent, we believe that the definition is meant to capture discounts and other price adjustments, regardless of whether such discounts or adjustments are provided directly or indirectly by the manufacturer."[4] It is not clear what is meant by "indirect" price adjustments in this context. PCMA believes that indirect price adjustments should be limited only to the provider purchases, and that they represent pricing adjustments negotiated between providers and the manufacturer and not intended to be inclusive of post provider payment rebates utilized to control program cost. Regardless, PCMA disagrees that Congress intended such a broad definition of AMP.

In a clear statement of his intent behind drug reimbursement reforms in the DRA, Representative Nathan Deal, Chairman of the House Energy and Commerce Health Subcommittee, made the following comments:

I believe that any effort to reform Medicaid drug reimbursement must reflect three basic principles: transparency, accuracy, and fairness. Payments for drugs must be transparent to the purchaser without hidden payments that undermine

[3] House Energy and Commerce Health Subcommittee Hearing, "Medicaid Prescription Drugs: Examining Options for Payment Reform," June 22, 2005, Hearing Report Serial Number 109-25, p. 44.
[4] NPRM, p. 77179

competition. Payments must also accurately reflect the costs pharmacists pay for the drugs. Finally, Medicaid reimbursements for both drugs and dispensing fees should fairly pay pharmacies for all of the costs of treating Medicaid beneficiaries.[5]

It appears Congress' intent in enacting the DRA and CMS' proposed redefinition of AMP are directly at odds. CMS proposes that AMP include all price concessions that reduce the net price to the manufacturer. Yet, Congress explicitly excluded customary prompt pay discounts given to wholesalers but not passed on to retail pharmacy precisely because it understood that including these discounts would unfairly lower Federal Upper Limits, and thus retail pharmacy reimbursement. A broadly defined AMP will not "accurately reflect the costs pharmacists pay" for drugs because it includes price concessions not passed on to retail pharmacy. Post provider payment discounts do not reduce the price paid to the manufacturer. They are a contractual obligations based on utilization, and do not represent a discount on purchase. They are not passed on to the purchasing pharmacy. As such there is no reduction in the net price paid to the manufacturer.

Recommendation: CMS should define AMP to ensure that AMP-based reimbursement to retail pharmacies will cover their acquisition costs and not cause a cost-shift to commercial payers.

PCMA is concerned that if AMP is inclusive of price concessions that retail pharmacy does not receive, such as mail service pricing or manufacturer rebates, AMP-based reimbursement to pharmacies will not cover their costs and pharmacies will look to make up the difference by shifting those costs to other payers.

The GAO recently compared AMPs of 77 drugs to the average pharmacy acquisition cost of those drugs and found that 59 out of the 77 drugs had AMPs below pharmacy acquisition cost, even when the 250 percent multiplier was added.[6] They found that the entire sample of 77 drugs had AMP-based FULs that were on average 36 percent below pharmacy acquisition cost. This review used AMP data that does not reflect the proposed changes by CMS, such as inclusion of PBM mail service and rebates. If mail service prices and rebates were to be included in those AMP calculations, the numbers would be even lower, potentially making these drugs unaffordable to retail pharmacy.

While reforms to Medicaid payments for drugs are warranted, reimbursements that are significantly below drug acquisition cost are problematic, not just for retailers filling Medicaid prescriptions but for commercial payers as well. Retail pharmacies, particularly independent pharmacies in rural areas, may have a difficult time purchasing drugs at or below the AMP. In areas where Medicaid sales are a substantial part of a pharmacy's business, this will threaten the very survival of these pharmacies. PBMs rely

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[5] House Energy and Commerce Health Subcommittee Hearing, "Medicaid Prescription Drugs: Examining Options for Payment Reform," June 22, 2005, Hearing Report Serial Number 109-25, p. 2.

[6] U.S. Government Accountability Office, "Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs" December 22, 2006, GAO-07-239R

on chain and independent pharmacies alike to provide access to prescriptions for their government and commercial clients and would not want to see that access put in jeopardy.

Proposed 447.504 (g): Price Concessions to be Included in AMP

Recommendation: CMS should explicitly exclude PBM rebates from the calculation of AMP, irrespective of whether they are associated with contracts negotiated for drugs distributed to the retail class of trade.

CMS proposes to include PBM rebates, discounts, or other price concessions for drugs provided to the retail class of trade for the purposes of determining AMP.[7] PCMA opposes including in AMP manufacturer fees, rebates, and other price concessions made to PBMs. CMS argues that their position is consistent with past policy. However, this argument is flawed.

The NPRM notes that CMS considered excluding PBM rebates and mail service pricing, but then determined, "such removal would not be consistent with past policy, as specified in manufacturer Releases 28 and 29..."[8] CMS past policy was to require the inclusion of PBM rebates only if and to the extent that PBMs acted as wholesalers, i.e., met the definition of "wholesaler" in the national rebate agreement. The definition of "wholesaler" in the national rebate agreement is "any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug."[9] Since PBMs generally do not purchase drugs from manufacturers, but instead negotiate and arrange for post provider payment rebate contracts from manufacturers, PBMs do not act as wholesalers as defined in the rebate agreement. As such, applying past guidance, PBM rebates should not be included in the calculation of AMP.

As already noted, PCMA does not believe manufacturer rebates and other price concessions or fees that are not passed on to retail pharmacy should be included in AMP. PBM rebates are negotiated to reduce the costs incurred by their health plan clients in connection with products dispensed for the treatment needs of their covered beneficiaries and these rebates are passed on, in whole or in part, to these health plans payers, not to the dispensing retail pharmacies.

Recommendation: CMS should not require reporting of PBM rebates, fees or other price concessions for inclusion in AMP.

PCMA opposes any requirement that PBMs report manufacturer rebates to drug manufacturers for the purposes of including them in AMP due to following reasons: 1) they do not impact the price paid to the manufacturer and 2) they represent a significant cost and administrative burden of reporting this information.

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[7] NPRM p. 77179
[8] NPRM, p. 77178
[9] Centers for Medicare and Medicaid Services, Sample National Rebate Agreement, p. 5, www.cms.gov.

CMS acknowledges that one of the greatest challenges with including PBM rebates and fees in the calculation of AMP is collecting this information and determining whether rebates and fees are held by the PBM or passed onto the client payer.[10] The degree to which manufacturer rebates are passed through or shared with PBM clients is privately held, competitively sensitive information that can differ from contract to contract. Drug manufacturers are not privy to this information and to acquire it would require a contract by contract review of rebate arrangements (of which there are literally thousands).

The Pharmaceutical Research and Manufacturers Association (PhRMA) has stated it does not think manufacturers could legally require such reporting nor do they want that responsibility. In its comments on the May 2006 OIG report, "Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005" PhRMA said, "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." They go on to point out that the administrative burdens of doing so, with the attendant liability risk in the event data reported is not accurate, could cause "prolonged delays in negotiating contracts important to their ability to sell products..."[11]

Proposed 447.504 (e): Definition of Retail Pharmacy Class of Trade

Recommendation: CMS should not include mail service pharmacy in the definition of "retail class of trade."

CMS proposed to include mail service pharmacy prices in the calculation of AMP by defining mail service pharmacy as part of the "retail class of trade." PCMA opposes mail service pharmacy being included in the definition of retail class of trade.

