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Congress of the United States

Washington, DC 20515

2007 FEB 20 PM 12:15

February 16, 2007

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

Dear Ms. Norwalk,

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

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

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

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

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

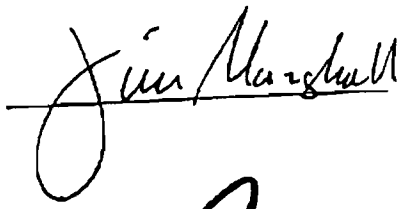
This proposed payment formula will be devastating to many community retail pharmacies, Medicaid beneficiaries, and the financing of the Medicaid program itself. We respectfully request that you delay the release of any AMP data until a final definition is adopted ensuring that AMP accurately reflects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

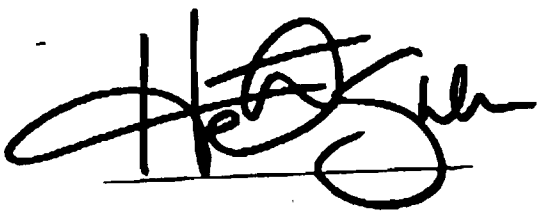
Sincerely,

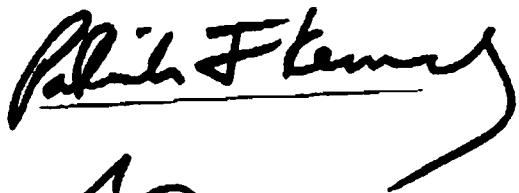
Marion Berry

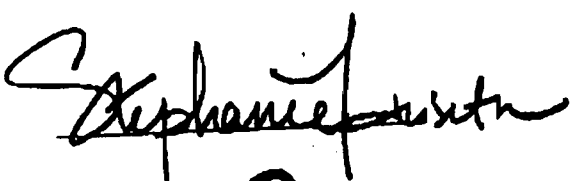
Jerry Moran

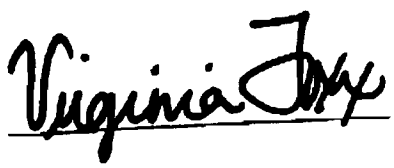
Robert B. Aderholt

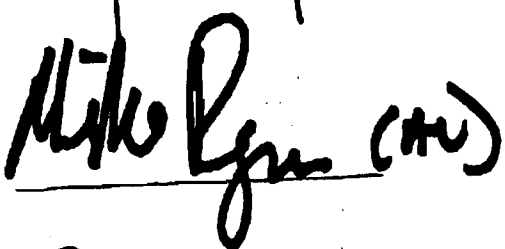


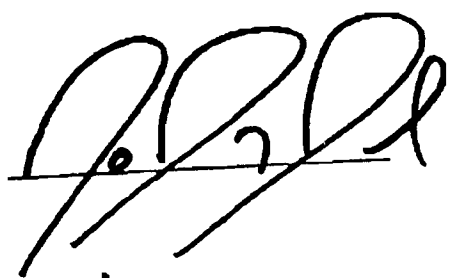


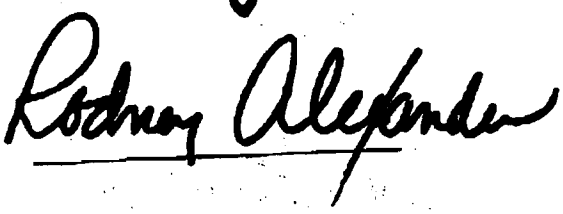




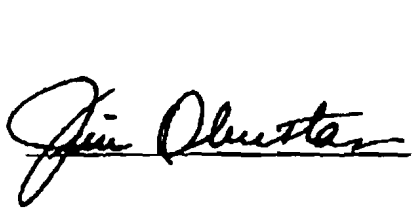


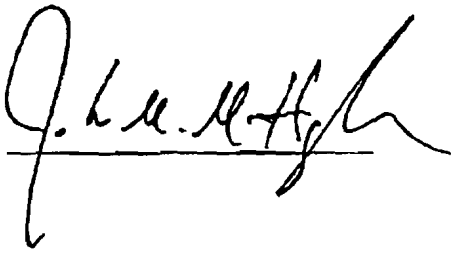


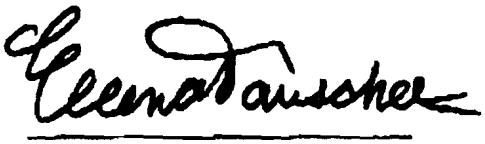


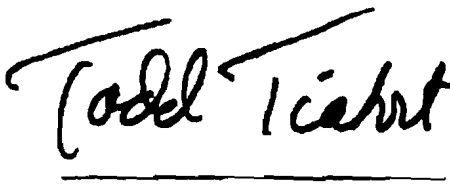


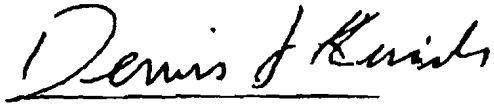
Mike Ross

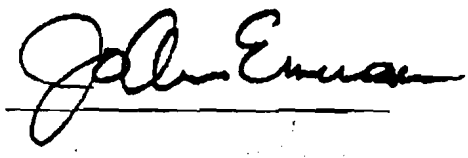


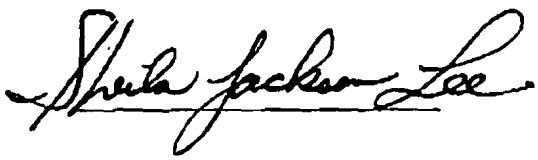


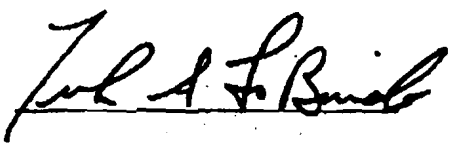


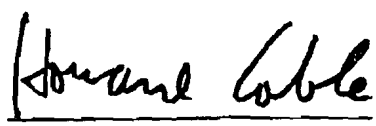


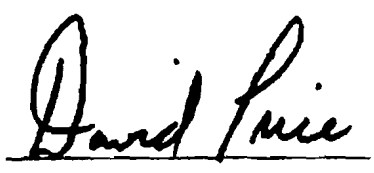


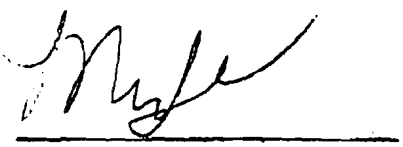


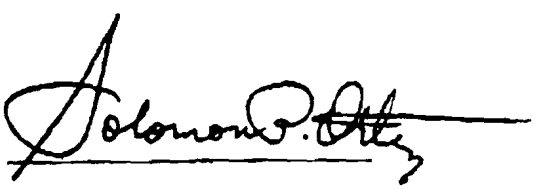












Peter Hoekstra

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Geoff Davis

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Jay Inslee

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Jason Altmire

Bruce Braley

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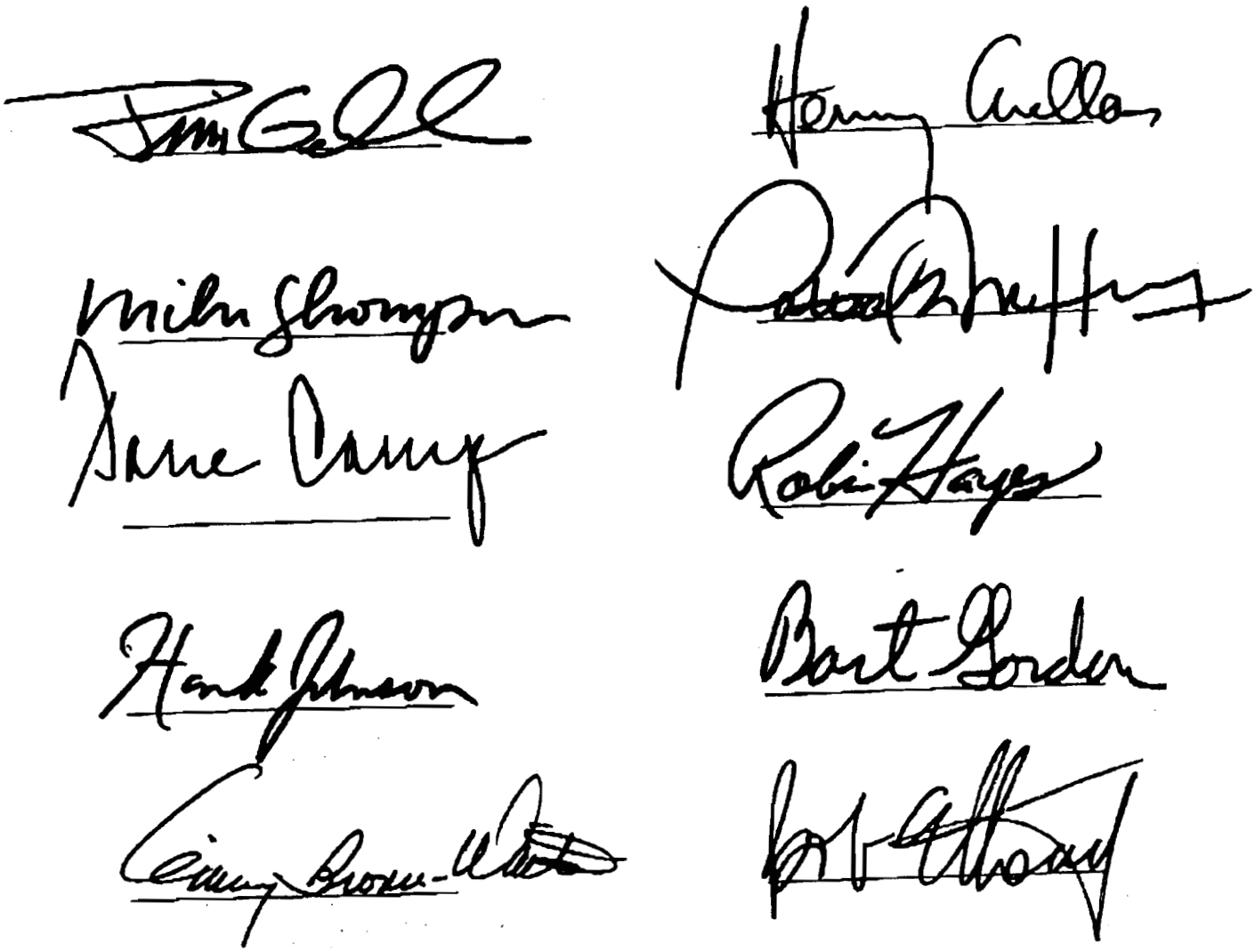

