Devine's
PHARMACY
374 North Avenue
Dunellen, N.J. 08812

Tel. 968-0003
Fax. 968-0005

Michael T. Ryan
Pharmacist

101

2-15-07

DEAR CMS,

Please explain to me how I am suppose to stay in business when your new ruling will reimburse me at 36% below my acquisition cost?

The formula for AMP based Federal Upper limits (FULS) in the proposed Rule will not cover pharmacy acquisition costs for multiple source generic medications.

The Average Manufacturer Price was never intended to serve as a basis for reimbursement.

To be an appropriate benchmark AMP must be defined to reflect the actual cost paid by Retail pharmacy. This will be accomplished by (1) Excluding all rebates and price concessions made by manufacturers which are not available to Retail Pharmacy

(2) Excluding all mail order facilities + 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 + mortar pharmacies are.

I don't mind paying my fair share – But this might put me out of business. Instead try to fix the problems above + if we have equal footing I'll gladly pay my fair share

Thank you
Michael T. Ryan

SIR,

I AM 68 YEARS OLD. I HAVE A PHARMACY IN A LITTLE TOWN IN NORTH ALABAMA. I HAVE MANY MANY MEDICAID PATIENTS. IF THINGS DON'T CHANGE I WILL HAVE TO DENY FILLING PRESCRIPTIONS FOR MEDICAID PATIENTS.

I MAY HAVE TO CLOSE MY PHARMACY. THE GOVERNMENT IS PUTTING SO MUCH (OTHER THAN JUST A LACK OF MONEY) THAT IT IS IMPOSSIBLE TO PRACTICE PHARMACY AND BE IN COMPLIANCE WITH THE LAW.

MAYBE YOU CAN HELP THE INDEPENDENT PHARMACY OR SEE MANY FAIL AND GO OUT OF BUSINESS.

SINCERELY,

TIM CANN, SR.

Dear sir,

Please note the formula for AMP in the proposed rule will NOT cover pharmacy acquisition costs!!!!. Second the AMP was never intended to serve as a basis for reimbursement. To be an approriate bench mark AMP must be defined to reflect the actual cost paid by the retail pharmacy. Any thing else is UNAMERICAN. This great nation was found on the backs of the small businessman. DO NOT put us out of business now. Be fair and pharmacy can serve the people of the great U.S.A.

Yours,

Richard Polack R.Ph

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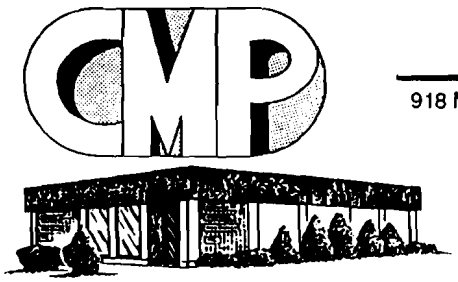

COMMUNITY MEDICAL PHARMACY INC.

918 Michigan Avenue, Niagara Falls, New York 14305 • Telephone: 716-282-1292
Fax: 716-285-3723

PHARMACIST: David Slepian

February 16, 2007

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

To Whom It May Concern:

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 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

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dispense generic drugs and would deny the Medicaid program and beneficiaries the savings gained from generic medications.

This proposed payment formula would 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 the AMP accurately reflects pharmacy acquisition costs.

Sincerely,

David Slepian

David Slepian

Homestead Pharmacy
601 Broadway
Long Branch, N.J. 07740
732-222-5400

Feb 15, 2007

Centers for Medicare & Medicaid Service
Dept of Health and Human Services
Attention: CMS-2238-P
PO Box 8015
Baltimore, Md. 21255-8015

Gentlemen:

Re. AMP

The proposed formula for AMP based on FULS will not come close to Covering my costs and will force me out of business.

AMP was never intended to serve as a basis for reimbursement.

Brick and mortar pharmacies are not extended the special prices accessible to mail order and PBMs. This 2 tier pricing system is allowed because so far the courts have ruled that Mail order and PBM pharmacy can influence market share and are entitled to special prices. We in independent pharmacy feel this is outrageous and are still in the courts fighting this issue.

Please approach this issue with a full knowledge of all details and ramifications. The future of thousands of pharmacies and tens of thousands of individual pharmacy employees is at stake. And most importantly, hundreds of thousands of Medicaid recipients will lose the ability to get vital medications.

Sincerely,

Robert Pearson
Owner

106.

NACDS
NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

20

February 20th, 2007

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

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

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

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

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

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

Public Release and Use of AMP Data Should be Delayed

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

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

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

AMP Definition Should be Revised to Reflect Retail Pharmacy Purchasing Costs

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

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

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

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

New Generic FULs Should be Suspended

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

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

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

States Need to Increase Pharmacy Dispensing Fees:

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

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

Sincerely,

Robert W. Hannan
President and CEO

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

I. Section 447.504 – Determination of AMP

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

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

Since 1990, federal law has defined AMP, with respect to a covered outpatient drug, as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1). A change made by DRA requires manufacturers to calculate AMP without regard to customary prompt pay discounts extended to wholesalers beginning on January 1, 2007. *Id.*

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

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

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

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

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

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

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

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

This was confirmed by a recent CBO report, when referring to manufacturer rebates paid to plans, which said: "when pharmacies do contact doctors to change prescriptions, they may be acting on behalf of PBMs or health plans using formularies to manage drug spending, in which case, any rebates would go to the PBMs or the health plans and not the pharmacies." (*See* CBO, Prescription Drug Pricing in the Private Sector, Congressional Budget Office, January 2007.)

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

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

In justifying this action, CMS correctly indicates that because long term care pharmacies do not generally dispense prescriptions to the general public – but rather only patients of the facility – their sales should be excluded from the calculation of the AMP. We agree. This same logic, however, applies to mail order pharmacies. These pharmacies are not generally "open to the public" like most traditional retail pharmacies. Individuals cannot "walk into" a mail order pharmacy to obtain a prescription, and there is limited ability for patients to obtain a prescription from a mail order pharmacy unless they belong to a health care plan that includes mail order as part of its benefit design. Moreover, given that there is extremely limited distribution of prescription drugs to Medicaid recipients through the mail, it makes little sense to include these prices, or associated rebates, in the calculation of AMP.

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

However, CMS says that it considers mail order "simply another form of how drugs enter into the retail pharmacy class of trade." Yet, CMS also recognizes that retail pharmacies may be disadvantaged by inclusion of these sales in the calculation of AMP because "retail pharmacies may not be able to meet the terms and conditions placed on mail order pharmacies to be eligible for manufacturer price concessions." CMS itself makes the argument as to why sales to mail order pharmacies should be excluded from the calculation of the AMP.

Inclusion of these sales and rebates – which are not available to traditional retail pharmacies – would result in an AMP that is not reflective of the prices paid by traditional retail pharmacies. This is confirmed by the CBO report which says that mail order pharmacies tend to get lower prices than conventional pharmacies for single source drugs. The report provides an example of how excluding mail order sales from the AMP calculation would increase the AMP. This confirms that including mail order sales would lower the AMP and not approximate the prices at which conventional retail pharmacies purchase medications.

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

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

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

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

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

PBM Rebates: There is wide documentation in government agency reports (OIG and GAO) that manufacturers have not been consistent in how they have handled PBM rebates in the calculation of the AMP. According to these reports, some have included, excluded or only partially included rebates paid by them to PBMs and health plans. (*See* GAO, Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States; February 2005). CMS issued a Medicaid drug rebate program labeler release in April 1997 that attempted to clarify how these PBM rebates should be handled both in the calculation of a drug's "best price" as well as its AMP. (*See* CMS Manufacturer Labeler Release #28, April 1997.) That release said that "Drug prices to PBMs have no effect on the AMP calculation unless the PBM is acting as a wholesaler."

The proposed regulation would suddenly change the policy that has been in effect for many years by requiring that drug prices to PBMs, which heretofore have only been included where the PBM was acting as a wholesaler, be included in the calculation of the AMP. Most disturbing is the proposed inclusion of "discounts rebates or other price concessions to PBMs associated with the sales for drugs provided to the retail pharmacy class of trade". Manufacturers can only include prices paid by wholesalers in the calculation of AMP.

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

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

The report also said that "...conventional retail outlets generally do not receive rebates for single source drugs." Therefore, including these rebates would lower the AMP for traditional retail pharmacies below their approximate acquisition costs. It is immaterial whether the PBM that receives the rebates passes through some or all of these rebates to the plan sponsor. These rebates ultimately do not affect the prices paid by retail pharmacies for prescription medications.

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

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

Thus, in theory, manufacturers' sales of drugs to wholesalers who sell to retail pharmacies would already include drugs that are dispensed to enrollees of these programs. However, including the rebates and discounts manufacturers provide to these programs would be inappropriate because federal law provides that only payments by wholesalers to manufacturers can be included in AMP calculations.