Mail service pharmacy is a separate and distinct business from retail pharmacy, with different overhead, inventory, equipment and personnel needs that distinguish its cost structure and function. CMS acknowledges this distinction in Medicare Part D when it explicitly defines retail pharmacy as *not* including mail order pharmacy. In § 423.120 (a) (3) regarding Part D pharmacy access standards, CMS identifies mail service pharmacies as "non-retail" and establishes different conditions as applying to retail versus non-retail pharmacy.[12] PCMA believes that CMS should maintain consistency in its characterization of mail service pharmacy as separate and distinct from retail across different federal programs.

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[10] NPRM, p. 77179

[11] Department of Health and Human Services, Office of the Inspector General, "Determining the Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005," (A-06-06-00063), Appendix F, April 7, 2006, p. 8.

[12] 42 CFR Ch. IV §423.120 (a) (3)

We are concerned CMS appears to include mail service pharmacy as part of the retail class of trade solely because it will likely lower AMP (CMS notes that not including mail service may lead to AMP "inflation.") It does not appear that consideration has been given to the actual functions performed and populations served by mail service versus retail pharmacy.

CMS states "that retail class of trade means that sector of the drug marketplace, similar to the marketplace for other goods and services, which dispenses drugs to the general public and which includes all price concessions related to such good and services."[13] CMS specifically exempts nursing home pharmacies because they do not dispense to the general public but believes that mail service pharmacy is "another form of how drugs enter into the retail class of trade..."[14]

The distinction that CMS uses to differentiate those sales it believes are associated with the retail class of trade and those that are not turns on whether the drugs are dispensed to the general public. Mail service pharmacies generally do not dispense drugs to the general public in the manner a retail pharmacy does. You cannot walk into a mail service pharmacy the same way you could a retail pharmacy to fill a prescription. Nor can you get a prescription filled through a mail service pharmacy without being a member of a health plan providing that benefit through that particular pharmacy. Furthermore, CMS exempts long-term care (LTC) pharmacies because they are deemed not to dispense drugs to the general public. LTC pharmacies and mail pharmacies each limit their services to defined groups of individuals (residents in the case of LTC pharmacies and plan members in the case of mail pharmacies.)

As AMP will serve as a benchmark for Medicaid FULs, it is appropriate to note that Medicaid beneficiaries can go to almost any retail pharmacy and get a prescription filled. However, mail service pharmacy is virtually non-existent in the Medicaid program and a Medicaid beneficiary could not fill a prescription through a mail order pharmacy unless that Medicaid program had a contract with such pharmacy. Thus, it is not appropriate to incorporate mail service in the definition of retail class of trade.

Recommendation: CMS should explicitly exclude specialty pharmacy from the definition of "retail class of trade."

The designation of specialty pharmacy is not directly addressed in the NPRM or past program guidance. In the absence of clear guidance from CMS on the treatment of drug and biologic sales to specialty pharmacy, there will likely continue to be differing interpretations by manufacturers regarding reporting requirements for these sales. To remedy this, PCMA recommends CMS explicitly exclude sales of drugs and biologics to specialty pharmacy from the definition of "retail class of trade."

Similar to the arguments articulated above regarding the treatment of mail service pharmacy, specialty pharmacy does not meet CMS' test of an entity that "dispenses drugs

[13] NPRM p. 77178
[14] NPRM p. 77178

to the general public" in order to qualify as being part of the retail class of trade. Similar to LTC pharmacy, which CMS exempts from the retail class definition, specialty pharmacy serves a very small patient population with chronic, rare and/or life-threatening conditions. Specialty pharmacies generally do not have store front operations where a patient could walk in a fill a prescription like in retail pharmacy but instead provide home delivery of patient therapies.

PCMA believes that establishing the standard of "dispenses drugs to the general public" as the determinant of whether a sale is included in the retail class of trade ignores critically important cost, infrastructure and functional differences that distinguish retail pharmacy from specialty pharmacy. For example, retail pharmacies need to be centrally located, need to carry a large and varied inventory of drugs and don't typically store injectible biologics on premises. Specialty pharmacies, on the other hand, maintain a small volume of very high dollar medications that often have special refrigeration and storage needs. These differences alone have a direct impact of the cost of drugs dispensed, and PCMA believes it is inappropriate to lump them together for the purposes of calculating AMP.

Beyond the infrastructure and inventory differences, specialty pharmacy provides hands-on clinical services not available at retail pharmacy. In fact, "specialty pharmacy" is somewhat of a misnomer because it implies simple drug dispensing when, in fact, specialty pharmacy provides patients with conditions like hemophilia, rheumatoid arthritis, multiple sclerosis and cancer not only their medications, but also the tools to care for themselves at home when clinically appropriate. This includes sending health professionals to patient homes to educate patients and their caregivers on self-injecting medicines, proper storage and disposal of medicines and supplies, and how to manage side effects. Patient support is provided 24/7 via home visits or telephone consultation with health professionals. We believe drugs distributed and care management provided by specialty pharmacy in no way compare to the transactional nature of drugs dispensed through retail pharmacy and therefore their sales should be excluded from the definition of retail class of trade.

Proposed 447.504 (f): Definition of Wholesaler

Recommendation: CMS should explicitly exclude PBMs from the proposed definition of "wholesaler."

CMS proposes to define wholesalers in regulation to include PBMs and solicits comments on "how and to what extent PBMs act as wholesalers."[15] PCMA opposes PBMs being identified, by definition, as wholesalers in regulation or other program memoranda, without any consideration given to whether they actually function as wholesalers in accordance with the long-established and well-understood meaning of the term, and as defined in the national rebate agreement. Such designation does not accurately characterize PBMs role in the drug distribution chain. Furthermore, such a

[15] NPRM p. 77179

designation may subject PBMs to new and inappropriate regulatory requirements reserved for licensed wholesalers when they are only functioning as PBMs.

CMS past policy guidance (as articulated in the drug manufacturer rebate agreement) defines a wholesaler as "...any entity (including pharmacy or chain of pharmacies) to which the labeler (manufacturer) sells the covered outpatient drug, but that does not relabel or repackage the covered outpatient drug."[16] By this definition, any entity that buys direct from a manufacturer and does not relabel a drug is a wholesaler.

Wholesale drug distribution is defined under the Prescription Drug Marketing Act PDMA) as, "distribution of prescription drugs to persons other than a consumer or patient..."[17] While PBMs may own mail and specialty pharmacies that do purchase drugs directly from manufacturers, those pharmacies distribute those drugs directly to patients as state licensed pharmacies, not wholesalers. Therefore, to identify a PBM as a wholesaler in regulation or program guidance would be incorrect and inappropriate.

Other Issues:

Time Delayed AMP: PCMA is concerned about the delay in reporting AMP when it is used as a reimbursement benchmark. Drug price changes can occur daily and the current system allows for updates to occur almost automatically with electronic data transfers. As put forth in the NPRM, AMP data will be 30 days old when reported to CMS. This data must then be reported by CMS to States and posted on a public web site, and may be revised for up to 30 days. Therefore, by the time AMP is publicly available, it will be at least 30 days old but likely more. It is not clear how this problem could be mitigated but it highlights, again, the challenges CMS faces in implementing AMPs new dual purpose of serving as a measure for quarterly Medicaid rebates and now potentially as a reimbursement benchmark.