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UNITED STATES
HOUSE OF REPRESENTATIVES

January 23, 2007

The Honorable Michael O. Leavitt
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Leavitt:

I write regarding an issue that directly impacts the ability of women in Minnesota and around the country to have access to the health care they need.

As you may know, the Deficit Reduction Act (DRA) (P.L. 109-362) included a provision to limit the ability of drug manufacturers to exclude drug sales at a nominal price from the determination of the best price for prescription drugs under Medicaid. Under the provision, manufacturers can only sell nominally priced drugs to organizations eligible for the 340B discount, intermediate care facilities for the mentally retarded, state-owned or operated nursing facilities, as well as, any other facility that the Secretary determines is a safety net provider. This provision went into effect on January 1, 2007.

Unfortunately, as a result of this restriction, there are publicly funded family planning clinics, such as the Family Tree Clinic in my district, which no longer qualify for nominal pricing for the contraceptives that they formerly provided to thousands of low-income, uninsured women. Ortho-McNeil Pharmaceutical used to provide many community and public health clinics with contraceptives for $3.25 per packet; however, Ortho-McNeil is no longer offering the reduced price and clinics are forced to pay the market rate of $36-$38 per packet, as a result of the DRA provision. This is not affordable, and it is simply not a realistic option for the women served by publicly funded family planning clinics. I am very concerned about this situation because the effect is that too many woman and families will lose access to comprehensive reproductive and family planning services. Access to contraceptives is critical in preventing unintended pregnancies and consequently, abortions. In addition, delaying access to preventative care will cause more expense in the long run.

For these reasons, I strongly urge you to use your discretion, under the DRA, to allow publicly funded family planning clinics, who are not Title X grantees, to be designated safety net providers so that they may continue to provide women with vital reproductive health care services.

Thank you for your prompt attention to this important matter.

Sincerely,

Betty McCollum
Member of Congress

610523

Secretary's Correspondence

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE SECRETARY
EXECUTIVE SECRETARIAT

From:	**Betty McCollum**	*OS#:*	**012920070034**
Organization:	**U.S. Congress**	*Date on Letter:*	**1/23/07**
City/State:	**Washington DC**	*Date Received:*	**1/29/07**
On Behalf Of:		*Type:*	**Congressional**

Subject: **Writes regarding provision of the Deficit Reduction Act to limit the ability of drug manufacturers to exclude drug sales at a nominal price from the determination of the best price for the drugs under medicaid. Feels restriction prevent publicly funded family planning clinics such as the Family Tree Clinic, from qualifying for nominally priced contraceptives provided to low-income, uninsured women.**

Assigned to:	**CMS**	*Dep.ES:*	**Ashley Files**
PC:	**Suzanne Hassett**	*Date Assigned:*	**1/29/07**
Action Required:	**Sec Sig**	*Date Reassigned:*	
		Reply Due Date:	**2/6/07**

Info Copies To: **Files, Ashley (HHS/OS); Hassett, Suzanne (HHS/OS); SWIFT, ASAM; SWIFT, ASBTF; SWIFT, ASL; SWIFT, ASPA; SWIFT, ASPE; SWIFT, FDA; SWIFT, IGA; SWIFT, OGC; SWIFT, OPHS**

Interim (Y/N):	**No**	*Date Interim Sent:*	
Comments:			
File Index:	**PO-2-3**	*CCC:*	**Ottis Hamilton**

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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

January 31, 2007

Via Electronic Transmission

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

Dear Acting Administrator Norwalk:

The United States Senate Committee on Finance (Committee) has exclusive jurisdiction over the Medicare and Medicaid programs. Accordingly, the Committee has a responsibility to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to oversee the proper administration of these programs, including reviewing pricing practices that could impact the cost to taxpayers of purchasing prescription drugs. In recent years, the cost to Medicaid of purchasing prescription drugs has grown faster than any other single area of the program. As a result of the combination of increasing costs and tight fiscal constraints, some States have been forced to reduce prescription drug benefits. Considering that prescription drugs are such an integral part of quality health care, such reductions in benefits may be detrimental to the health of Medicaid beneficiaries.

During the 109th Congress, the Committee studied issues relating to the Medicare and Medicaid programs' coverage of prescription drug benefits, including the use of the nominal price exception (NPE/nominal pricing) under the Medicaid Drug Rebate Program.[1] We write to share our findings to assist you in the rulemaking process in which you are currently engaged.

In particular, the Committee was concerned about the consequences of nominal pricing when used as a marketing tool, including, but not limited to, driving up best price and lowering the amount of rebates manufacturers pay States for Medicaid drugs. Based on the Committee's review of nominal pricing, our Committee Staff crafted legislative provisions regarding the NPE in the Deficit Reduction Act of 2005 (DRA), which the President signed into law on February 8, 2006. Section 6001(d) of the DRA requires manufacturers to report information on sales at nominal prices to the Secretary of Health and Human Services (HHS). It also specifies the purchasers for which sales at nominal prices may be excluded from the calculation of best price. It limits the merely nominal exclusion to sales at nominal prices to the following: a covered entity described in section

[1] Congress amended the Social Security Act by adding section 1927, which created the Medicaid Drug Rebate Program for outpatient pharmaceuticals, when it passed the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990).

340B(a)(4) of the Public Health Service Act (PHSA), an intermediate care facility for the mentally retarded (ICF/MR), a State-owned or operated nursing facility, and any other facility or entity that the Secretary determines is a safety net provider to which sales of drugs at a nominal price would be appropriate, based on certain factors such as type of facility or entity, services provided by the facility or entity, and patient population.

On December 16, 2006, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule seeking to implement the provisions of the DRA pertaining to prescription drugs under the Medicaid program. The proposed rule addressed the changes to the nominal price exception contained in section 6001(d) of the DRA, but failed to give the Secretary the full authority Congress intended. The proposed rule includes three of the four categories of purchasers for which manufacturers will continue to be able to exclude sales made at nominal prices from their best price calculations. CMS's elimination of the fourth category concerns us. The proposed rule also addresses a broad range of issues relating to the determination of average manufacturer price (AMP), determination of best price, treatment of authorized generics, and new manufacturer reporting requirements, among others. In particular, we noted that CMS raised concerns regarding the continued use of the NPE as a marketing tool:

> CMS has concerns that despite the fact that the DRA limits the nominal price exclusion to specific entities, the nominal price exclusion will continue to be used as a marketing tool. Historically, patients frequently remain on the same drug regimen following discharge from a hospital. Physicians may be hesitant to switch a patient to a different brand and risk destabilizing the patient once discharged from the hospital. We believe that using nominal price for marketing is not within the spirit and letter of the law. We are considering crafting further guidance to address this issue. CMS invites comments from the public to assist us in ensuring that all aspects of this issue are fully considered.

Based on the Committee's review of how the pharmaceutical industry has used the NPE under the Medicaid Drug Rebate Program, we share CMS's concern that nominal pricing may continue to be used as a marketing tool. The purpose of this letter is to report to CMS the Committee's findings with respect to its review of nominal pricing.