Moreover, there are several different types of MA-PD programs, including staff model HMOs and regional PPOs. Including sales of drugs to HMOs is explicitly proposed to be excluded from the calculation of AMP under proposed §447.504(h)(5). However, rebates paid by manufacturers to PPOs benefit the PPO, not the pharmacy. CMS should be well aware of how the financial transactions flow in Part D, and rebates paid to Part D plans by manufacturers are supposed to be passed through to the beneficiaries, not to the retail pharmacies.

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

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

b. The Proposed Rule Incorrectly Defines "Retail Class of Trade"

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

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

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

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

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

c. Scope of Discounts Included in AMP Must be Narrowed

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

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

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

d. Definition of Wholesaler Must be Narrowed

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

Only entities that are licensed by states as wholesalers should be considered wholesalers for the purposes of this final regulation. For example, according to the National Association of Boards of Pharmacy (NABP), "Wholesale Distribution":

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

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

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

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

Based on this NABP definition, PBMs do not perform wholesaling functions either. In fact, most PBMs are administrative service organizations that contract with health plans and other entities to provide prescription drug benefits. Pharmacies do not buy drugs from PBMs like they buy them from wholesalers.

PBMs that own mail order operations may obtain their drugs from wholesalers or may obtain them directly from manufacturers, but they do not perform traditional wholesaling functions in either case. Only prices paid to manufacturers by wholesalers can by law be included in AMP. PBMs should not be considered wholesalers.

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

- The Federal Food, Drug and Cosmetic Act defines wholesale distributor as any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

- Under the PDMA regulations, wholesale distributor means any person engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

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

e. Smooth AMP Data

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

A recent General Accountability Office report confirmed that AMPs for generics can fluctuate widely from quarter to quarter. (*See* GAO: Medicaid Outpatient Prescription Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs, December 22, 2006. GAO-07-239R). The study calls into question the credibility and reliability of AMP as a benchmark for generic reimbursement. That is because GAO found 66 of the 77 drugs (almost 85 percent) had significant variation in their lowest AMP between first and second quarters of 2006.

For example, 30 of the 77 drugs – or almost 40 percent of the drugs – had a decrease in their lowest AMP, averaging 33 percent. Fluctuations in AMP are concerning to pharmacies because their reimbursement would similarly fluctuate, which may not reflect similar variation in their own acquisition costs.

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

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

Bona Fide Service Fees: NACDS strongly supports the proposal that bona fide service fees should be excluded from the calculation of AMP, especially where these fees are not ultimately passed through to the product's ultimate purchaser. A bona fide service fee pays for a bona fide service, so it does not reduce its cost of purchasing the drug. However, if these price concessions are deducted from the AMP, it could reduce the AMP further below the purchaser's costs for the drugs. Therefore, price concessions or discounts that do not decrease the actual purchaser's market price for the drug should not be deducted from the AMP.

NACDS does not support an attempt to list specific bona fide service fees in the final regulation. This will allow for future flexibility and innovations to occur in a highly competitive marketplace. Manufacturers rely on wholesalers and others to perform various functions to allow their products to come to market in a safe and effective manner. A significant number of new biological products are likely to come to market over the next few years. For that reason, it is unclear as to what types of new services will be needed to be performed by wholesalers and chain pharmacy warehouses on behalf of manufacturers to assure that their products get to the ultimate purchaser for dispensing or administration to the ultimate user.

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

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

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

Definition of "Return Goods": Proposed §447.504(h)(13) would allow manufacturers to omit from the AMP "returned goods when returned in good faith." We support the exclusion of returned goods from the calculation of AMP when returned in good faith. However, we urge that the term "pursuant to manufacturer policies" be removed from the definition. That is because the final regulation should account for return goods policies that are negotiated in good faith between manufacturers and retail pharmacies.

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

These negotiated return goods policies take into consideration the unique burdens which retail pharmacies must absorb in order to effectuate the efficient return of expired pharmaceutical products to manufacturers. By mandating that only returns made pursuant to manufacturers' policies be excluded from the calculation of AMP, CMS could be voiding by default these negotiated return goods and could be forcing retail pharmacies to accept manufacturers' policies and their inherent deficiencies.

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

Definition of Manufacturer: NACDS recommends that the definition of manufacturer, found at proposed §447.502, be narrowed such that entities that repackage drugs simply for distribution to retail pharmacies – also known as retail pharmacy service repackagers – not be considered manufacturers. These entities should not be responsible for signing rebate agreements with the Secretary of HHS, or paying the rebates to Medicaid because these repackagers simply perform a function for thousands of retail pharmacies (i.e. preparing "unit of use" quantities in a highly efficient manner), that would otherwise have to be performed individually by retail pharmacies. Retail pharmacy service repackaging is performed in a central location by wholesalers on behalf of retail pharmacy operators.

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

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

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

II. Section 447.506 – Authorized Generic Drugs

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

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

III. Section 447.510 – Requirements for Manufacturers

a. Prohibit Restatements of Monthly AMP

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

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

We are concerned about whether a manufacturer's restatement of AMP could affect the reimbursement amounts already paid to pharmacies by Medicaid. If an AMP value is recalculated by a manufacturer after the time that it is reported to the states by CMS, these restatements should not be used as the basis for reducing the reimbursements already paid. Restating AMPs could cause significant disruption to pharmacies, as recoupment activities are generally extremely time consuming, labor intensive, and frankly unfair. We believe that CMS should only allow restatements for quarterly-reported AMPs rather than monthly-reported AMPs.

The proposed rule at §447.510 (d)(3) indicates that "in calculating monthly AMP, a manufacturer should not report a revised monthly AMP later than 30 days after each month, except in exceptional circumstances authorized by the Secretary." This appears confusing, given that it sounds like a manufacturer still has the ability to revise its monthly AMP 30 days after reporting its monthly AMP. This should not be the case and needs to be clarified.

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

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

b. Adjust AMPs to Reflect Lag in Data Reported

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

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

We are concerned that this timing issue has not yet been addressed or even sufficiently recognized and appreciated, and believe that CMS should address it directly and in detail before states and others are encouraged to use AMP as a reimbursement benchmark. One way to do this is to compare the AMPs for brand name drugs to the WACs, given that this published benchmark does approximate retail pharmacy acquisition costs for brand name drugs.

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

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

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

Publishing both the monthly AMP data and the quarterly AMP data will add more confusion to what is likely already going to be a confusing situation. The DRA requires that CMS update the public website on a quarterly basis. Does CMS intend to publish on the website the AMP values for the last month of the quarter or each month of the quarter that just ended? Moreover, CMS indicates that it will also be publishing a quarterly AMP value.

Does CMS intend to publish each monthly AMP value for a quarter as well as the quarterly AMP, or just the last monthly AMP for the quarter and the quarterly AMP? The quarterly AMP is likely to be lower than the monthly AMP, so how will CMS (and providers) explain to the public why these AMP values differ? If the AMP website is supposed to give the public a general idea of the current prices paid by retail pharmacies for medications (assuming that CMS fixes all the fundamentally flawed definitions in this proposed regulation), then releasing the last month's AMP data for the quarter would appear to be sufficient.

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

d. Continue to Delay Public Release and Use of the AMP Data

The preamble to the proposed regulation indicates that CMS will release AMP data sometime this spring. CMS should not post any AMP data on a public website until such time as a final AMP definition reflects the approximate prices paid to manufacturers by wholesalers for drugs sold to traditional retail pharmacies, and that these prices have been validated to be accurate.

The release and use of flawed AMP data could have a negative impact on patient access, if the resulting reimbursement rates are so inadequate that pharmacies are forced to close. Some may individually decide that they can no longer afford to participate in Medicaid or other programs. It is in the interests of all relevant parties – patients, payers and providers – to postpone use and disclosure of AMPs until such time as CMS finalizes a regulatory definition of AMPs, and that definition approximate retail pharmacies purchasing costs.

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

The AMP data that CMS would propose to release this spring are no better than the AMP data that CMS promised not to release. While DRA made some modest changes to the calculation of the AMP, there would still be wide-ranging documented inconsistencies in that data which would render them useless to states and potentially damaging to retail pharmacies.

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

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

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

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

e. Limit Release of AMP Data to Assess Validity

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

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

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

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

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

a. Suspend Implementation of AMP-Based FULs

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

Suspension of the FULs would be consistent with Congressional intent. In a "Dear Colleague" letter that then House Speaker Dennis Hastert sent to Members of the House in February 2006, he indicates that a DRA technical corrections bill would include a provision that would "permit the Secretary of HHS to delay the implementation of the new payment rates if the Secretary determines, based on information in the new GAO report, that the new payment rates' do not reflect pharmacy acquisition costs." Clearly the Congress that enacted the DRA believed that it should not move forward if the payment rates did not reflect pharmacies' acquisition costs. The GAO report has proven that to be the case.