Treatment of Part D Sales: As argued above, we believe that a publicly disclosed, broadly defined AMP will likely become a price floor for drug sales. By including sales to Part D in the AMP calculus, PCMA is concerned that CMS will undermine the Medicaid best price exclusion Congress granted Part D sales.

Sales of drugs to Part D were specifically excluded from the Medicaid "best price" requirement because Congress recognized that best price created a price floor below which drug manufacturers were not likely to provide discounts. By exempting Part D sales from the best price requirement, CBO estimated that taxpayers and beneficiaries would save $18 billion in Part D spending due to manufacturers offering deeper discounts on Part D drugs. To now require that these sales be included in AMP may change manufacturer discounting behavior for Part D.

We note with interest that the proposed inclusion of Part D sales in AMP and the proposed codification of Medicaid "best price" requirements in the NPRM come at a time

[16] CMS, Sample National Rebate Agreement, p. 5.
[17] § 203.3(cc) (21 CFR 203.3(cc))

when the Administration seeks legislative relief from these requirements. For two years in a row, the Administration has asked Congress to remove the "best price" requirement from the Medicaid statute precisely because it recognizes the deleterious impact "best price" has on drug price negotiation.

Treatment of Bona-Fide Service Fees: PCMA supports the exclusion of bona fide service fees from AMP. However, we believe that an unnecessarily narrow reading of what constitutes "fair market value" remuneration for legitimate services performed on behalf of a manufacturer may disrupt normal and legitimate business transactions between PBMs and manufacturers.

We also recommend that CMS not include the proposed distinction that a fee be "not passed on" in order to be considered a bona fide service fee. If the fee is for a legitimate service performed for the manufacturer, they are by definition not a price concession for drugs. It should not be relevant if the fee is passed on as to whether it constitutes legitimate payment for services provided. Moreover, the administrative burden for manufacturers to gather confidential information from PBMs and others in the drug channel regarding whether fees are passed on or not would be significant and may cause manufacturers to forgo any service arrangements.

Conclusion:

On behalf of PCMA, I appreciate the opportunity to comment on proposed rule CMS-2238-P. PCMA looks forward to working with the Administration to ensure fair and balanced implementation of the DRA with particular attention paid to the broader impact this rule may have on the drug distribution channel. Please don't hesitate to contact us if you have any questions about our comments.

Sincerely,

Mark Merritt
President & CEO

UNC PHYSICIANS & ASSOCIATES

February 20th, 2007

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

To Whom It May Concern;

On behalf of the University of North Carolina Physicians and Associates (UNC P&A) I am responding to the request for comments on regulations proposed to implement the Deficit Reduction Act of 2005 published in the Federal Register on December 22, 2006. UNC P&A is an organization of over 800 physicians within the University of North Carolina at Chapel Hill's School of Medicine. These providers are responsible for more than 750,000 patient visits each year, approximately 18% of which are Medicaid patients.

As a centralized practice plan, UNC P&A would find it extremely difficult to comply with the proposal that NDC numbers and units be printed on each claim for outpatient physician-administered drugs submitted to Medicaid. Indeed, this requirement would place a significant financial and administrative burden on UNC P&A and expose us to the possibility of audit penalties in spite of our best efforts to comply.

Pharmaceuticals are provided to UNC P&A clinics by the UNC Hospital's central pharmacy. Drug treatments that require mixing for infusions, e.g. chemotherapy, are often mixed and delivered by the pharmacy to the clinics responsible for administering the drugs. UNC P&A billing is likewise centralized; the clinics where the drugs are administered are located some distance away from the offices where the billing actually takes place. It is thus extremely difficult to communicate to the billing office the NDC number of the drugs acquired from the UNC Pharmacy and administered by clinical staff. Because any given drug might have several NDC numbers corresponding to several brands on the shelf at one time, it is simply not possible for a remote staff member to know which product was used.

Assuming that NDC information could be successfully captured, compliance with the new regulation would require UNC P&A to reprogram its billing system to hold relevant claims pending manual entry of NDC numbers and units. The costs associated with the technical component of this project, the use of additional staff, and the inevitable claim filing delays would negatively impact our organization. It is thus our hope that the proposed regulations be reconsidered in relation to the financial and administrative burden that they would impose upon our organization.

Sincerely,

Marschall S. Runge, MD
President, UNC Physicians

P.O. Box 168
Chapel Hill, NC 27514

Memorial
HEALTH
UNIVERSITY MEDICAL CENTER

February 20, 2007

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

Submitted electronically via http://www.cms.hhs.gov/eRulemaking

To Whom It May Concern:

On behalf of Memorial Health University Medical Center, I am responding to the request for comments on proposed regulations to implement the Deficit Reduction Act of 2005 (the "DRA"), published in the Federal Register on December 22, 2006. Memorial Health University Medical Center is a 530 bed hospital located in Savannah, Georgia, that qualifies as a disproportionate share hospital ("DSH") under the Medicare program and is enrolled as a covered entity under the federal 340B drug discount program. Our principal concerns about the proposed regulations are twofold.

First, the proposed regulations would create enormous administrative and financial burdens for our hospital by requiring the reporting of NDC information on drugs administered in hospital outpatient settings. While we maintain NDC in our computerized distribution and billing systems, the manpower associated with tracking each dispensed medication to an exact NDC match is insurmountable. It is not unusual to have two or more brands of a medication available in a pharmacy. This poses no clinical threat and is often due to contractual changes and/or drug shortages. Given a normal hospital formulary of 2500 to 3000 line items the CMS claim of "15 seconds" appears off target.

Second, CMS's proposed policies would significantly decrease the savings our hospital achieves through participation in the 340B program, to the extent that the new rules may result in States imposing manufacturer rebate obligations (and accompanying requirements for 340B hospitals to forego the benefit of 340B discounts) on hospital outpatient clinic drugs that should be treated as exempt from rebate requirements. The 340B program allows us to minimize the negative financial aspects of treating Medicaid patients. The proposed revision eliminates this advantage and in fact is contrary to reason 340B pricing exists.

Thank you for the opportunity to comment on these proposed regulations.

Sincerely,

Kenneth G. Jozefczyk, M.S., RPh, FASHP
Director of Pharmacy
Memorial Health University Medical Center
4700 Waters Ave
Savannah, GA 31403

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Tribal Technical Advisory Group

to the Centers for Medicare and Medicaid Services

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February 12, 2007

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

RE: Comments on proposed rule Medicaid Program; Prescription Drugs
71 Federal Register 77174 (December 22, 2006); File Code: CMS-2238-P

Dear Ms. Norwalk,

As Chair and on behalf of the Tribal Technical Advisory Group (TTAG), I would like to thank you for the opportunity to provide comments to the proposed regulations, published in the Federal Register on December 22, 2006, at Vol. 71, No. 246, implementing provisions of the Deficit Reduction Act (DRA) pertaining to prescription drugs under the Medicaid program.

It is our understanding that this proposed rule, in part, will limit State Medicaid expenditures for certain multiple source drugs. States will retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists, and may pay above or below the Federal upper payment limit (FUL) as long as overall payments for drugs subject to a FUL are under the annual aggregate cap. About 600 drugs are initially subject to the FULs, including drugs for the treatment of asthma, hypertension, pain relief, and depression. States can vary reimbursement levels and can, for example, target more favorable reimbursement to pharmacists in rural or inner city areas or to independent pharmacists. To implement these regulations, each State must amend their State Medicaid Plan and describe their approach.