In 2004, we sent letters to 19 pharmaceutical manufacturers requesting information and data to assess how frequently the NPE was used, in what contexts, and for what purposes. In addition, we sought to determine: (1) whether, and to what extent, the NPE is used to promote access to prescription drugs as intended by Congress; and (2) whether refinements should be made to the existing statutory language to ensure that the NPE is not used for purposes other than those intended. Our Committee Staff focused on the top twenty pharmaceutical manufacturers, based on U.S. sales in 2003.[2] Our Committee Staff also focused on data related to eight leading therapeutic drug classes by U.S. sales

[2] http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_42720942_44304255,00.html One of the top-twenty manufacturers was excluded because it did not manufacture a brand name drug.

in 2003.[3] The eight drug classes reviewed were: statins, proton pump inhibitors, anti-depressants, anti-psychotics, erythropoietins, seizure disorder drugs, calcium channel blockers, and anti-arthritics/non-steroidal anti-inflammatory drugs (NSAIDs).[4]

In 2005, we sent a second letter to the same 19 pharmaceutical manufacturers based on concerns that some manufacturers appeared to be applying the NPE more broadly than Congress originally intended. The second letter requested information to understand further how some manufacturers used the NPE and why some others were not using it. Some manufacturers were asked about their use of the NPE for periods of only one quarter. A number of manufacturers were asked why they did not utilize nominal pricing, whether the manufacturers' customer bases included charitable organizations, and whether other discounts or special pricing were offered to those customers. Finally, we sent a third letter to one manufacturer, after our Committee Staff determined that one manufacturer had used the NPE outside the timeframe of the Committee's inquiry. This third letter focused specifically on that manufacturer's past policies and practices with respect to the NPE. All manufacturers voluntarily complied with the Committee's requests for documents and information.

Our Committee Staff reviewed the manufacturers' responses, including information regarding written policies and procedures related to the NPE and sales information on specific drugs. After reviewing the first and second round of responses, our Committee Staff identified several specific practices and held meetings with the six manufacturers that engaged in one or more of those practices to learn more about them. The Committee Staff also contacted one manufacturer that did not engage in nominal pricing to learn more about why it had not used the NPE. During those conversations, our Committee Staff also solicited opinions from the manufacturers' representatives as to whether the NPE should be subject to legislative or administrative changes.

In addition to information gathered directly from the pharmaceutical manufacturers, our Committee Staff considered other relevant sources of information, including: reviewing various reports prepared by the Government Accountability Office (GAO) and the Office of Inspector General (OIG) at HHS related to prescription drug coverage under Medicaid; analyzing HHS regulations regarding the Medicaid Drug Rebate Program; and reviewing publicly available complaints and settlement agreements from lawsuits where the use of the nominal price exception was part of alleged misconduct by a number of pharmaceutical manufacturers. Our Committee Staff also held meetings with CMS, the Department of Veterans Affairs (VA), the HHS OIG, and the GAO to discuss the Medicaid Drug Rebate Program generally and the NPE specifically.

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[3] http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_42720942_44304299,00.html

[4] Some manufacturers did not produce a drug in any of the eight classes, therefore specific drug information and data were not obtained from those manufacturers.

Our Committee Staff determined that the NPE was used primarily as a competitive or marketing tool among the pharmaceutical manufacturers surveyed and was not used primarily for charitable purposes as intended by Congress. Our Committee staff made eight observations based on the information submitted to and obtained by the Committee:

1. Most manufacturers surveyed used the NPE inconsistent with Congressional intent

2. Most manufacturers' policies did not reflect use of the NPE for charitable purposes

3. Most manufacturers used the NPE for products in the best-selling classes of drugs

4. Hospitals appeared to be the primary recipients of nominal pricing

5. Most manufacturers did not differentiate between for-profit and not-for-profit entities when offering nominal pricing

6. A charitable purpose was rarely a factor considered by manufacturers in deciding to offer nominal pricing

7. Manufacturers' nominal pricing agreements frequently included market share requirements

8. Manufacturers' overall use of the NPE appears to have declined from 2003 forward

The Committee's findings and observations are discussed below in more detail, preceded by a brief background regarding the rationale for and Congressional intent behind the NPE and its use for charitable purposes.

Nominal Pricing Background

Congress included the NPE in the Medicaid reforms of OBRA 1990 to ensure that efforts to more closely align Medicaid's drug pricing with pricing for private purchasers did not threaten the steep discounts on pharmaceutical products offered to certain purchasers. Recognizing that charitable and other organizations that provide health care to populations with limited access to health care often receive special discount prices for pharmaceutical products, Congress wanted to encourage manufacturers to continue offering deep discounts to such purchasers. Specifically, by excluding nominal prices from a manufacturer's best price calculation, Congress, under the original law, intended to allow pharmaceutical manufacturers to continue offering discounts to charitable organizations without dramatically increasing the rebate due to states. If nominal prices were not excluded from a manufacturer's best price calculation, a manufacturer that offered discounts to charitable organizations greater than those offered to regular customers would have to remit to the State Medicaid program a rebate for the difference

between AMP and the deeply discounted price. Concerned that manufacturers might stop offering such discounts as a result, Congress saw the nominal pricing exception as a way to maintain the practice of deep discounts to charitable organizations while still attempting to more closely align Medicaid's drug pricing with pricing for private purchasers.

Legislative history provides some insight into the intended purpose of the NPE as originally crafted. In 1990, before Congress passed OBRA 1990, the then-Chairman of the Senate Special Committee on Aging prepared and submitted for publication in the Congressional Record a statement entitled "Analysis of Drug Manufacturer Medicaid Drug Discount Proposals and Necessary Elements of Medicaid Drug Price Negotiation Plan," which stated that under the Rebate Program, the "merely nominal" prices that were excluded from best price calculations were those "such as the sale of birth control pills for a penny a pack to Planned Parenthood." A report by the Senate Special Committee on Aging, entitled "Developments in Aging: 1990," echoed this explanation for the exception, stating that "Congress did not want to threaten" the dramatic discounts offered to "charitable organizations and clinics" by requiring manufacturers to calculate and remit rebates based on prices not calculated with the market or any profit motive in mind.[5] During Congressional deliberations on OBRA 1990, the Senate Committee on Finance refined this explanation of "nominal price" slightly by defining the prices offered to Planned Parenthood, for example, as "token" prices.

Our Committee Staff held discussions with CMS officials regarding the regulatory history of the NPE. CMS officials told our Committee Staff that the definition of nominal as less than ten percent of AMP was the product of negotiations involving pharmaceutical manufacturers, pharmacists and the States. Specifically, CMS officials stated that the charitable intent behind including the NPE in the original law was mentioned during those negotiations.

The Department of Veterans' Affairs (VA), a major purchaser of drugs, has defined nominal prices more narrowly than CMS and described the conditions under which it believes nominal pricing may be used. In 1996, the VA Office of General Counsel sent a letter to pharmaceutical manufacturers that included the following discussion of nominal pricing:

> The "nominal" pricing exclusion in the Veterans Health Care Act of 1992, Section 603 (38 U.S.C. 8126) was not intended to protect incentive use schemes by eliminating from non-FAMP calculations all below-cost sales of a covered drug that result from customers' purchases of sizable quantities of packages at a standard commercial price. VA views "nominal" pricing as being pricing, usually below cost, designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.

In addition, in 2000, the VA proposed amending its Master Agreement with pharmaceutical manufacturers to define "nominal price" as "[a]ny price less than 10% of the non-FAMP in the previous quarter from a sale (usually below cost) designed to

[5] S. Rep. No. 102-28(I) (Mar. 22, 1991).

benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a drug for an experimental or non-standard purpose.[6] VA officials advised our Committee Staff that the proposed change to the Master Agreement was never adopted due to opposition from the pharmaceutical industry, however, the VA's interpretation of nominal pricing as stated in the 1996 letter has not changed.

Nonetheless, several manufacturers surveyed by the Committee asserted that the NPE in no way limits sales at nominal prices to not-for-profit or charitable organizations. Several manufacturers, including those who did not use the NPE, stated to the Committee that sales at nominal prices are defined mathematically and are not limited to certain charitable organizations. For example:

> Company G: ". . . the Act does not restrict nominal pricing solely to not-for-profit entities . . . ."
>
> Company J: "It is the company's understanding that, as currently defined by Congress, the Medicaid Rebate Agreement and CMS, a nominal price is determined mathematically as any price less than ten percent of the AMP in the same quarter for which the AMP is computed."
>
> Company K: "[Company K] interpret[s] the phrase "nominal price," for purposes of the Medicaid program, to denote a quantitative test in accordance with Section 1.(s) of the Medicaid rebate template issued by [CMS]."

It appears to us that manufacturers were on notice that the primary intent of the NPE was to benefit charitable organizations. We note that some manufacturers have been legally counseled against broadly interpreting the NPE. For instance, one major law firm in Washington advised its clients in a "Health Care Reimbursement Client Alert: Medicaid Rebate Program," with the following precautionary statement:

> The exclusion of nominal prices from BP [best price] calculations was primarily intended to avoid a chilling effect on manufacturers' in-kind contributions to charitable programs. CMS has adopted a bright-line rule that a nominal price is any price lower than 10% of AMP for the quarter. . . . Clients should also be careful if relying on nominal price in ordinary commercial situations where the absence of a purchase requirement might be questioned, because the exclusion of nominal prices is likely to be interpreted narrowly by CMS and it could be an area of potential inquiry on audit.