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

The GAO study, which compared the new AMP-based FULs for 77 generic drugs compared to retail pharmacies' average acquisition costs for these drugs during the first quarter of 2006, found:

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

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

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

b. Allow for Electronic Certification of Brand Name Drugs

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

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

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

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

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

- In his May 12th, 2006 letter to HHS Secretary Leavitt, then Senate Finance Chairman Grassley said that, "CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs." In another colloquy, Senator Grassley indicated "states will need to review and increase the fees that they pay pharmacies for dispensing Medicaid prescriptions." *(See* Congressional Record, Senate, November 3, 2005, p. S12326).

- Former CMS Administrator Mark McClellan, in remarks made at the NCPA conference on May 22nd, indicated that "If states do not maintain the right incentives for generic utilization, any savings will be lost due to higher brand name utilization...CMS guidance encourages states to align incentives for generic utilization and consider paying pharmacies more in dispensing fees to support state savings from greater use of generics."

- The need to increase pharmacy fees was discussed in the context of paying pharmacies more accurately for their drug product acquisition costs by former House Energy and Commerce Committee Chairman Joe Barton (R-TX). Barton said, "I believe we should pay providers fairly for their services. I have got absolutely no problem with increasing dispensing fees if that is what we need to do..." *(See* Hearing of the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, December 7, 2004, opening statement of Chairman Joe Barton).

When new Federal Upper Limits (FULs) are phased in this spring, most states are likely to realize significant savings from reduced payments for generic drug products. As Senator Grassley further stated in his colloquy regarding the Medicaid section of the DRA, "The overall assumption made in the bill is that states will increase their fees to account for the fact that states would probably be paying pharmacists a lower amount for the drug product that more accurately reflects the cost of the drug product being dispensed."[1] (*See* Congressional Record, Senate, November 3, 2005, p. S12326). Yet, CMS gives little guidance to states about their obligations, consistent with Congressional intent, to increase their dispensing fees.

Today, Medicaid pharmacy dispensing fee payments are lower than the average pharmacy's cost to dispense a prescription. Recent state-specific studies have shown that the average cost of dispensing a Medicaid prescription is anywhere from $9 to $11, while the average current dispensing fee is only about $4.25.[2]

A recent national cost of dispensing study conducted by Grant Thornton and released on January 31 found that the average cost to dispense a prescription, weighted by prescriptions, is about $10.50. This amount varies by state. (*See* Grant Thornton LLP, "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies" (January 2007). The full report can be obtained from the Coalition for Community Pharmacy Action (CCPA) at www.rxaction.org). This amount is higher when weighted by stores. Therefore, while the Medicaid program will be paying pharmacies less for the generic drug ingredient cost when these new FULs take effect, we believe that CMS should mandate states to make sure that the dispensing fee is adequate and accurate for all pharmacies. This would be consistent with Congressional intent.

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

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

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

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

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

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

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

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

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

V. Section 447.514 – Upper Limits for Multiple Source Drugs

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

a. Identify Reference Product Used to Set FUL

Proposed §447.514(a) describes the criteria by which CMS would determine whether a multiple source drug product should have a FUL. The DRA changed the definition of multiple source drug from a covered outpatient drug for which there is at least two other drug products that are AB rated in the FDA *Orange Book* to a covered outpatient drug for which there is at least one other drug product that is AB rated in the *Orange Book.*

In this regard, CMS proposes that two criteria have to be met before an FUL can be established. First, at least two or more AB rated products have to be listed in the *Orange Book.* Second, at least two suppliers list the drug in the nationally-available pricing compendia.

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

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

b. Establish FULs Based on Weighted Average AMPs

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

Because Congress did not expressly state that the FUL had to be set based on the lowest AMP, we encourage CMS to base the FUL on 250 percent of the weighted average 11-digit AMPs for all the 100 package sizes (or most commonly dispensed package size by retail pharmacies) of all the nationally and widely available therapeutically equivalent products, weighted by sales. This would require that manufacturers report sales volume of their generics, as is done in the calculation of the ASP under Medicare Part B.

This is particularly important given that a recent GAO report found that using the lowest AMP would underpay pharmacies on average for generic drugs by 36 percent. Even when GAO calculated AMP-based FUL rates using the lowest AMP which had the highest value among several quarters of AMP data, it found that reimbursement rates were lower than pharmacy acquisition costs. This argues for an approach that would use, at a minimum, 250 percent of the weighted average AMPs (based on 11-digit NDCs) for the 100's package sizes or the package sizes most frequently dispensed by community retail pharmacies.

c. Use 11-Digit NDC Rather than 9-Digit NDC

CMS has asked for comments on whether the 11-digit NDC should be used to calculate the FUL or the 9-digit NDC. CMS offers a very compelling case in the proposed regulation's preamble as to why the 11-digit should be used, but then rejects its own arguments by saying that "the legislation did not change the level at which manufacturers are to report AMP, and we find no evidence in the legislative history that Congress intended that AMP should be restructured to collect it by 11-digit NDCs." As CMS knows, there are many items that Congress fails to specify in passing legislation, leaving the particulars to the implementing agency to develop the best possible approach. There is no evidence that Congress didn't intend that the AMPs be calculated at the 11-digit level for generic drugs in order to determine the FULs.

We believe that CMS should use an 11-digit weighted average AMP value for the most commonly-dispensed package size by retail pharmacies to calculate the FUL for a particular dosage form and strength of a drug, not the 9-digit weighted average AMP for the product. FULs are being set for generic drugs dispensed by retail pharmacies. Thus, the prices used to set the limits should be based on the most common package size dispensed by retail pharmacies. Current regulations specify that the FUL should be set on package sizes of 100 tablets or capsules or the package size most commonly dispensed by retail pharmacies. These entities can only be captured if the 11-digit package size is used. There is no legislative history to suggest that Congress intended to change this methodology in the existing regulation.

In fact, had Congress intended to change this, it would have amended the existing regulation through statute as it did to change the basis on which the FUL is calculated. Including the prices paid by other purchasers in a weighted average AMP, some of which may be bought in volumes larger than the traditional retail pharmacy can buy, can drive down the AMP below the prices traditionally available to retail pharmacies. According to a recent GAO report, the current AMPs are already well below retail pharmacies' acquisition costs for generic drugs. CMS needs to do all it can to assure that the basis of the AMP is high enough to assure that pharmacies will continue to encourage the use of generic drugs in Medicaid.

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

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

For example, we believe that only generic products that are AB-rated in the FDA *Orange Book*, and are widely and nationally available to pharmacies for purchase from the three major national wholesalers in adequate and consistent supplies, should be used in the calculation of the reference AMP.

Unit dose products, larger bulk package sizes (drum sizes, which are generally custom packed for a few select customers), and products that are limited and in short supply, should be excluded from the weighted average AMP calculation used to set the FUL. CMS has an obligation to proactively determine whether products are nationally available and in consistent supply, by contacting the manufacturers of these products on a regular basis, or the national wholesalers that stock them.

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

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

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

However, to minimize the possibility that an FUL would be set based on a product that is in limited or in short supply, the use of a percentage relationship between AMPs to determine outlier policies seems arbitrary. We believe that "outlier" policies could be avoided if CMS assures that the product used to set the FUL is nationally and widely available in the marketplace, and that the monthly AMP data for multiple source drugs are subject to a 12-month rolling average smoothing process.

Without this smoothing process, there is no way to know whether the so-called "outlier" AMP is actually the AMP of a widely available product whose AMP just happens to be artificially low in that month. That is because all or many of the rebates and discounts provided for that drug might just happen to be reported in a particular monthly AMP calculation period.

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

e. Provide Appeal Mechanism for Published FULs

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

VI. State Plan Amendment Requirements: Findings and Assurances

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

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

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

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

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

VII. Regulatory Impact Analysis

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

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

a. Analysis Substantially Underestimates Financial Impact to All Retail Pharmacies

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

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

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

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

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

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

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

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

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

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

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

b. Analysis Fails to Estimate Impact on Generic Drug Use

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

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

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

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

c. Rule Will Adversely Affect Many Retail Pharmacies

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

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

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

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

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

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

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

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

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

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

In addition, selling more items would require significant investments in larger front end areas, locating stores in high visibility, high traffic commercial locations, more staffing, and other changes that many pharmacy retailers may not be able to afford or may not have interest in providing. In essence, the impact analysis treats prescription drugs as simple commodities rather than medical products that require proper training on behalf of suppliers and consumers concerning their handling and use.

e. Changes to Purchasing Practices Are Not Certain

CMS also claims that pharmacies have the ability to mitigate the effects of the proposed rule and that they will *often* be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs. NACDS does not share this optimistic opinion.

CMS claims that the 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. However, a January 2007 report by the U.S. General Accounting Office estimated that retail pharmacies will be reimbursed on average 36 percent lower than their costs to purchase generic medications dispensed to Medicaid recipients. The study also indicated that pharmacies' would lose money on 59 of 77 generic drugs examined (76 percent). CMS to date has provided no evidence publicly to refute the GAO's research.

We do not agree that pharmacies *will* be able to purchase at lower costs. Today, pharmacies can negotiate lower prices for generics because they can move market share to that product. If all purchasers shift to the lowest cost manufacturer, that manufacturer has no incentive to offer lower costs. In fact, manufacturers may raise prices to larger buyers if they have to reduce prices to other purchasers, otherwise their revenues could be reduced considerably.