The Indian Health Service (IHS) and tribally operated pharmacies have authority to dispense, bill, and receive reimbursement from State Medicaid agencies for drugs prescribed to Medicaid beneficiaries. The State Medicaid agencies reimburse IHS and tribal pharmacies at cost per a payment methodology outlined in the State plan. IHS and tribal programs depend on the Medicaid reimbursements to supplement existing IHS appropriations to the IHS and tribal programs that are currently under funded. Many of these pharmacies are small and operate in remote rural areas. As such, any changes in Medicaid reimbursements can have a negative effect on their financial sustainability. The complexities of Indian health financing make it imperative that States consult with Tribes before and during the development of any amendments to their state plans. Without this consultation, implementation of this rule may have unintended negative consequences on Indian health programs.

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THE HOPI TRIBE

Ivan Sidney, Sr.
CHAIRMAN

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TO: Jaime Hoke, Assistant for Legislation & Policy

ORGANIZATION: National Indian Health Board

FAX NUMBER : (202) 742-4285

FROM: LEON A. NUVAYESTEWA Sr.

Comments: Attached is letter sent by Hopi Tribe per proposed rule making. Medicaid Program; Prescription Drugs 71 Federal Register 77174 ...

We request CMS insert language in the final rule encouraging States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies to protect this safety net for our Medicaid beneficiaries.

Your consideration of our comments and recommendations is appreciated.

Sincerely,

Mr. Todd D. Honyaoma, Sr., Vice Chairman/CEO
Office of the Vice Chairman
The Hopi Tribe

xc: Robert Sakiestewa, Jr., Chairman, Hopi Health Advisory Council
Marlene Sekaquaptewa, Chair, Arizona Indian Council on Aging
Melvin George, Chairman, Hopi Elderly Organization
Herman G. Honanie, Director, Dept. of Community Health Services
Leon A. Nuvayestewa, Sr., Director, Office of Elderly Services
Bruce Talawyma, Hopi Health Care Center
File

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February 12, 2007

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

RE: Comments on proposed rule Medicaid Program; Prescription Drugs
71 Federal Register 77174 (December 22, 2006); File Code: CMS-2238–P

Dear Ms. Norwalk,

As Chairman and on behalf of the National Indian Health Board (NIHB), I am providing comments to the proposed regulations, published in the Federal Register on December 22, 2006, at Vol. 71, No. 246, implementing provisions of the Deficit Reduction Act (DRA) pertaining to prescription drugs under the Medicaid program.

Established in 1972, the NIHB serves all Federally Recognized American Indian and Alaska Native (AI/AN) Tribal governments by advocating for the improvement of health care delivery to AI/ANs, as well as upholding the Federal government's trust responsibility to AI/AN Tribal governments. We appreciate the opportunity to comments on these rules.

It is our understanding that this proposed rule, in part, will limit State Medicaid expenditures for certain multiple source drugs. States will retain the authority to set their own reimbursement levels and dispensing fees paid to pharmacists, and may pay above or below the Federal upper payment limit (FUL) as long as overall payments for drugs subject to a FUL are under the annual aggregate cap. About 600 drugs are initially subject to the FULs, including drugs for the treatment of asthma, hypertension, pain relief, and depression. States can vary reimbursement levels and can, for example, target more favorable reimbursement to pharmacists in rural or inner city areas or to independent pharmacists. To implement these regulations, each State must amend their State Medicaid Plan and describe their approach.

The Indian Health Service (IHS) and tribally operated pharmacies have authority to dispense, bill, and receive reimbursement from State Medicaid agencies for drugs prescribed to Medicaid beneficiaries. The State Medicaid agencies reimburse IHS and tribal pharmacies at cost per a payment methodology outlined in the State plan. IHS and tribal programs depend on the Medicaid reimbursements to supplement existing IHS appropriations to the IHS and tribal programs that are currently under funded. Many of these pharmacies are small and operate in

remote rural areas. As such, any changes in Medicaid reimbursements can have a negative effect on their financial sustainability. The complexities of Indian health financing make it imperative that States consult with Tribes before and during the development of any amendments to their state plans. Without this consultation, implementation of this rule may have unintended negative consequences on Indian health programs.

On November 9, 2006 Dennis Smith, Director, Centers for Medicaid and State Operations issued a State Medicaid Directors' letter, SMDL #06-023. This letter encourages States to consult with Indian Tribes when implementing Deficit Reduction Act and submitting State Medicaid plan amendments. Specifically the letter states:

> "In light of the new Deficit Reduction Act of 2005 (DRA) and our continued desire for Medicaid programs to effectively serve Tribal communities, CMS is taking this opportunity to again encourage States to consult with Tribes in open, good faith dialogue, as a number of provisions within the DRA have the potential to impact Tribes and American Indian and Alaska Native (AI/AN) Medicaid beneficiaries. Given the States' new flexibility to change their Medicaid programs through State Medicaid plans rather than through Medicaid demonstrations, maintaining ongoing communication between States and Tribes in the redesign of Medicaid programs and services is even more important...CMS strongly encourages all States to consult with Tribes as they implement the DRA."

Consistent with CMS policy, we are requesting that CMS insert language in the final rule that would specifically remind States to consult with Tribes in the development of any State plan amendment to modify existing payment methodologies for prescription drug reimbursements. This reminder will allow each Tribe the opportunity to work with the State to assess local impacts and identify options prior to submission of State Plan amendments.

We are also requesting that CMS insert language in the final rule to encourage States to maintain their current level/type of reimbursement and filling fees to Tribal and IHS pharmacies because they are important safety net providers and will be harmed by the reductions. Because of the limited capacity of many Tribal and IHS pharmacies, and their dependence on prescription drug reimbursements to meet overhead and administrative costs, we believe that implementation of this proposed rule will result in Tribal and IHS pharmacies shouldering a disproportionate share of Medicaid prescription drug reductions. Tribal and IHS providers should be explicitly recognized as essential safety net pharmacies.

We appreciate the opportunity to comment on these rules.

Sincerely,

H. Sally Smith, Chairman
National Indian Health Board

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

SMDL #06-023

NOV 9 2006

Dear State Medicaid Director:

The Centers for Medicare & Medicaid Services (CMS) previously issued a letter dated July 17, 2001, encouraging States to engage with federally recognized Tribes (hereafter referred to as "Tribes") in the planning and development of Medicaid and State Children's Health Insurance Program demonstration proposals. In light of the new Deficit Reduction Act of 2005 (DRA) and our continued desire for Medicaid programs to effectively serve Tribal communities, CMS is taking this opportunity to again encourage States to consult with Tribes in open, good faith dialogue, as a number of provisions within the DRA have the potential to impact Tribes and American Indian and Alaska Native (AI/AN) Medicaid beneficiaries. Given the States' new flexibility to change their Medicaid programs through State Medicaid plans rather than through Medicaid demonstrations, maintaining ongoing communication between States and Tribes in the redesign of Medicaid programs and services is even more important.