It appears to us that language in the explanatory material submitted by the Committee during consideration of OBRA 1990 and the subsequent Senate Committee on Aging report support the rationale and Congress's intent to limit the use of the NPE to charitable purposes. Congress most certainly did not intend for manufacturers to use the NPE as a marketing tool. Recognizing that nominal price is not defined by statute and that the definition adopted by CMS did not limit its applicability to charitable organizations, Congress enacted the DRA provisions requiring manufacturers to report

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[6] The Committee does not have the original draft amended Master Agreement, but obtained this definition from the American Bar Association's response to the proposed amendments.

information on sales at nominal price to the Secretary and specifying the entities to which the nominal price exception applies.

Nominal Pricing Observations

1. Most Manufacturers Surveyed Used the NPE Inconsistent with Congressional Intent

Based on the information provided to the Committee by the manufacturers surveyed, it appears the pharmaceutical industry's practice with respect to the NPE can be grouped into three general categories: 1) manufacturers that appeared not to use the NPE; 2) manufacturers that appeared to use the NPE consistent with Congressional intent; and 3) manufacturers that appeared to use the NPE inconsistent with Congressional intent. Four manufacturers fell into category 1, three fell into category 2, and the majority of the manufacturers—12 out of 19—fell into category 3.

Manufacturers J, L, O and R, reported that they did not use the NPE. Manufacturer R, however, stated that it ". . . may consider use of the NPE under circumstances where it is commercially useful to do so and where it can be offered for all sales of a particular product to the relevant customer or customers for a period of at least one full calendar year." All 19 manufacturers reported having charitable organizations in their customer base and no manufacturers reported refraining from nominal pricing because it was ambiguous. Manufacturers L and R indicated that although they did not use the NPE, they provided their products for free through patient assistance programs and other organizations.

Manufacturers C, G, and M provided information to the Committee that appeared to demonstrate use of the NPE consistent with Congressional intent. Manufacturers C and G sold drugs at nominal prices exclusively to not-for-profit organizations and did not place any conditions on sales at nominal prices. These manufacturers did not make nominal prices available to any not-for-profit organizations and only a very limited number of drugs were made available at nominal prices. In addition, Manufacturer C only offered nominal pricing for a limited period and did not offer any of its drugs for sale at a nominal price at the time of the Committee's inquiry. Manufacturer M had a general policy not to offer its drugs for sale at nominal prices, but continued to offer a drug it acquired to a single not-for-profit organization pursuant to a pre-existing agreement.

Twelve manufacturers—A, B, D, E, F, H, I, K, N, Q, P, and S— provided information to the Committee that appeared to demonstrate use of the NPE inconsistent with Congressional intent. Information regarding use of the NPE inconsistent with Congressional intent is discussed more fully below.

2. Most Manufacturers' Policies Did Not Reflect Use of the NPE for Charitable Purposes

Not one of the 19 manufacturers surveyed had written policies or procedures that addressed use of the NPE; however, several manufacturers provided policies, operations

procedures, best price assumptions, or similar documents that explicitly defined nominal price and/or addressed the inclusion of nominally priced drugs in calculating best price. Most manufacturers provided a description of their nominal pricing policy, but this was typically limited to a description of how pricing practices/proposals/contracts are evaluated or a statement that the company does not routinely make sales involving the NPE. Most manufacturers' policies did not reflect an intent to use the NPE for charitable purposes. The policy descriptions provided by the manufacturers surveyed included the following statements:

> "[Manufacturer Q] does not routinely make sales at nominal price, therefore we are not able to describe in detail the factors and circumstances which [Manufacturer Q] takes into account in determining whether sales of covered outpatient drugs should be made at prices that are considered to qualify for the nominal price exception. Instead, [Manufacturer Q] would review each transaction on a case-by case basis to ensure that the transaction met all legal requirements and that the transaction had a rational business purpose..."

> "Contract Prices that are less than 10% of a quarter's Average Manufacturer Price ("AMP") are excluded from Best Price." [Manufacturer P]

> "Some products in [Manufacturer P's] product line have generic alternatives, and [Manufacturer P] sometimes elects to lower prices to establish price parity with generic products. From time to time, this price matching may have resulted in a price that could be calculated as nominal according to the definition set forth in the statutes. [Manufacturer P] has generally applied the NPE to these prices."

> "Specific pricing at ten percent of AMP or less is not offered as a condition of sale; however, when various discounts or other price concessions for a particular customer are aggregated, it may be that some portion of the total price reduction may be conditioned on the promise to purchase one or more additional drug products. We note that such offers are contemplated by and protected by elements of federal law, to the extent that certain conditions are met. " [Manufacturer F]

In addition, only two manufacturers—G and I—specifically described the types of entities eligible for the NPE and only Manufacturer I specifically indicated that its policy was to use the NPE for charitable purposes.

3. Most Manufacturers Used the NPE for Products in the Best-Selling Classes of Drugs

The Committee obtained information regarding 84 drugs that were offered at nominal prices by the manufacturers surveyed. Eighteen of these products were among the eight best-selling classes of drugs. Ten of the 15 manufacturers that offered nominal pricing offered at least one of these drugs at the NPE. Three manufacturers only offered nominal pricing for their products in the eight best-selling classes of drugs. Of at least 30 drugs still offered at nominal prices as of March 2005, four were in the eight-best selling classes.

Two of the three manufacturers that used the NPE consistent with Congressional intent offered nominal pricing on drugs from the eight best-selling drug classes. Manufacturer C offered nominal pricing on only one drug and, of the three drugs offered by Manufacturer G at nominal prices, two were in the eight best-selling classes.

4. Hospitals Appeared to be the Primary Recipients of Nominal Pricing

Hospitals appeared to be the primary recipients of nominal prices offered by those manufacturers that used the NPE consistent with Congressional intent. For those manufacturers that provided nominal prices only to not-for-profit entities, the NPE was only available to select not-for-profit entities. Manufacturer C offered nominal pricing to disproportionate share hospitals (DSH) that were participating covered entities in the 340B program, acute care teaching hospitals, and Federal government facilities purchasing from the Federal Supply Schedule. Manufacturer G offered nominal pricing "only with respect to certain of its products and only for certain not-for-profit hospitals."

Hospitals were also the primary recipient of nominal pricing offered by those manufacturers whose use of nominal pricing appeared inconsistent with Congressional intent. Of the 12 manufacturers that offered nominal pricing to both for-profit and not-for-profit customers, six manufacturers indicated that hospitals were their only, or main, recipients of nominal prices. Another three manufacturers indicated that HMOs were offered nominal pricing. Some manufacturers identified the types of hospitals that received nominal pricing, which included acute care hospitals, DSH hospitals, teaching hospitals, and public hospital systems. Other recipients of nominal pricing identified by the manufacturers surveyed included Public Health Service covered entities, entities that serve the uninsured and organizations that offer family planning services.

By making the NPE available almost exclusively to hospitals, it appears manufacturers may have encouraged use of their drugs to the exclusion of competing products. They may also have created a spillover effect whereby patients who received their drugs while in the hospital continued to use them after discharge. Based on the information provided by manufacturers, the Committee cannot conclude that the primary intent of those manufacturers offering nominal pricing to hospitals was to compete against other manufacturers' products or create a spillover effect. However, other information obtained by the Committee suggests that the use of nominal pricing in hospitals may increase demand for a product outside the hospital setting.

For instance, comments submitted to the VA in response to its efforts to narrow the definition of nominal price acknowledge that market penetration was the primary goal of providing nominal pricing to hospitals. The American Bar Association and at least one law firm representing a manufacturer, wrote to the VA concerning the nominal price definition in VA's 2000 draft Amended Master Agreement, and stated: "Nominal prices have historically been granted to entities that do not fit within the VA's narrow definition. For example, a manufacturer may grant nominal prices to hospitals in order to penetrate an established market . . ."

5. Most Manufacturers Did Not Differentiate Between For-Profit and Not-for-Profit Entities

Although many of the hospitals and other organizations that were offered nominal prices may have been not-for-profit companies, not one of the manufacturers surveyed indicated that this was the reason for offering nominal pricing. The Committee asked the 12 companies that appeared to use nominal pricing beyond Congressional intent to identify differences in the way they treated for-profit and not-for-profit customers with respect to determining eligibility for nominal pricing. One manufacturer did not address the question, and the remaining 11 manufacturers indicated that there was no difference in how for-profit and not-for-profit organizations were treated. The following are sample responses from a few of these manufacturers:

> "Purchasers are not limited to non-profit entities." (Manufacturer P)
>
> "In offering nominal pricing, [Manufacturer A] does not distinguish between for-profit and not-for-profit entities, consistent with the Medicaid rebate statute and the Medicaid rebate agreement."
>
> "[Manufacturer B] has not made distinctions between for-profit and not-for-profit hospitals when determining eligibility for nominal prices."

6. A Charitable Purpose Was Rarely a Factor When Offering Nominal Pricing

The Committee asked manufacturers to describe the factors and circumstances taken into account when determining whether sales of covered outpatient drugs should be made at nominal prices. Only one of the 15 manufacturers that reported using the NPE indicated that the existence of a charitable purpose was a factor considered when offering nominal pricing, while most manufacturers that reportedly used the NPE indicated that competitive market factors were taken into account when offering nominal pricing. Four manufacturers did not indicate to the Committee the factors and circumstances they took into account when offering nominal prices. One manufacturer reported that it used nominal pricing on a case-by-case basis when all legal requirements were met and a rational business purpose existed. Seven manufacturers listed a variety of factors, including: the business or competitive environment for a product; the degree of formulary control exercised by eligible customers; potential to increase patient access to the product; health outcomes information; and patient population, affordability and public policy considerations.