Manufacturers may compete on price initially, but if all manufacturers' prices are public, then pressures from purchasers should drive pricing towards comparable if not identical prices. At that point, manufacturers' incentives to hold down prices are reduced as any price increase would provide more revenues to them and higher reimbursements to retail pharmacies.

We also are concerned that the lowest-cost manufacturer or manufacturers may not be able to produce sufficient supplies to serve large numbers of new buyers. They also may not be able to increase capacity to produce more supplies quickly. However, pharmacies literally pay the price when the manufacturer is unable to provide adequate supplies.

f. Pharmacies have other costs beyond simply purchasing drugs that must be covered

A recent national study determined that the average cost of dispensing a prescription in a retail pharmacy is $10.50 per prescription. Conducted by the accounting firm Grant Thornton, LLP, the 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.

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

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

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February 19, 2007

Ms. Leslie Norwalk
Acting Administrator
Center for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

RE: Medicaid Program; Prescription Drugs

Dear Administrator Norwalk,

Express Scripts appreciates the opportunity to provide comment on the proposed rule CMS-2238-P, "Medicaid Program; Prescription Drugs; Notice of Proposed Rulemaking (hereafter referred to as NPRM) published in the *Federal Register* on December 22, 2006, implementing provisions of the Deficit Reduction Act of 2005 (DRA.)

Express Scripts, headquartered in St. Louis, Missouri, is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to over 55 million patients through facilities in 13 states and Canada. Express Scripts serves thousands of client groups, including managed-care organizations, insurance carriers, third-party administrators, employers and union-sponsored benefit plans.

Additionally, Express Scripts is a member of the Pharmaceutical Care Management Association (PCMA). PCMA has also commented on this proposed rule. Express Scripts strongly agrees with PCMA's comments and incorporates them by reference. We would also like to take the opportunity to stress the following points.

Widely available, publicly reported AMP that is highly inclusive of all supply chain discounts will lead to higher prices for the entire pharmaceutical market. This will not lead to lower, long-term prices, but rather is likely to evisorate all discounting in the marketplace once the AMP effectively becomes the floor below which manufacturers will not lower their prices. We also believe that an AMP that is highly inclusive of all supply chain discounts will reduce competition, particularly in the generic market, as manufacturers make the decision to exit production of certain products. These factors together will *raise* pharmaceutical prices.

Pharmacy benefit managers, unlike retail pharmacies, utilize formularies to drive discounts in prescription drug pricing. Retail does not—and can not—use the formulary tool and it is inappropriate to accrue rebate discounts to their reimbursement methodology.

Attempting to capture PBM rebates in the retail class-of-trade fundamentally misunderstands the marketplace. Rebates are after-the-fact payments paid to PBMs and shared with their client sponsors. PBM rebates are negotiated to reduce the cost to health plan clients in connection with sales made by pharmacies. They reduce cost to payers, not retail pharmacies. In fact, they never pass through retail pharmacies and should not be included in the retail class-of-trade as if retail had access to these discounts.

It is inappropriate to include mail order in the retail class-of-trade—particularly for establishing a benchmark reimbursement methodology for retail. The Medicaid population does not use, and in fact in some states, is prohibited from using mail order. Mail order is also not open to the general public as is retail pharmacy, and is a separate and distinct business with different overhead, inventory, equipment and personnel needs that distinguish its cost structure and function. Moreover, in the Medicare Part D program, CMS explicitly defines retail pharmacy as *not* including mail order pharmacy.

In conclusion, we appreciate the opportunity to provide comments on the proposed rule. We welcome any questions you may have on how core functions of PBMs (such as mail order, obtaining rebates, etc.) are different from retail pharmacy and how they should not be included in the retail class-of-trade.

Regards,

Janice Forsyth
Vice President and Deputy General Counsel
Express Scripts, Inc.

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02/15/2007

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

Ms. Norwalk,

The purpose of this letter is to comment on the proposed rule (CMS-2238-P) regarding the reimbursement of pharmacy providers based on the AMP model as set forth in the Deficit Reduction Act of 2005.

I am going to speak to you from the heart. I own an independent pharmacy in a rural town of 1800. I know I can compete every day with chains, mail order and any other delivery system out there if I have a level playing field because my overhead is so much lower than theirs. If you look at the average prescription costs between idependents and the mail orders and chains, you will find we are the lowest because every day we help patients cut costs. We have been the ones promoting generics because we have never had the back in deals that the chains and mail orders and PBM's get paid because of the lack of transparentcy in our system. And we have done this while at the same time paying more for medications than practically anyone in the world. Higher than countries like Canada, Mexico and even Switzerland, higher than chains, higher than mail orders (who are owned or have financial ties to PBM's, chains or drug manufacturers).

And now the goverment wants to add AMP to the unlevel playing field. As a small independent, we will always be on the wrong side of any average formula. This will do more to put us out business than all the decreases that have happened to us in just the last two years, decreased Medicaid reimbursemnets, Medicare Part D, Discount Cards given to everyone. No industry I know has more cost controls on the despensing side. And has this hepled? NO, it hasn't, because the problem is not the despensing side, it is the cost of the product. Even if you negotiate discounts, the manufactures just go up on the costs so in 2 years the prices are right back where they were or higher.

In the past, generics were where a drugstores profit came from. Take that away and you will see less and less generics being used. If a stores average cost of doing business if between $9-10.00 and you are paid less than half that to dispense a "cheap generic" then there is no incentive to dispense that generic. You will see larger costs on the drug side of the equation.

So how do you cut cost? Pay more on the dispensing side so patients will have face to face contact with pharmacists to guide them and consult them on the medications. Look at what PBM's are paid. When CVS which has a book valvue of 27 billion tries to buy a PBM for 27 billion, then something is wrong. The PBM is making way too much now

compared to the 10 to 20 cents a claim when they first started out adjudicating claims. Now they have made a whole now busines on how to get paid to drive market share of high price drugs which has added to the cost of medications. Look at the drug manufactures. I have a bottle of 90 generic Zocor for $9.78 then have the same tablet that Merck sells me for $388.52. The same tablet. Pass laws to allow my co-op to negotiate for the same prices that VA, and mail order do. Do away with class of trade laws that have put us on an unlevel playing field. Pass laws to make PBM's transparent. Pass laws that make PBM's pass savings on to the companies that have hired them to look out after their interest. Pass laws that give us the right to negotiate rates with PBM's. Now it is take it or leave it. Come up with a viable reimbursement formula for the despensing of prescriptions tied to the true cost of despensing a prescription not mainly to the cost of the medication. Pass laws that allow the federal goverment to negotiate the price of drugs for the medicare part D patients. We can fill these prescritions and give face to face consultation at a less cost if we have access to the same cost of goods. AMP is not the answer without change the rest of the formulas. One can not come before the other.

Sincerely,

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NOVARTIS

February 19, 2007

BY OVERNIGHT DELIVERY

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

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

Dear Administrator Norwalk:

I am pleased to submit the following comments on behalf of Novartis Pharmaceuticals Corporation ("Novartis"), regarding the above-referenced rule (the "Proposed Rule").[1] We provide a broad portfolio of innovative, effective, and safe products in diversified treatment areas, including oncology, primary care, transplantation, and ophthalmics. In addition, Novartis aims to harness the latest advances in biomedical research and technology to develop new therapies with the potential to benefit millions of patients throughout the world.

Novartis appreciates the valuable guidance that the Centers for Medicare & Medicaid Services ("CMS") has provided in the Proposed Rule regarding the calculation of average manufacturer price (AMP) and Best Price and supports many of CMS' proposals. We write, however, to highlight areas where we believe there is continued uncertainty and where manufacturers would benefit from additional clarification in the Final Rule.

I. Novartis Asks for Further Clarification on the Treatment of Certain Entities for Purposes of AMP and Best Price Determinations.

Novartis is pleased that CMS has provided specific guidance in the Proposed Rule on which entities are included in the retail class of trade for purposes of the AMP calculation. Novartis supports many of CMS' proposals with respect to the treatment of different categories of entities and believes that this guidance will help to reduce confusion in this area and ensure accurate and consistent AMP calculations. Nonetheless, Novartis has identified several areas of ongoing concern and asks that CMS provide additional clarification with respect to these particular categories of entities.

A. Novartis Interprets the Proposed Rule To Require the Inclusion of All Pharmacy Benefit Manager (PBM) Discounts and Does Not Anticipate Operational Difficulties if All Discounts to PBMs Are Included in AMP.

[1] 71 Fed. Reg. 77,173 (Dec. 22, 2006).