As States are well aware, Federal Agencies are required by Presidential Order and Executive Memorandum to consult with Tribal Governments. CMS, through the establishment of a Tribal Technical Advisory Group, is working to strengthen our ongoing Tribal consultation process. Many States also have continued their efforts to strengthen their State-Tribal consultation mechanisms. CMS is encouraged by this, particularly as it relates to Medicaid programs, which the States and Federal Government jointly fund.

The Medicaid program is critical to the ability of health programs administered by the Indian Health Service, Tribes, and Tribal organizations, and Urban Indian health programs, to ensure the provision of needed medical services. It has been widely documented that the AI/AN population suffers significant health disparities. It has been reported that a large percentage of this population is eligible for Medicaid services. To access even the most basic of healthcare, this population must overcome barriers such as poor economic conditions, remote or isolated geographic locations, or language barriers.

Tribal Consultation has become a regular institutional practice among Federal Agencies and we know many States also work closely with Tribes. CMS strongly encourages all States to consult with Tribes as they implement the DRA. If you have questions, please feel free to contact your CMS Regional Office Native American Contact. The list of these individuals and their contact information is enclosed.

Sincerely,

Dennis G. Smith
Director

Enclosure

cc:
CMS Regional Administrators

CMS Associate Regional Administrators
for Medicaid and State Operations

Martha Roherty
Director, Health Policy Unit
American Public Health Services Association

Joy Wilson
Director, Health Committee
National Conference of State Legislatures

Matt Salo
Director of Health Legislation
National Governors' Association

Stacy Bohlen
Director
National Indian Health Board

Charles W. Grim, D.D.S., M.H.S.A.
Director
Indian Health Service

Valerie Davidson, Chair
CMS Tribal Technical Advisory Group

Jacalyn Bryan Carden
Director of Policy and Programs
Association of State and Territorial Health Officials

Christie Raniszewski Herrera
Director, Health and Human Services Task Force
American Legislative Exchange Council

Lynne Flynn
Director for Health Policy
Council of State Governments

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Diamond's
Ursula Plaza
444 Ocean Blvd. North
Long Branch, NJ 07740
(732) 222-1299

2/15/07

Dear Medicare/Medicaid

Retail Pharmacy does NOT receive the same discounts or rebates Hospital or Mail order Pharmacies receive! "AMP" MUST take these price differences into ACCOUNT If we are to provide services and survive in the future!

Your sympathy of our plight is desperately needed!

Thank you

STUART Eisenberg, R.Ph.

Lukas Pharmacy
134 S. Main Street
P. O. Box 480
Lynchburg, OH 45142

February 12, 2007

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

RE: CMS-2238-P 9AMP ISSUES)

Dear Acting Administrator Norwalk:

On behalf of Lukas Pharmacy, I would like to take this opportunity to provide our comments on the Proposed Rule CMS-2238-P "Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005."

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that a CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
A proper definition of AMP is the first step towards fixing this problem. I understand that the Secretary of the Department of Health and Human Services (HHS) has been given wide leeway in writing that definition. I ask that AMP be defined so that it reflects pharmacies' total ingredient cost. If AMP were defined so that it covers 100% of pharmacists' ingredient costs, then an adequate reimbursement could be attained. As it is currently defined, AMP is estimated to cover only **HALF** the market price paid by community pharmacy. Currently, each manufacturer defines AMP differently, and without a proper definition, Medicaid reimbursement will not cover pharmacy costs.

Pharmacies that are underpaid on Medicaid prescriptions will be forced to turn Medicaid patients away, cutting access for patients, especially in rural communities. Additionally, the reimbursement cuts will come entirely from generic prescription drugs so unless AMP is defined to cover acquisition costs an incentive will be created to dispense more brands that could end up costing Medicaid much, much more.

Lukas Pharmacy
134 S. Main Street
P. O. Box 480
Lynchburg, OH 45142

February 12, 2007

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible before AMP takes effect.

Respectfully,

Tom Black, RPh.
Managing Pharmacist

Lonsinger Pharmacy
244 North Main Street
Utica, OH 43080

February 12, 2007

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

RE: CMS-2238-P 9AMP ISSUES)

Dear Acting Administrator Norwalk:

On behalf of Lonsinger Pharmacy, I would like to take this opportunity to provide our comments on the Proposed Rule CMS-2238-P "Implementing the Medicaid Drug Rebate Program provisions of the Deficit Reduction Act of 2005."

The proposed AMP definition under CMS-2238-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that a CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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Lonsinger Pharmacy
244 North Main Street
Utica, OH 43080

February 12, 2007

Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible before AMP takes effect.

Respectfully,

Melanie Main, Pharm D, RPh

Melanie Main, RPh.
Managing Pharmacist

Submitter : Dr. Robert Maley **Date:** 02/07/2007

Organization : Dr. Robert Maley

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The proposed AMP definition under CMS-~~2238~~-P Prescription Drugs will cause great harm to my pharmacy. It is estimated that the reimbursement will be far below what it actually costs my pharmacy to buy the drugs. I respectfully request that CMS redefine AMP so that it reflects what I actually pay for the product. If reimbursements do not cover costs, many independents may have to turn their Medicaid patients away.
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Please issue a clear definition of Average Manufacturers Price that covers community pharmacy acquisition costs. The definition should be issued as soon as possible, before AMP takes effect.

Submitter : Ms. Debra Shaw **Date:** 02/08/2007

Organization : Triplitt Drug Corp, Independent Pharmacy

Category : Pharmacist

Issue Areas/Comments

Regulatory Impact Analysis

Regulatory Impact Analysis

To more accurately reflect actual dispensing costs with each preseription dispensed, you must consider drug cost + cost of dispensing. Cost of dispensing includes many factors such as pharmacist time, tech time, label cost, ink cost, bottle cost, consulting time, overall operating costs, clerk time, etc. The figure is in the $10 per prescription area. If you want to make drug cost figures more reflective of drug cost, then you must also make dispensing time (related fees) more reflective of reality. AWP was an appropriate way to calculate drug costs 25 years ago when very few generics existed. AWP is not really a good way today. AMP may be nearer to reality, but please don't ignore the second component to prescription dispensing which is generated at the pharmacy. AMP is different for many organizations. Government agencies dictate what they will pay. Large corporations (like mail-order and retail giants like Walmart, CVS, and Walgreen) have buying power capacity. Independent pharmacies have neither opportunity for cost containment. Even our wholesalers, who profess to be looking after us, are more interested in getting their fair share (as it is when you have stockholders watching every move).
Please don't forget your independent pharmacist who has worked very hard to build pharmacy into the most respected profession in the U.S.A. We want to continue to help people understand their medicine and to help them sort through the Medicare Part D information, and be the professional they can talk to.
Changing AWP to AMP without also making the dispensing fee in line with reality will negatively impact independent pharmacy's ability to survive.

CMS-2258-P-12

Submitter : Mrs. Kelly cash **Date:** 02/16/2007

Organization : Exper-Med

Category : Drug Industry

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Reimbursment for independant pharmacies on there generic purchasing determing by AMP(average manufacturing price)VS AWP(average wholesale price)

GENERAL

GENERAL

I work for a generic distributing company. I speak with several Independant pharmacy owners daily. If you proceed with this new way of reimbursment for medicare/medicaid patient providers you are garaunteed to force them into financial ruin. They will go out of business and there Will no longer be any independant pharmacys. Can you imagine the hundred of thousand people you are going to put out of there jobs. Not only the owners, but the employees and those who like me supply them with there generics. We have 100 people alone just in our facility. Worse yet think of your grandmother who does not live any where near a Walmart or CVS. She is diagnosed with a fatal illness. Who do you think delivers her medication to her. I assure you it is not your chain pharmacies. It's the little guy that truely cares and will send a driver to every day. Not only to deliver her medication but to check and make sure she is ok and has every thing she needs to be comfortable. You are making a huge mistake. I hope your family doesn't have to pay for it!