The following statements were made by manufacturers that indicated factors other than a charitable purpose, such as competitive marketing, when determining whether sales of covered outpatient drugs should be made at prices that are considered to fall within the NPE:

> "[Manufacturer I] may offer Nominal Pricing on Multiple Source Drugs (i) to meet generic pricing on that same drug or (ii) to government entities and to not-for-profit institutions for charitable purposes."
>
> ". . . .[Manufacturer P] sometimes elects to lower prices to establish price parity with generic alternatives to its products. From time to time, this pricing parity may have resulted in a price that could be calculated as nominal according to the

definition set forth in the Medicaid Rebate Agreement, and in such instances, [Manufacturer P] has applied the NPE to these prices."

"[Manufacturer E was presented with credible evidence of] a price offer from a generic manufacturer that was nominal relative to the Company's pricing structure for [drug]. The Company exercised its right of first refusal and entered into a contract to sell [drug] to [customer] at the low price, hoping to maintain brand loyalty through [customer's] significant presence in the market."

"Again, the determinative criteria were the competitive product pricing and the degree of formulary control involved." (Manufacturer S)

"[Manufacturer K] consider[s] the market for the product (e.g., sites of demand, training medical practitioners, ability to influence prescriber or patient behavior, or formulary position), the nature of the customer, and the competitive environment (existence of generic or lower cost competition)."

"When determining whether and to whom sales of covered outpatient drugs should be made at nominal prices, as that term is defined in the rebate statute and rebate agreement, [Manufacturer A] takes into account the relevant customer(s) and the relevant economic and market conditions for sale of that particular product. For example, [Manufacturer A] will consider the overall pricing strategy for the product, the performance and pricing of competitive products, other discounts offered on the product, the type of customer, the potential to increase patient access to the product, and the effect of any discounts (nominal or otherwise) on net sales."

"The existence of alternative products has generally been a factor in [Manufacturer N's] contracts with nominal pricing in that [Manufacturer N] typically entered into those contracts at or near the time of patent expiration for certain products in order to try to retain sales in the face of competition from generic alternatives. While far less common, [Manufacturer N] has also from time to time entered into nominal pricing arrangements for certain products not facing generic competition in situations involving alternative products, such as situations involving nominal pricing from a competitive branded product."

[Manufacturer H] takes a number of factors into consideration in developing pricing and contracting strategies, including any decisions about whether nominal pricing would be included in our strategies. Those factors include, among others, the business environment for a specific product, the number of competing products, health outcomes information, patient population, competitor pricing, affordability, and public policy considerations.

7. Nominal Pricing Agreements Frequently Included Market Share Requirements

A majority of the 15 manufacturers that reported using nominal pricing placed conditions or limits on the offer of nominal pricing. The Committee asked manufacturers what types of contractual arrangements govern their company's drug sales that fall under the NPE and specifically mentioned market share requirements and single quarter nominal pricing. Three manufacturers—F, G, and Q—did not provide information on the contractual terms associated with nominal pricing. Another three manufacturers—C, E, and M—indicated that there are no conditions attached to their offers of nominal pricing,

and one manufacturer—B—stated that, except for nominal price contracts with DSH hospitals, contracts for sales at nominal prices generally included a market share requirement. The remaining eight manufacturers—A, D, H, I, K, N, P, and S—all indicated that contracts for sales at nominal prices involved one or more of the following requirements or arrangements: market share requirements, volume requirements, nominal prices offered only for a single quarter of the year, formulary placement requirements, and unrestricted access requirements. Examples of manufacturer's statements about these terms follow:

> "Contracts offering Nominal Pricing may include a market share percentage provision." (Manufacturer I)
>
> "Generally, [Manufacturer A] pricing to institutional customers, including hospitals, conditions discounts on various factors such as agreements to make products available to patients on a less restrictive basis than would otherwise be the case and market share performance criteria."
>
> 'Market share requirements may or may not be the basis for some of a series of discounts or other price concessions that may result in NPE pricing." (Manufacturer F)
>
> "A market share percentage is included in [Manufacturer B's] contracts with hospitals as a requirement for eligibility for nominal pricing."
>
> "Certain historical contracts that included nominally priced products required formulary access for the nominally priced product, and/or for some or all of the other products in the contract." (Manufacturer N)
>
> "Certain historical contracts that included nominally priced products may have required, in addition to formulary access or availability, the customer to make a greater commitment to using the nominally priced and/or certain other products in the contract by granting them 'preferred' or 'exclusive' positioning." (Manufacturer N)

All of these conditions or terms appear designed to increase the use of the product being offered at a nominal price. The Committee believes that the inclusion of such terms in nominal pricing contracts signals that the primary intent of the nominal price offer was to increase market share, and was therefore inconsistent with Congressional intent.

Use of the NPE May Be Declining

As of March 2005, most of the manufacturers that reported using the NPE indicated that they had reduced their use, stopped using it, or planned to stop using it once existing NPE contracts expired. While most of the practices uncovered would not be permitted under the DRA, only two manufacturers did not indicate an intention to eliminate or limit use of the NPE. Five manufacturers no longer used the NPE at all, and eight manufacturers had reduced or limited their use of the NPE. One manufacturer explained that it was reducing use of the NPE because it originally used nominal pricing only in an effort to meet price competition from a competitor that was offering its

products at nominal price. Two manufacturers explained their decision to stop using nominal pricing as follows:

> "[Manufacturer N] discontinued its nominal pricing practices after concluding that the technical and administrative complexity and cost needed to sustain the nominal pricing programs outweighed the limited commercial benefits of preserving such programs."

> "[Manufacturer S] evaluated the commercial results of each of its nominal price contracts and determined that these discounts were not commercially justified."

As with some manufacturers' rationale for offering nominal pricing, the rationale offered for discontinuing nominal pricing also appear related to pricing or business strategies.

We respectfully submit these findings and observations to assist CMS as it considers crafting further guidance to address the use of the nominal price exception as a marketing tool. In addition, we respectfully request that CMS keep the Committee fully informed regarding the development of additional guidance and/or regulations pertaining to the NPE. Finally, please let us know whether or not further statutory changes may be necessary to address our shared concern regarding the NPE.

We look forward to hearing from you regarding the contents of this letter by February 15, 2007. In particular, we are interested in your addressing the reason why, in the proposed rule, the Secretary was not given the full authority Congress intended. Any questions or concerns should be directed to our Committee Staff, David Schwartz and Emilia DiSanto, at (202) 224-4515. *All correspondence should be sent via facsimile to (202) 228-2316 (majority) and (202) 228-2131 (minority), and original by U.S. mail.* All formal correspondence should be sent via electronic transmission in PDF format to thomas_novelli@finance-rep.senate.gov or via facsimile to (202) 228-2131 and original by U.S. mail.

Sincerely,

Max Baucus
Chairman

Charles E. Grassley
Ranking Member

United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510–6200

February 14, 2007

2007 FEB 15 AM 11:04

Via Hand Delivery

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

Dear Acting Administrator Norwalk:

I am writing regarding my concerns with how CMS is implementing certain Medicaid pharmacy pricing provisions of the Deficit Reduction Act of 2005 (DRA). Specifically, I am concerned with several provisions in CMS's December 15, 2006 notice of proposed rulemaking on Medicaid drug pricing.

While I was encouraged by the speed with which you issued the proposed regulation and by your multiple requests for public comment, a number of decisions you made are likely to adversely affect community pharmacies. In my view, CMS should issue a final regulation that protects Medicaid beneficiaries' access to their local community pharmacist, creates incentives to use generic drugs, and strengthens the pharmacy infrastructure. Your proposed regulation falls short of achieving these goals.

Publication of AMP Data

In a letter I sent to then-Administrator McClellan on May 23, 2006, I said that the release of inaccurate and inconsistent average manufacturer price (AMP) data could cause disruptions in the Medicaid program and the broader pharmaceutical marketplace, and could have devastating unintended consequences to community pharmacies in Montana and across the country. In that regard, I believe that CMS made the correct decision last spring to not release the AMP data.

CMS has now said that it will release AMP data for brand name and generic drugs this spring. Nothing, however, has changed in the way that manufacturers calculate AMP that would make it a more consistent or reliable benchmark for pharmacy reimbursement. Because AMP has never been used as a basis for pharmacy reimbursement before, it is imperative that it be as accurate and consistent as possible. Therefore, I continue to

believe that AMP data should not be released until it is calculated based on a uniform definition that is used by all manufacturers.

The DRA required that such a definition be developed through the rule-making process, but that process is not yet completed. It makes little sense to release current AMP data for use by states and the public if they are not consistently calculated by manufacturers, or if the method by which they will be calculated will change once the regulation's definition of AMP is made final. It does not seem that the problems that former Administrator McClellan identified with the release of AMP data in mid-2006 have been corrected, so I believe that publication now would have the deleterious effects that he foresaw. Therefore, I ask that CMS continue to delay release of AMP data until a final AMP definition is in effect.