In the preamble to the Proposed Rule, CMS invited comment on the operational difficulties associated with CMS' proposal to include in AMP calculations discounts, rebates or other price concessions to PBMs associated with sales of drugs to the retail pharmacy class of trade.[2] Novartis agrees with CMS that PBM arrangements should be included in the retail pharmacy class of trade and does not believe that including PBM arrangements in AMP calculations will create significant operational difficulties, as Novartis interprets the Proposed Rule to require that all PBM discounts are included in AMP. Novartis does believe that operational difficulties would be presented if manufacturers were required to segregate price concessions provided on mail order utilization from that provided on other PBM utilization, as such detail is not necessarily available from the PBMs to facilitate separate quantifications of these two figures. However, Novartis does not interpret the Proposed Rule to require this, but rather the inclusion of all PBM price concessions, regardless of whether those concessions relate to mail or non-mail utilization, and also regardless of whether the PBM passes on any portion of those price concessions to its network pharmacies or member plans. Novartis asks CMS to confirm this interpretation and include it in the Final Rule.

B. CMS Should Clarify that Discounts Negotiated on Behalf of Dependents of Retirees Enrolled in Qualified Retiree Prescription Drug Plans Also Are Excluded from Best Price.

The Medicaid drug rebate statute excludes from the definition of Best Price "any prices charged which are negotiated . . . by a qualified retiree prescription drug plan (as defined in section 1395w-132(a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A or part B of such subchapter."[3] Consistent with the statute, CMS has proposed to exclude from Best Price "[a]ny prices charged which are negotiated . . . by a qualified retiree prescription drug plan . . . with respect to such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare."[4] Novartis asks CMS to include a clarification in the Final Rule that this exemption also applies to discounts negotiated on behalf of the retiree's dependents covered under the retiree's plan. Novartis' rebate agreements for qualified retiree prescription drug plan utilization apply the same price structure to all of the individuals covered by the plan, and the data Novartis receives pursuant to these agreements is not segregated between retirees and dependents of retirees. Novartis is unable to distinguish between utilization of retirees and utilization of their dependents because these plans treat both populations the same and as entitled to the same benefit. Including a clarification in the Final Rule that the Best Price exemption applies to utilization of both retirees and their dependents will enable manufacturers to continue providing significant discounts to these plans.

C. Novartis Supports the Proposed Treatment of State Children's Health Insurance Program (SCHIP), Medicare Part D, and State Pharmaceutical Assistance Program (SPAP) Sales and Discounts.

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2 Id. at 77,179.

3 42 U.S.C. § 1396r-8(c)(1)(C)(i)(VI).

4 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(5)).

CMS proposes to include in AMP all sales and associated rebates, discounts and other price concessions under the SCHIP, SPAP, and Medicare Part D programs that are associated with sales of drugs provided to the retail pharmacy class of trade.[5] This proposal would include all sales dollars and units associated with these entities in the calculation of AMP and then also reduce AMP sales dollars (the numerator of the AMP calculation) by discounts provided to these entities. Novartis supports this approach and urges CMS to include this proposal in its Final Rule.

D. CMS Should Clarify that Drugs Dispensed Through Company Stores Are Not Included in AMP or Best Price Because Company Stores Do Not Dispense to the General Public.

The Proposed Rule includes in the calculation of AMP "[s]ales directly to patients."[6] Some of Novartis' products are dispensed directly to patients through company stores that sell only to the company's employees. Company stores do not meet CMS' proposed definition of the retail pharmacy class of trade because they do not "sell[] or provide[] the drugs to the general public."[7] Company stores also should be exempt from the calculation of Best Price because these are not commercial sales but rather discounted prices made available solely to manufacturer employees, and individual consumers/patients are not one of the purchaser types included in the statutory definition of Best Price.[8] Novartis requests that CMS clarify in the Final Rule that direct patient sales made through company stores are not included in AMP or Best Price determinations for these reasons.

II. Novartis Asks That CMS Clarify the Treatment of Patient Coupons.

CMS is proposing to exclude from the calculation of AMP and Best Price patient discount coupons redeemed by the consumer directly to the manufacturer.[9] Coupons redeemed by any entity other than the consumer would be included in the calculation of AMP and Best Price under the Proposed Rule. The Proposed Rule does not describe how this broad definition would apply to coupons redeemed through non-purchaser third party vendors retained by the manufacturer, or coupons redeemed through a retail pharmacy where the redemption does not affect the price realized by the pharmacy. Novartis asks that CMS provide additional detail in the Final Rule to better address the full scope of patient coupon arrangements, as discussed in more detail below. Without such clarification, Novartis is concerned that manufacturers will significantly curtail coupon arrangements because of uncertainty regarding their treatment in AMP and Best Price, with the result being the limitation of an important means for promoting patient access to needed therapies. Those coupons that CMS does propose to exempt, which consumers must submit directly to the manufacturer, are significantly less efficient and convenient for the consumer, and thus any regulation that limits exempt coupons to this type is likely to cause a significant decline in patient participation.

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5 Id. at 77,180, 77,197 (proposed 42 C.F.R. pt. 447.504(g)).

6 Id. at 77,197 (proposed 42 C.F. R. pt. 447.504(g)(7)).

7 See id. at 77,196 (proposed 42 C.F.R. pt. 447.504(e)).

8 42 U.S.C. § 1396r-8(c)(1)(C)(i) ("The term 'best price' means . . . the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.").

9 71 Fed. Reg. at 77,181, 77,183.

One form of patient coupon is the mail-in rebate, where the patient submits the coupon and proof of purchase to the manufacturer for payment of the coupon's rebate amount. The Proposed Rule would exempt such coupons from AMP and Best Price where redeemed directly to the manufacturer. In many cases, however, these coupons are redeemed not to the manufacturer directly but rather to a third-party vendor that administers the coupon program on behalf of the manufacturer and that otherwise is not a purchaser of product. Novartis does not believe such arrangements affect the price realized by any purchasing entity because there are no purchasers involved in the redemption process, but notes that the Proposed Rule could be interpreted as requiring the inclusion of such arrangements in AMP and Best Price because the coupon is redeemed to a vendor rather than the manufacturer itself. Novartis therefore asks CMS to clarify that patient coupons redeemed through non-purchaser third-party vendors may be considered as being redeemed directly to the manufacturer and have no effect on the AMP and Best Price calculations.

CMS suggests in the preamble to the Proposed Rule that when a coupon is redeemed through an entity other than the manufacturer, such as a retail pharmacy, it will necessarily affect the price paid by the entity. In Novartis' experience, however, coupons that are redeemed through a purchaser, such as a retail pharmacy, do not have an effect on the price realized by that entity. A patient using a point-of-sale copayment coupon or card receives a discount on his or her out-of-pocket expense at the time of the transaction, and the manufacturer reimburses the pharmacy only for the amount not received from the patient. The manufacturer may also pay the pharmacy a fair market value processing fee. In either case, the manufacturer's payment has not exceeded the pharmacy's own expense so there is no effect on the price realized by the pharmacy, and the transaction therefore also should have no effect on AMP and Best Price.

Free goods coupons provide the patient with product at no charge, and represent an increasingly important avenue for providing trial or sample product to those patients whose prescribers are either unable or unwilling to stock and dispense PDMA-compliant samples. Under these arrangements, the pharmacist provides the drug to the patient at no cost and redeems the coupon to the manufacturer. The manufacturer reimburses the pharmacy through either replacement product or monetary reimbursement. The pharmacy may also receive a fair market value dispensing fee. Where the manufacturer reimburses the pharmacy with replacement product, there is no impact on the price realized by the pharmacy because the pharmacy has received payment in kind for what it dispensed, and the transaction should be excluded from AMP and Best Price. Where the manufacturer instead provides the pharmacy with monetary reimbursement, the price realized by the pharmacy is affected only where the reimbursement exceeds the pharmacy's out-of-pocket costs. Novartis typically has no way of determining a pharmacy's acquisition costs for product and so employs a formula for estimating that amount, currently either Wholesale Acquisition Cost plus some amount or Average Wholesale Price less some amount. In this case, Novartis reimburses the pharmacy based on its best estimate of acquisition costs, and, as such, the reimbursement does not affect the price realized and the transaction should be excluded from AMP and Best Price.

Should CMS determine that these patient coupon programs must be included in AMP and Best Price, Novartis urges CMS to provide additional details regarding that proposal and the opportunity for further comment by industry, particularly in relation to the methodology for including such transactions in the calculations. It is operationally very difficult for manufacturers to capture this data and Novartis believes that it is important for CMS to provide the opportunity to comment on any proposed methodology before it is included in a Final Rule.

III. CMS Should Clarify the Treatment of Patient Assistance Programs.

CMS also has proposed excluding from Best Price "[g]oods provided free of charge under [ ] manufacturers' patient assistance programs."[10] The preamble to the Proposed Rule does not discuss this proposed exclusion or include a definition of a "patient assistance program.". By its own terms, however, this exception is limited to "goods provided free of charge" under such programs. Novartis believes this exception is overly narrow, as patient assistance programs also in some circumstances require patients to make limited payments in relation to the products they receive through such programs. Novartis is concerned that such payments would disqualify a patient assistance program from the proposed exception. As CMS has proposed other exceptions to Best Price for manufacturer-sponsored patient discounts, i.e. the exceptions for manufacturer sponsored Drug Discount Card Programs and also manufacturer coupons redeemed by the consumer,[11] Novartis urges CMS to expand the patient assistance program exception to cover those programs as a category, regardless of whether they provide goods free of charge or at limited cost to patients.