Submitter : Mr. Frank Wishnia.R.Ph **Date:** 02/17/2007

Organization : WISH'S DRUGS #1 INC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

[redacted]BASED FULS ON AVERAGE ARE 36% LOWER THAN AVERAGE PHARMACY ACQUISITION COSTS. AMP IS NOT AN APPROPRIATE BASE FOR REIMBURSEMENT AND MUST BE BASED TO REFLECT PHARMACY COST.

THE FORMULA FOR AMOP-BASED FULs WILL NOT COVER PHARMACY ACQUISITION COSTS FOR MULTIPLE-SOURCE GENERIC MEDICATIONS.

AMP MUST BE DEFINED TO REFLECT THE ACTUAL COST PAID BY RETAIL PHARMACY.

WE HAVE BEEN OPERATING IN THE SAME LOCATION FOR 50 YEARS AND COUL NOT AFFORD TO STAY IN BUSINESS WHEN WE LOOSE THIS MUCH MONEY. WE WOULD NOT BE ABLE TO CONTINUE TO SERVE THIS POPULATION AND THEY WOULD HAVE TO FIND ANOTHER PHARMACY, NO PHARMACY WOULD CONTINUE TO PARTICIPATE LOSING THIS MUCH MONEY. EVEN THE ONE WITH "DEEP POCKETS" WOULD DEMAND HIGHER PRICES WHEN ALL THE REST OF US "LITTLE GUYS" WERE OUT OF BUSINESS.

PLEASE RECONSIDER AND OFFER A FAIR PRICE FOR THE ALREADY OVER-EXTENDED PHARMACIES/PHARMACISTS.

THANK YOU.
SINCERELY,
FRANK WISHNIA R.PH PRESIDENT
WISH'S DRUGS #1 INC
9615 WHIPPS MILL RD
LOUISVILLE KY 40242
502-425-1146
FAX 502-423-9668
WISHDRUG@BELLSOUTH.NET

Submitter : Mr. peyton taylor **Date:** 02/17/2007

Organization : goochland pharmacy

Category : Pharmacist

AMP ?

Issue Areas/Comments

Collection of Information Requirements

Collection of Information Requirements

Until retail pharmacy has a level playing field as far as discounts/rebates etc, this pricing structure will NOT work. Every retail pharmacy will have to drop out of the program. WE CANNOT ACCEPT ANY FURTHER REDUCTIONS IN REIMBURSEMENT.

GO AFTER THE MANUFACTORS & PBM'S - THEY HAVE THE MONEY.

Submitter : Mr. TILAK MARWAHA **Date:** 02/19/2007

Organization : MADISON PINE PHARMACY

Category : Pharmacist

AMP

Issue Areas/Comments

GENERAL

GENERAL

I AM A PHARMACY OWNER CURRENTLY SURVING APPX 2000 PAIENTS IN A UNDERSERVED AREA OF CHICAGO. AMP PRICING FOR MEDICAID WILL SEVERELY IMPACT MY BUSINESS AS I CURRENTLY DO APP 60% OF MEDICAID PRESCRIPTIONS. OUR PHARMACY ASSOCIATION STUDY SHOWS THAT 59 DRUGS OUT OF 77 SAMPLED HAVE APPX 36 PERCENT LOWER PRICE THAN MY ACQUISITION COST. I CAN NOT IMAGINE TO CONTINUE FILLING PRESCRIPTIONS AT A LOSS AND MAY HAVE TO CLOSE THE BUSINESS. IF THIS IS THE INTENT OF CMS OR CONGRESS, YOU WILL SUCCEED IN YOUR AGENDA. PLEASE RECONSIDER THE PRICING STRUCTURE AND MAKE SURE THAT THE PHARMACIES ARE REIMBURSED FOR THEIR ACQUITION COST PLUS THE DISPENSING FEE. WHO EVER CAME UP THE IDEA OF AMP MUST BE A GENIOUS IN HIS OWN SENCE WHO MUST HAVE THOUGHT OF SAVING THE MONEY AT THE COST OF OTHER.

PLEASE PLEASE PLEASE RE RETHING

THANKS

Submitter : **Delanie Sullivan** **Date:** **02/21/2007**

Organization : **University of Tennessee College of Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-2258-P-16-Attach-1.DOC

AMP

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Ted Strickland
Governor

OHIO Job & Family SERVICES

Helen E. Jones-Kelley
Director

30 East Broad Street Columbus, Ohio 43215-3414
jfs.ohio.gov

February 15, 2007

Office of Strategic Operations and
Regulatory Affairs
Division of Regulations Development
ATTN: Melissa Musotto [CMS-2238-P]
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room C4-26-05
7500 Security Boulevard
Baltimore MD 21244-1850

Office of Information and Regulatory
Affairs
Office of Management and Budget
Room 10235
New Executive Office Building
Washington, DC 20503
ATTN: Katherine Astrich
CMS Desk Officer, CMS-2238-P
Katherine_astrich@omb.eop.gov
FAX: (202) 395-6974

Comments on the Collection of Information Requirements
For the Proposed Rule Concerning the Medicaid Program: Prescription Drugs
CMS-2238-P

Dear Ms. Musotto and Ms. Astrich:

Thank you for the opportunity to comment on collection of information requirements reported in the proposed rules regarding the Medicaid prescription drug program changes outlined in sections 6001 (a)-(d), 6002, and 6003 of the Deficit Reduction Act of 2005 (DRA). Within the Ohio Department of Job and Family Services, the Office of Ohio Health Plans administers Ohio Medicaid and the Medicare Premium Assistance Program. These programs cover 1.7 million Ohioans each month.

Preserving access to prescription drugs for Medicaid recipients should be a priority for the Centers for Medicare and Medicaid Services (CMS). The Ohio Medicaid program is concerned that the information collection requirements outlined in this Notice of Proposed Rulemaking (NPRM) are understated.

Ohio Medicaid is particularly concerned that the requirement that physicians bill using National Drug Code (NDC) in addition to Healthcare Common Procedure Coding System (HCPCS) code for physician-administered drugs will create a new billing procedure that is used only for Medicaid, creating an administrative burden that many physicians may not be able to carry. This causes Medicaid patients to be treated differently than other patients in the practice, and physicians may choose to not accept Medicaid patients. We believe that this will create a barrier to access.

Section III: Collection of Information Requirements

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

Ohio Medicaid disagrees with the estimates that CMS has proposed for the time for physician office staff, hospital outpatient departments, and other entities to bill using both NDC and HCPCS. The estimate of 15 seconds, or nine cents per claim, significantly discounts the time and funds that will be required for these providers to learn the requirements, train staff, and implement the procedures. In addition to the individual administering the drug, the entire billing staff will need to be trained to include NDC on the claim. While the ongoing effort may be small, the initial training will be intensive for both providers and for Medicaid programs.