Create Accurate Benchmark for AMP and RSP

In the letter I sent CMS last May, I said that it was critical that the drug pricing information that CMS provides to the states and public is accurate and useful. In theory, AMP is supposed to represent the approximate prices paid by retail pharmacies for medications. I am concerned, however, that AMP as defined in your proposed regulation blends the prices paid by different types of purchasers, each of which may pay a different net price for medications. For example, in addition to traditional retail pharmacy sales, manufacturers would be required to include mail order sales and pharmacy benefit manager rebates in their AMP calculations. I question the utility of a new retail pharmacy reimbursement benchmark that includes these purchasers and discounts because they distort the benchmark beyond the point where it can accurately approximate prices paid by retail pharmacies.

Moreover, CMS has also proposed to define retail survey price (RSP) as an average of prices paid by different purchasers, including traditional retail pharmacies, as well as mail order and nursing home pharmacies. I also question the usefulness of an RSP that includes a blend of all these purchasers. For that reason, I ask that CMS revisit the proposed definitions of AMP and RSP to make them more consistent with the intended purposes of these measures.

Assess Impact of New Generic Reimbursement Formula

According to CMS, the new Medicaid payment formula for generic drugs will reduce pharmacy payments for these drugs by $8 billion over the next 5 years. I am concerned that these reductions may discourage the use of lower-cost generic drugs in Medicaid. Adding to this concern is the recent Government Accountability Office (GAO) report that found that these new generic payment limits would be about 36 percent below the cost at which retail pharmacies can purchase generic drugs.

While I recognize that the GAO report has its limitations, many of which you pointed out in your comments on a draft version of the report, I am struck by the number of generic products that the report claimed would be reimbursed below the costs at which

retail pharmacies can purchase generics. Many of the drugs that GAO studied are popular and frequently used by Medicaid beneficiaries. We need to do all that we can to continue to encourage the use of lower-cost generic drugs in Medicaid when appropriate. I would like to better understand CMS' perspective on this GAO report, and ask that you expeditiously provide me with better information and data about how these new generic payment limits will affect generic drug use in Medicaid. I would also like to know what CMS is doing to encourage states and pharmacies to continue to dispense lower-cost drugs in Medicaid, which save significant amounts of federal and state taxpayer dollars.

Mitigate Financial Impact on Retail Pharmacies

Finally, I am very concerned about the collective negative economic effect of these proposed DRA changes on the traditional retail pharmacies in Montana and across the country. I believe that retail pharmacies, many of whom are already bearing the financial brunt of lower payments under Medicare Part D, will be hit hard by these changes. Community pharmacies are often the only health care providers in many communities, especially in rural areas. Given how much community retail pharmacies have done to help Medicaid programs to control their drug costs and to encourage use of generic drugs, it makes little sense to take billions of dollars out of this infrastructure. I ask that you work with me to strongly communicate with state governors and Medicaid programs about the need to increase dispensing fees, particularly for generic drugs.

Thank you for your prompt attention to my concerns. I would be happy to discuss them with you further. I look forward to your response by February 28, 2007. Please have your staff direct any questions to David Schwartz of my Finance Committee staff at (202) 224-4515.

Sincerely,

Max Baucus
Chairman

RICHARD SHELBY
ALABAMA

CHAIRMAN—COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS
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CHAIRMAN—SUBCOMMITTEE ON COMMERCE, JUSTICE, AND SCIENCE
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DHPC
611953

January 31, 2007

15 FEB 2007
7:18 am

Director
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Director:

Enclosed, please find a copy of correspondence I received from Matthew A. Colvin.

Please review the enclosed and address the concerns raised. I have notified my constituent to expect a timely reply directly from you.

Sincerely,

Richard Shelby

Richard Shelby

RCS/ept
Enclosure

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411490
655345

Ider Discount Drugs, Inc.
10705 Hwy 75
Ider, AL 35981
Ph: (256) 657-5151
Fax: (256) 657-2275

Honorable Shelby:

It is do my dismay that I once again have to write you asking for your help in the survival of my business. My name is Matt Colvin and I'm the owner of Ider Discount Drugs, Inc., in Ider, AL. Over the past several years, pharmacy has been the brunt of many cutbacks and questionable practices by PBMs (Pharmacy Benefit Managers) including irrational pricing and mandated mail order. It seems that now we face the largest hurdle of them all.

Medicaid will now reimburse under a new pricing model beginning July 1st. GAO (Government Accountability Office) has finally supplied us with information on the new reimbursement model for pricing generic medications. According to the information given on 77 of the most commonly prescribed drugs, pharmacy will lose an average of 36% on each prescription filled. On high end expenditure drugs, we'll lose approximately 65%. This is a result of pricing by AMP (Average Manufacturer Price) which is a figure that was never intended to be used for reimbursement.

Can you tell me how any business can survive by selling a majority of their products at a loss? Pharmacy is no different, we will not be able to continue to service our poor population if this pricing model is enacted. If I have to stop taking Medicaid in this rural area because I am losing money on each prescription filled, I may have to shut my doors. At best, I will have to cut jobs in an area where many jobs are not available.

It is my request that you examine this situation for us. Please work with the pharmacy organizations to correct this ill-fated situation before it is too late. Pharmacists are the front line in health care. We are accessible and we care about our people, rich and poor. Unfortunately, it appears we are going to be driven away because our government does not want to properly reimburse us.

Thank you for your time and if I can supply any additional information, please contact me.

Sincerely,

Matthew A. Colvin, R.Ph.

RICHARD SHELBY
ALABAMA

CHAIRMAN—COMMITTEE ON BANKING, HOUSING, AND URBAN AFFAIRS
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January 31, 2007

Mr. Matthew A. Colvin
Ider Discount Drugs, Inc.
10705 AL Highway 75
Ider, Alabama 35981-4627

COPY

Dear Mr. Colvin:

Thank you for taking the time to contact me regarding the new Medicaid pricing model which will begin July 1.

I have contacted the Centers for Medicare & Medicaid Services on your behalf and have asked them to respond to your concerns. You should expect a reply to your concerns directly from the agency in a timely manner. Please do not hesitate to contact me about this or other matters in the future.

Sincerely,

Richard Shelby

Richard Shelby

RCS/ept

COPY

imany™

February 16, 2007

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
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Washington, DC 20201

Finance and Administration:

I-many, Inc.
6th Floor
511 Congress Street
Portland, ME 04101

ph 207 774 3244
fax 207 828 0491

Attn: Kimberly Howell

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

Dear Ms. Howell:

We are contacting you from I-many, Inc., the leading provider of Government Pricing and Medicaid Rebate claims processing software to the pharmaceutical industry. Our many clients include 21 out of the top 25 pharmaceutical companies in the world, while over 30 US-based companies use our Government Pricing software and over 60 use our Medicaid rebating software. This position within the industry affords us a unique perspective on system issues related to the DRA. We are therefore submitting questions/comments to you via the open DRA comment period with the hope that our communication assists our clients in navigating these new regulations.

Many of our clients disagree with the statement in the preamble to the proposed rule that manufacturers should be able to accommodate DRA-related system changes with an approximate budget of $50,000.00 (71 Fed. Reg. 77192). This figure appears quite low in relation to most of our larger clients; in fact, the cost of DRA modifications at some companies has reached several times this amount, and that does not include changes that will be required after the rule is finalized. Nor does this figure include the ongoing impact of additional resources required to oversee the 12 additional annual submissions required by monthly AMP reporting and authorized generic blending. Our understanding is that manufacturers are not trying to push back on the costs necessary to comply. Rather, because CMS has asserted a conclusion regarding the financial impact of the proposed rule on manufacturers, they want to have the true costs of implementing the proposed rule and its impact on their business acknowledged by amending or withdrawing the $50,000.00 statement, which is incorrect.

Our clients have also expressed concern about reporting information. One area of concern is the discrepancy between the proposed rule and the file formats provided for the DDR system. The proposed rule indicates that manufacturers will be allowed to recalculate a DRA base date AMP to avoid a penalty caused by a change in the definition of AMP, and that quarterly customary prompt pay information should be reported quarterly (71 Fed. Reg. 77185). The most recent version of the DDR formats, however, no longer provides for these values. Additionally, despite the statement in the preamble that the amendment to the base date AMP is proposed "so that the additional rebate would not increase due to changes in the definition of AMP," the proposed rule seems to limit recalculated base date AMP to changes in accordance with the definition of AMP in section 447.504(e), which is the definition of retail pharmacy class of trade, rather than changes to the definition of AMP more generally. Nor does this explain how the revised base date AMP would be used for URA calculation purposes.

Another question relates to the timing of the product submissions. In the past, those have been sent quarterly, but with new monthly reporting, our clients are unclear as to whether the

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product filing should also be on a monthly basis. The proposed rule indicates that manufacturers are to submit "only AMP" on a quarterly basis (71 Fed. Reg. 77185). Please specify when product reports should be submitted.

Manufacturers would like clarification around all of these issues, with enough lead time for them to update their calculation and reporting systems as necessary.