Patient assistance programs are programs through which manufacturers provide patients with free or reduced price drug product based on patient income levels. They are a critical means of assuring that patients who lack insurance coverage for a needed, and often life-saving, therapy can access that medication regardless of their ability to pay. CMS should ensure, therefore, that its Best Price exception for these programs is broad enough to capture their diverse forms. For example, a patient assistance program may be offered through a drug discount card , where the patient, once approved for enrollment, receives a discount card from the manufacturer and presents that card to a pharmacy and receives drug product in that way. Use of a card-based approach is more likely with a product that typically is dispensed to a patient through a retail pharmacy. Under such a program, the patient may pay nothing, or in some cases, the patient may be obligated to pay a nominal co-pay to help defray the pharmacy's dispensing costs, while still providing the product at no charge. Even where a patient assistance program does not use a card approach but rather ships the product directly to the patient or to the patient's health care provider for administration to the patient, as may be the case with physician-administered or self-administered injectible products, the program may provide the drugs free of charge to those with the lowest incomes, while charging a limited, income-based, fee to those with incomes that are higher but still below the program's income ceiling . Novartis believes that all of these diverse arrangements are patient assistance programs, as they are all tied to the patient's income level and lack of insurance coverage, and that therefore all should be excluded from Best Price.

Patient assistance programs clearly serve a crucial function for low income and uninsured patients, and manufacturers structure their programs to provide the most efficient and effective means for patient access. The exemption of these programs from Best Prices should not require that the manufacturer use a discount card or coupon approach, however the current language of Best Price exemption would force manufacturers to restructure any such programs that require some limited amount of patient payment so that they fit within one of those exceptions. CMS can avoid this anomolous result by exempting patient assistance programs as a category from Best Price, with a parallel exception for AMP, and Novartis strongly urges CMS to do so.

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10 Id. at 77,198 (proposed 42 C.F.R. pt. 447.505(d)(9)).

11 Id. (proposed 42 C.F.R. pt. 447.505(d)(7)-(8)).

IV. CMS Should Clarify the Customary Prompt Pay Reporting Requirement.

Section 6001(c)(2) of the Deficit Reduction Act (DRA) amends the Social Security Act to require manufacturers to report customary prompt pay discounts.[12] The Proposed Rule implements this statutory provision by requiring the quarterly pricing reports to include "discounts paid to all purchasers in the rebate period."[13] In general, however, customary prompt pay discounts are not "paid" to the purchaser; rather, the entity qualifying for the discount deducts the discount amount from the remittance it makes to the manufacturer during the specified prompt payment period. It is therefore difficult for a manufacturer to quantify the discounts taken by a purchaser, or deducted from payments made during the rebate period, as doing so requires the manufacturer to reconcile the deductions relating to prompt pay discounts and deductions taken for other reasons, such as shortages in the amount of product shipped. Even if the manufacturer could quantify such deductions, moreover, that amount would relate to the invoices paid rather than sales made in the rebate period. In contrast, Novartis believes that manufacturers readily can quantify the customary prompt pay discounts offered during a rebate period. This figure is less burdensome to calculate and has the advantage of relating to the sales figures used to calculate quarterly AMP and Best Price. For these reasons, Novartis asks CMS to clarify that manufacturers may comply with the reporting requirement by reporting the customary prompt pay discounts offered during the rebate period.

V. CMS Should Provide Additional Clarification on the Exclusion of Manufacturer-Sponsored Drug Discount Card Programs from Best Price.

Under the Proposed Rule, prices negotiated "under a manufacturer's sponsored Drug Discount Card Program" are to be excluded from Best Price.[14] Novartis asks that CMS include a definition of "Drug Discount Card Program" in its Final Rule, and explain how such a program differs from a patient coupon program. Novartis also requests that CMS confirm that this exemption from Best Price would apply to the Together Rx Access savings program, which CMS previously exempted from Best Price pursuant to the attached letter.[15] Novartis historically has included these sales transactions in the AMP calculation, but not used the associated discounts to reduce the AMP sales dollars figure. Novartis requests that CMS clarify that this is the appropriate approach and that CMS also therefore include a parallel exclusion from AMP for manufacturer-sponsored Drug Discount Card Programs.

VI. Novartis Asks CMS to Clarify that the Proposed Treatment of Medicaid Rebates in AMP Calculations is Prospective Only.

CMS explains in the preamble that it is "clarify[ing]" that the units associated with Medicaid sales should be included in the AMP calculation and that Medicaid rebates "should be excluded from AMP calculations but that price concessions associated with the sales of drugs in the retail pharmacy class of trade which are provided to Medicaid patients should be included."[16] Novartis agrees that there is a need for clarification of the treatment of Medicaid sales and rebates. As CMS noted in the preamble, one of the specific recommendations of the Office of Inspector General (OIG) in its May 2006 report

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12 Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6002(c)(2).

13 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. pt. 447.410(a)(3)).

14 Id. (proposed 42 C.F.R. pt. 447.505(d)(7)).

15 Letter from Dennis Smith, Director, Center for Medicaid and State Operations, CMS, to John W. Treece, Sidley Austin Brown & Wood LLP (undated).

16 71 Fed. Reg. at 77,180.

"Determining Average Manufacturer Prices for Prescription Drugs under the Deficit Reduction Act of 2005" was that CMS should clarify the treatment of Medicaid sales because prior to the Proposed Rule, there was no guidance on the subject.[17] In that report, the OIG specifically noted that "[t]he exclusion of Medicaid sales [from AMP] is not addressed in section 1927 of the Act, the rebate agreement, or any of the releases."[18] Novartis appreciates that CMS is now directly addressing this issue by providing an explicit methodology, but believes that because this is the first time CMS has provided any such guidance it must be implemented on a prospective basis only. Novartis asks that CMS make this clear in the Final Rule.

VII. CMS Should Clarify that Administrative Fees Paid to Group Purchasing Organizations (GPOs) Should Not be Included in AMP and Best Price Determinations Because GPOs are Non-Purchasers.

CMS has proposed that manufacturers include all administrative and service fees in AMP and Best Price except for those fees that meet the new definition of "bona fide service fees."[19] CMS proposes to use the same definition of bona fide service fee that CMS adopted for purposes of the Average Sales Price (ASP) calculation in its Final Rule on the 2007 physician fee schedule (the "2007 Physician Fee Schedule Rule").[20] This definition includes fees paid by a manufacturer to an entity "whether or not the entity takes title to the drug," and the Proposed Rule would require that the fees be included in AMP and Best Price unless the definition is met.[21] CMS did not discuss the treatment of administrative fees paid to GPOs in the Proposed Rule, but in the preamble to the 2007 Physician Fee Schedule Rule CMS specifically declined to address the issue and instead stated that it would study the matter further.[22] In the absence of specific guidance, CMS advised manufacturers that they may make reasonable assumptions in their ASP calculations "consistent with the general requirements and the intent of the Act, Federal regulations, and [their] customary business practices."[23]

Novartis believes that administrative fees paid to GPOs that do not purchase product should not be included in the AMP and Best Price calculations because they are not paid to a purchaser. The inclusion of administrative fees paid to GPOs in AMP and Best Price determinations would be a significant change from current CMS guidance. As described in the preamble to the Proposed Rule, under CMS' current policy administrative fees "should be included in the calculation of AMP, if those sales are to an entity included in the calculation of AMP."[24] Administrative fees paid to GPOs are not paid to an entity included in the AMP calculation because GPOs generally are not purchasers. Instead, GPOs negotiate drug discounts with manufacturers on behalf of their health care provider members who are purchasers. In the preamble to the 2007 Physician Fee Schedule Rule, CMS recognized the complexity of manufacturer arrangements with GPOs and concluded that it was "premature" to provide specific guidance on the treatment of fees paid to GPOs for purposes of the ASP calculation without

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17 Id. at 77,178.

18 Department of Health and Human Services, Office of the Inspector General, Determining Average Manufacturers Prices for Prescription Drugs Under the Deficit Reduction Act of 2005 (A-06-06-00063) at 7 (May 2006), available at http://oig.hhs.gov/oas/reports/region6/60600063.htm.

19 71 Fed. Reg. at 77,180, 77,183.

20 71 Fed. Reg. 69,624 (Dec. 1, 2006).

21 71 Fed. Reg. at 77,180, 77,195 (proposed 42 C.F.R. pt. 447.502).

22 71 Fed. Reg. 69,669.

23 Id.

24 71 Fed. Reg. at 77,180.

further study.[25] Novartis now asks that CMS make explicit in the Final Rule that fees paid to non-purchasers such as GPOs are not relevant to AMP and Best Price determinations.