We are also concerned with CMS's position that no state will need to apply for a hardship waiver for this provision. Ohio's Medicaid Management Information System (MMIS) became operational in 1986, and it will be virtually impossible to implement the inclusion of the NDC in the existing claims payment system. We are in process of contracting for a new Medicaid Information Technology System (MITS) and plan to include this functionality in the new system. However, this system will not be operational until at least 2009. Ohio Medicaid asks that CMS reconsider its position that it will not accept hardship waiver requests from any state. We also believe that the estimate for the time that it would take a state agency to apply for a hardship waiver is not accurate. Five hours is not enough time for a state to gather the information, synthesize it into the format required by CMS, and gain approval of the request from all stakeholders that would need to be involved.

Recommendations:

* CMS should reconsider the financial impact on providers that bill for drugs administered in the provider setting.
* CMS should accept and approve hardship waiver requests from those states that will be unable to implement the procedure due to technology limitations or provider resistance to the change.

Ohio Medicaid looks forward to working with CMS on the implementation of the Deficit Reduction Act changes to the Medicaid pharmacy program. Preserving access to prescription drugs for Medicaid consumers is a priority. Please consider these recommendations before issuing final regulations. If you have any questions, please do not hesitate to contact me at (614) 466-4443.

Respectfully Submitted,

Cristal A. Thomas
State Medicaid Director

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Shore Pharmaceutical Providers, Inc.

55 W. Ames Court, Suite 200
Plainview, NY 11803
516/938-8080
516/938-9812 Fax

R02-N04
613424

05 MAR 2007
9:28 am

February 7, 2007

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Ms. Norwalk,

On behalf of Medicaid beneficiaries and retail pharmacies in our districts, we are writing to express our deep concern with the Centers for Medicare and Medicaid Services' (CMS) proposed changes in the payment for prescription drugs in the Medicaid program. These proposed changes, announced in December of 2006, would implement provisions of the Deficit Reduction Act of 2005 (DRA).

The current method that manufacturers use to define Average Manufacturer Price (AMP) has never been fully defined by CMS, which has resulted in variations in how these values are calculated. Government studies and reports have documented these inconsistencies, demonstrating significant differences between AMP and the actual prices at which retail pharmacies purchase drugs.

In the proposed rule, CMS defines AMP to address these problems. It was our expectation that this definition would approximate the prices at which retail pharmacies purchase medications from manufacturers and wholesalers. However, the proposed rule is flawed in that it allows manufacturers to include mail order sales and pharmacy benefit manager rebates in the calculation. This change will result in an AMP that does not reflect the prices paid by retail pharmacies.

In addition, the proposed rule released by CMS dictates that the Federal Upper Limit (FUL) for a generic drug will be based on 250% of the product that has the lowest AMP for all the versions of that generic medication. However, a December 22, 2006 Government Accountability Office (GAO) report that analyzed the impact of the new FUL formula found that retail pharmacies will be reimbursed on average 36 percent lower than their costs to purchase generic medications dispersed to Medicaid beneficiaries. This change would clearly fail to cover the pharmacy's costs of purchasing generic medications. In fact, the formula would create a disincentive to dispense generic drugs and would deny the Medicaid program and beneficiaries the savings gained from generic medications.

This proposed payment formula will be devastating to many community retail pharmacies, Medicaid beneficiaries, and the financing of the Medicaid program itself. We respectfully request that you delay the release of any AMP data until a final definition is adopted ensuring that AMP accurately reflects pharmacy acquisition costs.

of any AMP data until a final definition is adopted ensuring that AMP accurately reflects pharmacy acquisition costs.

Sincerely,

Paul Meyeroff, RPh
General Manager

172

Sent: Friday, March 09, 2007 3:28 PM
To: Bryson, Stacey L. (CMS/OSORA); Hayes, Yolanda K. (CMS/OSORA)
Cc: Cooper, Cheryl C. (CMS/CMSO); Reed, Larry L. (CMS/CMSO); Duzor, Deirdre D. (CMS/CMSO)
Subject: CMS-2238-P Another Letter

Hi there,

We received another letter electronically. Please add this to the public comment log for the AMP rule.

Thanks,
Marge
x64361

Giannotto's Pharmacy
195 First Avenue
Newark, NJ 07107
973-482-8220
FAX:973-482-0615
Trushar A. Sheth, RPh
President

VIA ELECTRONIC SUBMISSION

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

CMS file code: CMS - 2238 - P

Federal Register
Publication Date: December 22, 2006

Dear Acting Administrator Norwalk:

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

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

Inclusion of all mail order pharmacy prices in retail pharmacy class of trade.
Public Access Defines Retail Pharmacy Class of Trade
CMS is correct to exclude hospital and nursing home sales from the retail pharmacy class of trade for two reasons. First, hospital and nursing home pharmacies are extended prices not available to retail pharmacy. Second, nursing homes and hospitals are not deemed to be "publicly accessible." Mail order facilities are operated almost exclusively by PBMs, and as such they meet both of these criteria. Mail order facilities are extended special prices and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible. Sales to mail order facilities should not be included in calculating the AMP.
"Retail pharmacy class of trade" definition should only include independent pharmacies, independent pharmacy franchises, independent chains, traditional chains, mass merchants and supermarket pharmacies – a definition that currently encompasses some 55,000 retail pharmacy locations.

Inclusion in AMP of PBM rebates, discounts, and other price concessions for drugs provided to retail pharmacy class of trade.
Inclusion in Best Price of PBM rebates, discounts and other price concessions.
Treatment of Manufacturer coupons with regard to Best Price.
Inclusion of Direct-to-Patient Sales with regard to AMP.
AMP Must Differ From Best Price
If AMP is to represent the price of drugs bound for the retail pharmacy class of trade, it should include and exclude components according to their impact on the acquisition price actually paid by the retail pharmacy class of trade.
CMS rightly excludes manufacturer rebates paid to state Medicaid programs, to the Department of Defense under TRICARE and to the Department of Veterans Affairs (VA). CMS should also exclude rebates paid to PBMs from AMP calculation: These rebates are not available to the retail pharmacy class of trade, and indeed, none of these funds are ever received by retail pharmacy; and the Retail Pharmacy Class of Trade does not have access to Direct to Patient Sale prices, and therefore these transactions should also be excluded from AMP calculation.
The Medicaid drug rebate program was created for states to collect rebates from manufacturers in much the same way that PBMs