As a final note, the industry is very concerned that decisions made by the PHS 340-B administration may necessitate the continuing use of pre-DRA methodology solely for the purpose of administering PHS contract pricing. As you know, 340-B ceiling prices are determined by reducing AMP by the rebate percentage. Since the calculation of the AMP is changing due to the DRA, manufacturers are being asked to calculate ceiling prices referencing an AMP that includes customary prompt pay. This is because the 340-B program believes that the ceiling price must be calculated using the AMP as defined in 1992 when that program was enacted, although AMP was not defined to include CPP until the Social Security Act was amended in 1993.

If the ceiling prices must be calculated based on pre-DRA definitions, our clients would have to calculate a separate AMP to take into account other changes, as well as a second best price to be used in calculating the rebate percentage. Requiring manufacturers to accommodate calculation of two AMPs and two rebate percentages every quarter places undue burden on them, as well as being difficult to implement in their calculation and reporting systems. Although we understand that your organization is not affiliated with the 340-B program, we ask that you collaborate with them to determine if the 340-B program can transition to DRA methodology, which would alleviate the cost and burden of dual pricing maintenance.

Respectfully submitted,

Erica Bartlett
Ericalynn Bartlett
I-many Medicaid Adjudication Product Manager
I-many, Inc.
Office: 207-228-2235
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GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

February 20, 2007

VIA HAND DELIVERY
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Comments to the Medicaid Program; Prescription Drugs Proposed Rule [CMS-2238-P]

Dear Sir or Madam:

The Generic Pharmaceutical Association ("GPhA") is pleased to submit these comments on the *Medicaid Program; Prescription Drugs Proposed Rule* (the "Proposed Rule").[1] GPhA shares the commitment of the Centers for Medicare and Medicaid Services ("CMS") to implement the Medicaid Drug Rebate Program reforms mandated by the Deficit Reduction Act of 2005 ("DRA") in ways that save money for the Medicaid program, that are practicable for manufacturers, and that do not adversely impact the care furnished to Medicaid recipients. Accordingly, GPhA appreciates this opportunity to respond to CMS' requests for comments on the Proposed Rule and to address some of GPhA's own concerns about such rule.

GPhA is an association representing the manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Together, the members of GPhA manufacture more than 90 percent of all generic pharmaceuticals dispensed in the United States.

As the primary source of generic pharmaceuticals in the country, GPhA members are committed to ensuring patient access to affordable prescription drugs. In order to ensure that this effort is not compromised, CMS should provide clear guidance and impose only operationally feasible requirements on manufacturers in connection with their calculation and submission of average manufacturer price ("AMP") and best price data. For purposes of CMS' guidance, we urge the agency to speak with sufficient clarity and specificity to ensure that manufacturers understand what is required of them. At the same time, CMS must take care to ensure that compliance with these requirements is

[1] 71 *Fed. Reg.* 77174 (Dec. 22, 2006).

feasible for manufacturers, which necessitates that manufacturers actually have access to the information that they are required to report.

In light of these concerns, GPhA supports CMS' efforts to clarify the definitions of significant terms as well as the treatment of various types of sales and prices in manufacturer calculations. However, we do have a number of recommendations for further clarification and request guidance for treatment of certain transactions when compliance with the proposed requirements is not operationally feasible for manufacturers. This operational infeasibility arises because the regulations, as proposed, require manufacturers to make calculations using data to which they do not have access. Because a chief purpose of the Proposed Rule is to obtain uniformity and accuracy in manufacturers' AMP calculations, it is critical that manufacturers understand the requirements and have the ability to implement them. We highlight this point throughout our letter.

Not only are AMP calculations skewed by this lack of data, but they are also easily misinterpreted. This misinterpretation occurs when payers, State agencies, and consumers rely on AMPs to indicate actual prices available in the marketplace. On the contrary, AMP represents only a snapshot in time (as discussed more fully below) of a complex set of sales records. In fact, given the spectrum of variables impacting AMP, there will be a different AMP for the same sale depending on the timing of the AMP calculation.

While we acknowledge that CMS has statutory obligations concerning AMP, many of our comments stem from our recognition of the flaws inherent in AMP data and the dangers of AMP publication. Accordingly we open our comments below by discussing our concerns with public disclosure. We organize our remaining comments based on the corresponding sections in the Proposed Rule.

Requirements for Manufacturers – Section 447.510[2]

Adverse Effects of Public Disclosure of AMP on the Medicaid Program

In the Proposed Rule, CMS indicates its intention to publish not only monthly AMP data, but also quarterly AMP, on the agency's website. As CMS implements this new publication provision, we strongly recommend that multiple source AMPs be reported to States and posted on the CMS website in an aggregated, industry-wide weighted average format that combines individual manufacturer AMPs into one AMP for each drug.

The public disclosure of AMP envisioned by the DRA is a concept modeled after the disclosure of Part B average sales price ("ASP"). The DRA requires that, "the Secretary shall provide on a monthly basis to States . . . the most recently reported

[2] As mentioned above, we are only addressing public disclosure of AMP here and will address other aspects of "Requirements for Manufacturers – Section 447.510" later in this letter.

average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website . . .".[3] Also, the DRA allows the Secretary to disclose "through a website accessible to the public," AMPs. However, the DRA does not provide further guidance to CMS regarding how to implement these publication provisions. Instead, the DRA leaves CMS considerable discretion concerning implementation of the public disclosure provisions.

Thus, CMS should exercise its discretion and report only the aggregated, industry-wide weighted average AMPs for multiple source drugs. Though it is unwise to make these data public at all, if CMS feels it must do so, then we recommend that the agency take into account the following important considerations when determining how to implement this publication requirement.

1. *Limitations on the Usefulness of AMP*

AMP is mistakenly perceived as an indicator of market prices. However, it bears little relevance to market price. A variety of normal business activities cause periodic deflations or inflations of AMP from month-to-month. Some such activities include reduced sales of a product due to: backorders; temporary discontinuation of a product; or low demand from a manufacturer's current customer base. Fluctuations also occur in ordinary sales where there are timing differentials between the particular sales and the application of the associated customer credits, and swings in sales and credits that make AMPs particularly unreliable during the first few months of a product launch.

By way of example, one particular type of transaction producing such a timing differential is a sale with a market share rebate. Market share rebates are always processed on a lag because the manufacturer needs to obtain customer data reflecting the percent of prescriptions filled with product from a particular manufacturer compared with product filled from all manufacturers. The lag period can result in an additional 30 to 45 or more days until the transaction is fully closed, during which time the data are compiled by the customer and verified by the manufacturer for reasonableness.

Another source of timing differentials is the stocking adjustment, which is required when the manufacturer implements a price change. A stocking adjustment is processed on a lag because the manufacturer needs to obtain customer data reflecting the inventory levels for a product at a customer's distributor centers at the date the price was reduced by a manufacturer. The lag period, again, can result in 30 to 45 or more days after the applicable period after data are compiled by the customer and verified by the manufacturer for reasonableness. Stocking adjustment dollar values can be substantial depending on inventory levels at a customer and the amount of the price decrease. The impact on AMP is even greater because of the timing of the processed credit during the period when the manufacturer is billing a customer at the new price. For example, if the manufacturer had a price of $20 during January 2006 and lowered the price to $12 during February 2006, then an adjustment claim of $8 a bottle would be processed in March 2006 when the price is $12 and give the false impression via AMP of a net $4 price or

[3] DRA § 6001(b)(1)(B).

less during March 2006 ($12 new price less the $8 adjustment for Jan 2006 inventory) depending on the customer inventory levels of the adjustment.

As these examples indicate, AMPs fluctuate regularly and sometimes significantly in the ordinary course of business. Moreover, even aside from any of these discount-related fluctuations, each product has at least three possible prices that may be included in AMP throughout its life cycle under ordinary conditions. These three prices are the following: (1) the price the wholesaler pays to the manufacturer, (2) the price the customer pays to the wholesaler, and (3) the price ultimately experienced by the manufacturer after chargebacks and other discounts in the ordinary course of business are taken into account. Because the erratic timing of transactions occurs within the ordinary course of business, AMPs published on the CMS website would not provide an accurate portrayal of the market. Using a "smoothing" mechanism to lag some of these transactions can help reduce some of the fluctuations in AMP (as discussed in more detail later in this letter) but cannot transform AMP into a reliable number.

2. *The Benefits of Generic Utilization*

Although the AMP changes are directed to Medicaid, the impact of those changes will be seen in other government health programs, such as Medicare. Analysts and policy makers routinely attribute the success of Medicare Part D to its emphasis on the use of generics, and they expect the importance of generic drugs in pharmaceutical cost management to grow over the next several years.

For example, on September 21, 2006, then-Administrator of CMS, Mark McClellan, MD, PhD, testified before the Senate that:

> The utilization of generic drugs has played an important role in the low costs and expected further cost reductions in the drug benefit. Due in part to increasing generic drug availability, strong competition in the prescription drug marketplace has led to slower rates of growth in overall prescription drug spending. Also, the availability of excellent coverage of generic drugs in the Part D drug benefit, as well as personalized information and support to help beneficiaries find out about how they can save using generics, have been important contributors to costs that are much lower than expected. Continuing to promote greater reliance on generics when available among Medicare beneficiaries is an important strategy to keep the new drug benefit affordable over the long term.[4]

As additional evidence, CMS itself just issued a press release acknowledging the role of generic drugs in reducing prescription drug costs for both consumers and payers nationwide.[5] In the course of implementing the switch from average wholesale price

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[4] "Generic Drug Utilization in the Medicare Prescription Drug Benefit," Testimony before Senate Special Committee on Aging (Sept. 21, 2006), *available at* http://www.hhs.gov/asl/testify/t060921.html.