Should CMS consider including GPO fees in the calculations of AMP and Best Price, such a requirement should be limited to those fees that exceed the 3% threshold provided in the GPO safe harbor to the federal healthcare program antikickback statute[26] and also apply prospectively only. The safe harbor's use of a 3% threshold reflects both industry standard fee rates as well as the OIG's determination that fees equal to or less than that amount present little risk of abuse. A requirement to include GPO fees of any amount would be a change from existing CMS policy for the reasons identified above and as stated in the preamble itself, and so also should be limited to prospective application.

VIII. Novartis Supports the Exclusion of Returned Goods from the AMP Calculation and Asks for Additional Clarification on the Good Faith Standard.

Novartis is pleased that CMS has proposed to exclude returned goods from the calculation of AMP when the goods are returned in good faith.[27] The Proposed Rule recognizes that manufacturers have experienced some difficulties under the current policy requiring the inclusion of returns in AMP, because this can result in a substantially reduced or even a negative AMPs. As CMS knows, returns are excluded from the calculation of ASP. The treatment of returned goods in the calculation of AMP in a manner consistent with their treatment for purposes of the ASP calculation will reduce the administration burden on manufacturers. Novartis also believes that the exclusion of returns will result in a more accurate AMP.

Novartis urges CMS to finalize this proposal and also requests that CMS include two clarifications in the Final Rule that Novartis believes would further advance these goals. First, CMS should clarify that manufacturers may exclude returned goods based on the good faith of the manufacturer in accepting the return, because manufacturers do not have a basis to determine the good faith of the returning purchaser. Second, Novartis requests that CMS clarify that goods that are returned in accordance with the manufacturer's written return policies will be deemed to have been made in good faith.

IX. CMS Should Provide Additional Guidance Regarding Recalculating Base Date AMP.

CMS included a provision in the Proposed Rule allowing manufacturers to recalculate base date AMP so that additional rebates, defined as the difference between the quarterly AMP reported to CMS and the base date AMP trended forward using the consumer price index – urban, would not increase due to changes in the definition of AMP.[28] Novartis supports CMS' including this provision in the Final Rule, but asks CMS to provide additional guidance regarding the recalculations.

As CMS noted in the preamble to the Proposed Rule, "manufacturers may not have the data needed to recalculate base date AMP or may find the administrative burden to be more costly than the savings gained."[29] Therefore CMS explained that it intended to give manufacturers the "option" to

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25 71 Fed. Reg. 69,669.

26 42 C.F.R. § 1001.952(j)

27 71 Fed. Reg. at 77,181, 77,197 (proposed 42 C.F.R. pt. 447.504(h)(13)).

28 Id. at 77,185.

29 Id.

recalculate base date AMP. Novartis asks CMS to clarify that manufacturers are not required to submit revised base date AMP, even if they have the data necessary to do so, and that they may make the decision whether to recalculate for each product individually. Novartis believes it is important that CMS also clarify that manufacturers should use their current methodologies when recalculating any base date AMPs, inclusive of the changes required by the Final Rule.

The text of the Proposed Rule states that manufacturers may only recalculate base date AMP to reflect the changes to the definition of retail pharmacy class of trade.[30] This is inconsistent with CMS' guidance in the preamble, which stated that the agency would allow manufacturers to recalculate base date AMP "to reflect the changes to AMP as set forth in the DRA."[31] The DRA contains a provision excluding customary prompt pay discounts from AMP.[32] CMS should clarify that manufacturers recalculating base date AMP may take the exclusion of customary prompt pay discounts into consideration in addition to the new definition of retail pharmacy class of trade. This will ensure that the changes to the definition of AMP do not cause manufacturers to face increased additional rebate liability.

Finally, Novartis asks CMS to revise its guidance to provide manufacturers with more time to recalculate base date AMP. As currently provided, manufacturers would have to submit recalculated base date AMP with their quarterly submissions for the first full quarter after the Proposed Rule is finalized.[33] Manufacturers will be unable to evaluate whether to recalculate until after the Final Rule is published, because only then will manufacturers know the extent to which the retail pharmacy class of trade definition has changed.. That leaves manufacturers less than two full quarters to evaluate the Final Rule, determine whether to recalculate, and actually perform the recalculation. Novartis believes that this is not a sufficient amount of time and asks CMS to provide manufacturers with four quarters to perform this effort.

X. Novartis Urges CMS to Clarify that Monthly AMP Is To Be Reported Only Through a Product's Termination Date.

The DRA requires manufacturers to report AMP now on a monthly basis, in addition to their continuing obligation to report AMP on a quarterly basis. The Proposed Rule explains that this new reporting requirement is intended both to facilitate the new AMP-based federal upper payment limits mandated by the DRA, and also to encourage State Medicaid Programs to use monthly AMPs to set reimbursement rates.[34] The Proposed Rule itself recognizes that only AMPs for currently marketed products should be used to set FULs, and therefore excludes AMPs for terminated drugs from use in calculating FULs.[35] Novartis supports this exemption for terminated products, but requests that CMS then clarify that a manufacturer's reporting obligation for monthly AMP also ceases with the product's termination date. The reporting obligation for quarterly AMP figures would continue to be through four quarters beyond the quarter in which a product's last lot expires, to ensure AMP data remains available to determine Medicaid rebates through that period.

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30 Id. at 77,198 (proposed 42 C.F.R. pt. 447.510(c)(2)).

31 Id. at 77,185.

32 Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6001(c).

33 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. pt. 447.410(c)(1)).

34 Id. at 77,187.

35 Id. at 77,199 (proposed 42 C.F.R. pt. 447.514(c)(1)).

In the context of ASP, which also is used to set reimbursement rates, CMS has provided that manufacturers are not required to report ASP data for an NDC "beginning the reporting period after they report the ASP data for the quarter during which the expiration date of the last lot sold occurs."[36] Monthly AMP data should be subject to this same reporting limitation, as modified to begin with the month after the month in which the last lot sold expires, given that the Proposed Rule itself directs that CMS will not use monthly AMP figures for FUL determinations after this same date. States also should not be able to set reimbursement rates based on such AMPs as they do not reflect the acquisition price of a product that currently is available for purchase by the retail pharmacy class of trade. For all these reasons, Novartis requests CMS to clarify that manufacturers are not required to report monthly AMP after the NDC has been terminated, beginning with the first monthly report after the expiration date of the last lot sold.

XI. CMS Should Clarify a Number of Issues Relating to Authorized Generics.

Section 6003 of the DRA amends the Medicaid rebate statute to require manufacturers holding the New Drug Application (NDA) for a particular product to include in AMP and Best Price calculations for that product the sales for all other products sold under that same NDA.[37] CMS includes a proposed regulation implementing this provision in the Proposed Rule:

> A manufacturer holding title to the original NDA to the authorized generic drug must include the direct and indirect sales of the drug in its AMP . . . [and] must include the price of such drug in the computation of best price for the single source or innovator multiple source drug . . . .[38]

CMS has asked for comment regarding authorized generics,[39] and in response to that request Novartis asks the agency to clarify a number of issues, described in more detail below.

A. CMS Should Clarify That Intercompany Transfer Payments Are Not Included in the Brand Drug's Price Reporting.

CMS discusses the authorized generic provision at some length in the preamble to the Proposed Rule. In that discussion, CMS explains that "sales of the authorized generic drugs by the secondary manufacturer that buys or licenses the right to sell the drugs" are included in the AMP and Best Price calculations of the brand drug.[40] Novartis interprets this direction to mean that intercompany transactions between the primary and secondary manufacturer, including royalty, licensing, or transfer payments made by the secondary manufacturer to the primary manufacturer, are not to be included in the AMP and Best Price of the brand drug. Rather, only sales by the authorized generic's manufacturer to eligible purchasers are included in the brand product's AMP and Best Price calculations. This interpretation avoids the operational problems inherent in any attempt to capture and include such intercompany transactions in the AMP and Best Price calculations and also ensures that the sales transactions included in the blending calculation involve the same types of entities for both the authorized generic and brand products. This approach also ensures that the blended AMP and Best Price reflect the true market price

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36 71 Fed. Reg. 10,975 (Mar. 3, 2006).

37 Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6003(a).

38 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. pts. 447.506(b)-(c)).

39 Id. at 77,184.

40 Id.

and reported AMP and Best Price for the authorized generic. Novartis therefore asks CMS to clarify that manufacturers may comply with the DRA and Proposed Rule in this way.

B. CMS Should Clarify That the Primary Manufacturer May Rely on the Reported AMP and Best Price of the Authorized Generic To Derive the Blended AMP and Best Price for the Brand Product.