receive manufacturer rebates off of the market price of those drugs. Should manufacturers include PBM rebates in AMP calculation, the AMP would be driven below available market price thus undermining the FUL and shrinking the rebates states receive.
For states to receive a rebate benefit more closely matching the marketplace, Best Price was created as a contrasting measure to AMP. Manufacturers must pay states either a percentage of AMP or the difference between AMP and Best Price, whichever is greater. In this context, Best Price is then the most appropriate vehicle in which to include PBM rebates, discounts and other price concessions as well as Direct-to-Patient sales and manufacturer coupons.
PBM price concessions reporting to CMS.
PBM Transparency Necessary to Assess Manufacturer Rebates
PBMs are not subject to regulatory oversight, either at the federal or state levels. Therefore to include the rebates, discounts, or other price concessions given the current state of non-regulation would be improper. Specifically, to include such provisions in the calculation of AMP without any ability to audit those "adjustments" to the net drug prices is inappropriate. CMS requested comments on the operational difficulties of tracking said rebates, discount or charge backs. The difficulty in doing so begins with the lack of regulatory oversight, laws and/or regulations that require the PBMs to either disclose that information or make it available upon request by a regulatory agency. Further, the difficulty continues because PBMs have been allowed, due to a lack of regulation, to keep that information hidden, i.e., there is no transparency in the PBM industry.
PBMs, have fought in both the national and state legislative arenas, to keep that information from review by the government and their own clients. Their contracts are not subject to audit provisions, except in some cases where the client selects an auditor that the PBM approves. Lastly, the PBM is allowed - again through lack of regulation - to self refer to its wholly owned mail order pharmacy. No other entity in the health care arena is allowed to self-refer to its own wholly owned business.
Allowing the use of 12-month rolling average estimates of all lagged discounts for AMP.
AMP Must Be Reported Weekly
There are frequent changes in drug prices that are NOT accurately captured by a monthly reporting period. Under the proposed rule, manufactures supply CMS the pricing data 30 days after the month closes, which means that the published pricing data will be at least 60 days behind the market place pricing. Invoice pricing to community pharmacy, however, continues to change daily. In order to accurately realize market costs and reimburse retail pharmacy accordingly, AMP data must be reported weekly rather than by using a 12 month rolling average.
Use of the 11-digit NDC to calculate AMP.
AMP Must Be Reported At The 11-Digit NDC to Ensure Accuracy
We concur with the many reasons CMS offers in support of an 11-digit NDC calculation of the FUL. CMS suggests calculating the FUL at the 11 digit NDC would offer advantages to the program, will align with State Medicaid drug payments based on package size, will allow greater transparency, and would not be significantly more difficult than calculating the FUL from the 9 digit code.
Pharmacies already purchase the most economical package size as determined by individual pharmacy volume. Pharmacies should not be mandated by CMS to purchase in excess of need just to attain a limited price differential.
Additionally, based on the GAO study on Medicaid Federal Upper Limits, a FUL based on the 9-dight NDC would NOT adequately cover pharmacy acquisition cost. The 11-digit NDC must be used when calculating the FUL.
Assessment of impact on small pharmacies, particularly in low income areas with high volume of Medicaid patients.
Impact on small pharmacies demonstrated by (General Accountability Office (GAO) findings
The GAO findings demonstrate the devastating impact the proposed rule will have on small independent pharmacies. No business can stay in operation while experiencing a 36% loss on each transaction. This deficit cannot be overcome by aggressive purchasing practices, rebates, generic rebates or even adequate dispensing fees.
The impact on independent pharmacies also cannot be mitigated by an increase in state-set dispensing fees. IF state Medicaid programs take the suggested initiatives of the CMS Medicaid Roadmap and increase these dispensing fees, states are still prohibited from exceeding the FUL in the aggregate on prescription reimbursements. It is also unlikely that states would set dispensing fees high enough to cover the average $10.50 per prescription cost of dispensing as determined by the most recently completed Cost of Dispensing Study.
Conducted by the accounting firm Grant Thornton, LLP, the Cost of Dispensing study used data from over 23,000 community pharmacies and 832 million prescriptions to determine national cost of dispensing figures as well as state level cost of dispensing information for 46 states. This landmark national study was prepared for the Coalition for Community Pharmacy Action (CCPA), with financial support from the Community Pharmacy Foundation.

If these dispensing costs, in addition to drug acquisition costs, are not covered, pharmacies simply cannot afford to continue participation in the Medicaid program. By law, CMS cannot mandate minimum dispensing fees for the Medicaid program; however, the proposed rule must provide a comprehensive definition on Cost to Dispense for states to consider when setting Dispensing Fees.
CMS Must Employ a Complete Definition on Cost to Dispense
The Definition of "Dispensing Fee" does not reflect the true costs to pharmacists/pharmacies to dispense Medicaid drugs. This definition must include valuable pharmacist time spent doing any and all of the activities needed to provide prescriptions and counseling such as communicating by telephone, fax and email with state Medicaid agencies and PBMs, entering in billing information; and other real costs such as rent, utilities and mortgage payments.
Community pharmacists regularly provide pick-up and delivery, house calls and third party administrative help to beneficiaries. Most importantly, they provide an important health, safety and counseling service by having knowledge of their patients' medical needs and can weigh them against their patients' personal preferences when working to ensure that a doctor's prescription leads to the best drug regimen for the patient.
Policing and Oversight Process for AMP and Best Price Must Be Included
The new proposed Dual Purpose of AMP requires that AMP be calculated and reported properly and accurately. Both the GAO and the HHS Office of Inspector General have issued reports citing historical variances in the reporting and calculation of AMP. While some of these concerns will be corrected in the new rule, CMS has not proposed nor defined a policing and oversight process for AMP and Best Price calculation, reporting and auditing.
All calculations should be independently verifiable with a substantial level of transparency to ensure accurate calculations. An AMP-based reimbursement that underpays community pharmacy will have dire consequences for patient care and access.

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

- The formula for AMP-based Federal Upper Limits (FULs) in the proposed rule will not cover pharmacy acquisition costs for multiple-source generic medications
- Average Manufacturer Price (AMP) was never intended to serve as a basis for reimbursement.

To be an appropriate benchmark, AMP must be defined toθ reflect the actual cost paid by retail pharmacy. This will be accomplished by
1. Excluding all rebates and price concessions made by manufacturers which are NOT available to retail pharmacy.
2. Excluding all mail order facilities and PBM pricing from AMP calculation. Mail order facilities and PBMs are extended special prices from manufacturers and they are not publicly accessible in the way that brick and mortar pharmacies are publicly accessible.
θ Reporting AMP at the 11-digit NDC level to ensure accuracy.
Thank you for the opportunity to submit my comments on this proposed rule and I hope you will seriously revise this proposal in order to ensure the continued access of Medicaid prescription patients to their community-based pharmacies.

Respectfully,

Trushar Sheth, R.Ph., CCP,
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VIRGIL H. GOODE, JR.
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Congress of the United States
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February 9, 2007

Mr. Kevin Berna, Congressional Affairs Group
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW, Room 341 H
Washington, DC 20201

Dear Mr. Berna:

I write with concerns that have been expressed to me by several pharmacists in my District who own independent pharmacies. The concern expressed relates to the decision the Centers for Medicare and Medicaid Services has made to base federal reimbursement for pharmaceuticals on the use of the Average Manufacturing Price (AMP). Concerns have been raised that for an independent pharmacy to compete with the very large pharmacies, such as WalMart is hard enough; to compete with mail order houses, which can purchase for up to 25% less, is impossible.

Pharmacists in my District are concerned that the policy enacted by CMS will lead to similar policy by the private insurance companies. A suggested possible option, which has been suggested to my office, would include CMS considering the category, such as Mail Order, Nursing Home or Retail, when basing the reimbursement and not just the Average Manufacturing Price.

I appreciate your consideration of the independent pharmacists and look forward to hearing from your office. With kind regards, I am

Sincerely,

Virgil Goode, Jr.

Virgil Goode, Jr.

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U.S. HOUSE OF REPRESENTATIVES
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Mr. Kevin Berna, Congressional Affairs Group
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