The Proposed Rule does not provide any specific guidance regarding the method that a brand manufacturer must or should use to incorporate the authorized generic sales data into the brand product's AMP and Best Price. Novartis believes that one reasonable approach for combining the data is to rely on the authorized generic's own calculated and reported AMP and Best Price figures. Under this approach, the primary manufacturer would determine the blended AMP for the brand drug by combining the two products' AMP-eligible sales dollars and dividing that amount by the two products' combined AMP-eligible sales units. The AMP-eligible sales dollars and units figures for the authorized generic would be the same used by the secondary manufacturer to derive the authorized generic's own reported AMP. For the blended Best Price figure, the primary manufacturer would report the lower of the Best Price it calculates for the brand drug and the Best Price calculated and reported by the secondary manufacturer for the authorized generic.

The secondary manufacturer must determine AMP and Best Price for the authorized generic to fulfill its own reporting obligations. Allowing the primary manufacturer to rely on this data in calculating the blended AMP and Best Price for the brand drug will minimize the potential for error in the blending calculation and ensure that the blended AMP and Best Price figures accurately reflect the market and reported prices for the authorized generic. This approach also will significantly streamline price reporting for the brand drug by eliminating the need to include all transaction level sales data for another drug into the primary manufacturer's calculation. For these reasons, Novartis asks CMS to clarify that this approach to calculating blended AMP and Best Price is a permissible means for complying with the Proposed Rule.

C. CMS Should Clarify That the Secondary Manufacturer's Certification Serves to Hold the Primary Manufacturer Harmless.

As noted above, Novartis believes that allowing primary manufacturers to rely on the authorized generic's calculated AMP and Best Price figures when determining the blended AMP and Best Price will reduce errors as the primary manufacturer will not have to include all of the sales data for another drug in its calculation. Nonetheless, there may be instances when the blended AMP and Best Price reported by the primary manufacturer for the brand drug are inaccurate because of inaccuracies in the data as reported by the secondary manufacturer. Novartis asks CMS to clarify that in such instances the secondary manufacturer's certification of its price to CMS serves to hold the primary manufacturer harmless for any resulting inaccuracies in the AMP and Best Price of the brand drug.

D. CMS Should Clarify that the Authorized Generic Provision Also Applies to NDC Changes of the Brand Drug.

The DRA amendments require manufacturers, for the first time, to aggregate sales data across NDCs for all products "that are sold under a new drug application approved under section 505(c)of the Federal Food, Drug, and Cosmetic Act [(FFDCA)]."[41] Under CMS' interpretation of this provision in the Proposed Rule, the original NDA-holder is required to include drugs sold under the NDA in its AMP and

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41 Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6003(a)

Best Price calculations even where such drugs are "marketed, sold or distributed directly or indirectly under a different product code, labeler code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) then the listed drug."[42] While this provision surely captures sales of authorized generic as that term is generally understood, it also seemingly applies to sales of the brand drug alone when the brand drug is sold under two different NDCs, which can occur where there is a transfer in ownership of the product between different labelers or a manufacturer changes a product's NDC. Novartis asks CMS to clarify that the authorized generic provision also applies in these situations.

In the course of marketing a given brand drug, the primary manufacturer may migrate that brand drug to a different labeler code of the primary manufacturer, or sell that brand drug to a different manufacturer. When this occurs, there may be sales of the same drug under two different NDCs in a given reporting period, month or quarter. In these situations, the drug at issue is being sold under two different NDCs, but the same NDA, and therefore would appear to be subject to the authorized generic provision of the DRA and Proposed Rule. Novartis interprets this to mean that during such times the sales data for the drug sold under each NDC should be combined to calculate the AMP and Best Price. In this situation, both NDCs are "brand" products, as opposed to one being the brand and the other the authorized generic, and so Novartis believes that the combined data should be used to derive a single AMP and Best Price that is to be reported for both NDCs. If there is an authorized generic also marketed during the same period, this combined brand data also would incorporate any sales data for the authorized generic marketed during the period. Novartis believes that this interpretation is the correct one under the DRA and is consistent with CMS' implementation of the DRA provision in the Proposed Rule.[43] Novartis therefore ask CMS to clarify in the Final Rule that the authorized generic provision applies to sales of the brand drug under a new labeler code.

XII. CMS Should Clarify the Limitation on Manufacturer Rebate Liability for Utilization Submitted After the 60-Day Statutory Deadline.

The Medicaid rebate statute requires States to "report to each manufacturer not later than 60 days after the end of each rebate period" drug utilization data for the rebate period.[44] Despite this explicit statutory requirement, CMS has never enforced this provision and, in fact, has indicated that manufacturers are liable to pay rebates even when States submit utilization data to manufacturers beyond the 60-day deadline.[45] It is unclear what CMS' basis for this interpretation of the statute is, especially in light of legislative history indicating that utilization data "must be transmitted promptly to the manufacturer."[46] Novartis strongly urges CMS to include this existing statutory requirement in the Final Rule.

CMS previously has recognized that some limitation on manufacturer liability is necessary and proposed that a one-year statute of limitations is reasonable.[47] CMS proposed this time limit in its 1995 Proposed Rule, which was never finalized. In discussing that proposed time limit, CMS articulated a number of reasons to impose such a limit generally, and the reasonableness of a one-year limit in

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42 71 Fed. Reg. at 77,198 (proposed 42 C.F.R. pt. 447.506(a)).

43 This interpretation also is consistent with CMS' treatment of redesignated NDCs in the Average Sales Price context. See 71 Fed. Reg. 69,624, 69,672-73 (Dec. 1, 2006).

44 42 U.S.C. 1396r-8(b)(1)(A).

45 60 Fed. Reg. 48,442, 48,460 (Sept. 19, 1995).

46 H.R. Rep. No. 101-964, at 823 (1990) (Conf. Rep.).

47 60 Fed. Reg. at 48,460.

particular. For example, allowing States up to one year after a rebate period ends to submit utilization data translates into a manufacturer "being responsible for rebates for more than three years after the drug is dispensed,"[48] and a three-year time period comports with general business principles and Internal Revenue Service requirements. The new DRA requirement that States submit rebate claims for physician-administered drugs raises the importance of the time limit.[49] Although States always have had the option of claiming rebates for these drugs, many have not done so previously, and Novartis is concerned that States now will begin seeking these rebates for prior rebate periods, even when those periods are several years old. Such a result is specifically prohibited by statute and presents manufacturers with a risk of significant financial liability for years long since closed for financial accounting purposes. For all of these reasons, Novartis asks CMS to enforce the existing 60-day statutory deadline for States to submit drug utilization data, or, at a minimum, impose the one-year statute of limitations it previously proposed and found to be reasonable.

XIII. CMS Should Clarify How it Will Reconcile the Final Rule with the Existing Medicaid Rebate Agreement.

CMS proposed to define national rebate agreement as "the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his designee and a manufacturer to implement section 1927 of the [Social Security] Act."[50] The agency did not, however, explain how it will reconcile the existing Medicaid rebate agreement[51] with the Final Rule, which will substantially change a number of the definitions and requirements of the agreement. When CMS proposed changes to the Medicaid drug rebate program in 1995, the agency indicated that it would "amend the national rebate agreement to reflect any new regulatory requirements and definitions" after publication of the final rule.[52] Novartis urges CMS to include a similar provision in the Final Rule, clarifying how the agency will reconcile the Final Rule with the Medicaid rebate agreement and when it will issue new agreements to manufacturers. Novartis also asks CMS to specify that it will not incorporate into a revised rebate agreement any definitions or requirements not explicitly provided for in the Proposed Rule until such provisions have been subject to notice-and-comment rulemaking.

* * * * *

We thank CMS in advance for its serious consideration of these comments and look forward to working with you to ensure accurate Medicaid price reporting. Please feel free to contact me at 862-778-4653 if you have any questions regarding our comments or need additional information.

Sincerely,

Serafina Oxner
Executive Director, Healthcare Contract Administration
Novartis Pharmaceuticals Corporation

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48 Id.

49 See Deficit Reduction Act of 2005, Pub. Law No. 109-171, § 6002(a).

50 71 Fed. Reg. at 77,196 (proposed 42 C.F.R. pt 447.502).

51 56 Fed. Reg. 7049 (Feb. 21, 1991).

52 60 Fed. Reg. 48,442, 48,477 (Sept. 19, 1995).

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Center for Medicaid and State Operations

John W. Treece
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Dear Mr. Treece:

Thank you for your letter to Administrator McClellan, presenting to us the methodology for the proposed Together Rx Access savings program. As we understand it, the Together Rx Access program operates as follows:

- The program is focused on extending pharmacy assistance to certain low-income individuals and families with incomes below 300 percent of the Federal Poverty Level (FPL), who are not otherwise eligible for Medicare nor have public or private prescription drug coverage.

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

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

- The pharmacy reimbursement formula provides that the pharmacy will be reimbursed based upon the lower of (a) a formula "ceiling price" equal to AWP – 13 percent + $2.00 or (b) the pharmacy's usual and customary price for the drug.

- The pharmacy collects no additional payment, other than the benefit amount, from the Together Rx Access program.

The Centers for Medicare & Medicaid Services does not believe that the specific facts described above would have implications for the determination of best price under section 1927(c)(1)(C) of the Social Security Act (the Act).

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

Sincerely,

Dennis G. Smith
Director