[5] "Generic Drug Utilization on the Rise: Consumers and Payers Benefit as More Americans Turn to Generics as One Way to Save Money and Improve their Health" (February 8, 2007), *available at* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2081&intNumPerPage=10&checkDate=&

("AWP") to AMP as a reimbursement benchmark, it is important that CMS not undercut the benefits that generic pharmaceuticals bring to health care cost containment by rushing to publicize generic manufacturers' most sensitive and proprietary pricing information.

3. *The Dangers of AMP Publication*

a. *Reduced Competition*

Unlike single source drugs where the manufacturer has wide latitude to establish and maintain the price, many generic drugs are viewed as commodities to be purchased at the lowest possible price. While competition is usually healthy, publishing manufacturer-specific AMPs for generic drugs has the potential to do more harm than good by creating a never-ending downward price spiral. Such a dynamic will result in less competition in the marketplace as generic manufacturers cease to offer products that are no longer profitable within these pricing dynamics. With less competition, the end result may be higher costs for CMS for some generic products due to fewer generic choices. Publication of only aggregated, industry-wide weighted average AMPs for multiple source drugs will mitigate against this outcome.

b. *Anticompetitive Concerns*

Publishing manufacturer-specific AMPs, moreover, raises significant anticompetitive concerns. As GPhA observed in its June 9, 2006 letter to Dr. McClellan, publication of aggregate data such as an industry-wide average is supported by long-standing interpretations of the Sherman Act, which condemn conduct that could facilitate anticompetitive collusion among competitors. In the health care industry in particular, the federal antitrust enforcement agencies have consistently recognized the potential anticompetitive impact of the sharing of specific companies' internal price-related information.[6] GPhA is concerned that, as a simple matter of economics, publication of prices in such manner will lead to less competition and greater uniformity in prices. It is not that companies will act improperly, but that with greater public information, prices will just naturally tend to stabilize as manufacturers react rationally to the information available.

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[6] *See, e.g., In re Mich. State Med. Soc'y*, 101 F.T.C. 191, 270 (1983) ("There is ... some inherent danger in allowing any collective dialogue with third party payers on questions directly related to reimbursement amounts or policies."); *see also* Federal Trade Commission, Staff Advisory Opinion from Arthur N. Lerner, Assistant Director, to Dennis L. Dedecker, D.D.S., Secretary, Utah Society of Oral & Maxillofacial Surgeons (February 8, 1985) ("Depending upon the purpose or effect of the conduct, dissemination of price information by an organization of competitors can be found to constitute or facilitate an unlawful price agreement."); *see also* Department of Justice/ Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (August 1996).

c. ***Confusion Among Purchasers and Payers***

Yet another concern regarding publication of AMPs is the confusion that published prices would cause purchasers and payers. For a variety of reasons, as discussed above, many of the published prices would not be accurate indicators of the market. In addition, many of these prices would not be widely available. For instance, a manufacturer that chooses to sell a product to a single entity, regardless of volume, at a discounted price would have an atypically low AMP. A manufacturer with a large proportion of sales to large volume purchasers at discounted prices (based on the purchase of bulk package sizes) could also have a very low AMP. In both these cases, manufacturers may not be able to make these prices available to all purchasers.

Because purchasers and payers viewing these published prices would not know the reasons for the low AMPs, they might mistakenly think the prices are widely available and that the prices they have paid are unreasonable in comparison. Moreover, all the published prices – even those that are not unusually low or temporarily deflated – would represent wholesale prices and not prices to the ultimate consumers, which would include dispensing fees and wholesaler/distributor markup fees. Thus, even published prices that were widely available as wholesaler prices would seem low to certain purchasers, who would likely be unaware of the nature of the published prices. Month-to-month fluctuations in manufacturers' AMPs (for reasons discussed above) would also be likely to confuse customers who were unfamiliar with the many complicated transactions in pharmaceutical manufacturing and sales.

4. ***Proposed Partial Solution***

In light of these concerns, we recommend that CMS do the following:

- ***Publish only aggregated, industry-wide weighted average AMPs.*** CMS should publish only the aggregated, industry-wide weighted AMPs for multiple source drugs.

- ***Delay disclosure of AMPs until after adequate compliance period.*** CMS should not disclose AMPs until the rule is finalized and manufacturers have had sufficient time to come into compliance with its requirements. This compliance period should last at least 180 days from the time the Final Rule is issued. Given manufacturers' need for additional clarity on many key issues in the Proposed Rule (discussed herein), manufacturers will not be able to publish consistent AMP data until CMS makes the required clarifications and manufacturers have time to absorb the information and implement the required changes. Before these things happen, different manufacturers may be employing disparate assumptions to calculate their respective AMPs, which will result in variability across AMPs and prevent meaningful comparison of pricing data across manufacturers. If, however, CMS waits a sufficient amount of time after the issuance of the Final Rule to publish AMPs, then there will be at least some assurance that all

stakeholders are calculating AMP in the same way. This will, in turn, ensure that the comparison of manufacturer AMPs is a fair one.

- ***Allow a testing period for AMP data.*** As discussed later in this letter, CMS should provide for a 90-day testing period, after the 180 day compliance period, during which AMP information may be used for research and verification purposes only. CMS should indicate that AMP data may not be used for reimbursement purposes during this testing period, since manufacturers will need time to gain experience with the new system.

- ***Allow refiling of monthly AMPs.*** As highlighted later in this letter, we urge CMS to allow manufacturers to refile monthly AMPs for up to three years after initially submitted, as is currently allowed with respect to quarterly AMP data. This allowance is needed in recognition of the complexity of AMP calculations and of the timing issues surrounding the availability of the data needed in these calculations.

- ***Provide a disclaimer with any public disclosure AMP.*** On the CMS website, CMS should indicate the limitations on AMP data and advise purchasers and payers that these data may not necessarily reflect the price that is available to all consumers. Such a disclaimer could help reduce purchaser and payer confusion.

Definitions – Section 447.502

1. ***"Dispensing Fee"***

Currently, individual States determine the dispensing fees paid to pharmacies. Under the Proposed Rule, the term "dispensing fee" would be defined similarly to how it is defined under the Medicare Part D program. CMS states that, "[w]e are defining this term in order to assist States in their evaluation of factors in establishing a reasonable dispensing fee to pharmacy providers. We note that while we propose to define this term, we do not intend to mandate a specific formula or methodology which the States must use to determine the dispensing fee."[7] Thus, there is no requirement in the Proposed Rule that States must pay a fair dispensing fee that accurately reflects the actual costs associated with providing the full range of pharmacy services.

However, with the potential reduction in generic drug reimbursement that will be triggered by the switch to AMP, dispensing fees become increasingly important in ensuring that pharmacies are paid fairly for filling generic prescriptions. This will influence the extent to which pharmacies can promote generic utilization. As discussed in the previous section, generic utilization has been a key force behind the reduction in prescription drug costs for consumers and for the government. To preserve these cost-saving opportunities, CMS must keep in mind the need to incentivize generic usage over

[7] 71 *Fed Reg.* 77176.

brand usage when making changes to the Medicaid Drug Rebate Program. To ensure continued and aggressive dispensing of generic products by Medicaid, CMS should encourage States to incentivize generics through State program releases that advocate fair dispensing fees.

2. *"Manufacturer"*

GPhA is concerned that the proposed definition of the term "manufacturer" may unintentionally affect the rebate reporting and payment obligations of some entities that do not own a particular National Drug Code ("NDC") but only produce a drug under license from another company. The proposed definition states that "manufacturer" will include any "entity that does not possess legal title to the NDC," in the case of "private labeling arrangements."[8] Under current Medicaid rebate rules, only manufacturers who legally possess the NDC report and pay rebates on those drugs.[9] Whereas the definition of "manufacturer" in the rebate statute is broad enough to cover both parties in a private labeling relationship,[10] the sample rebate agreement clarifies that the term "manufacturer" refers to "the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug."[11]

The NDC refinement in the rebate agreement is an important added directive for determining who has the rebate reporting and payment obligation for a private labeled product. We are concerned that the Proposed Rule's definition of "manufacturer" could be interpreted as an intention by CMS to change the rebate agreement's definition and to require that the party without legal title to the NDC also report and pay rebates. In that case, a manufacturer could potentially be required to report on and pay a rebate for Medicaid sales of someone else's product – an outcome that would be unjust and irrational.[12] The rebate reporting and payment obligation should be on the NDC owner/manufacturer, as it is under the current system.

We believe that CMS' purpose in the Proposed Rule was to ensure that these private label sales be included in the AMP computation – not to require that both parties report and pay rebates. Thus, to ensure the proper placement of this obligation on the NDC owner, we recommend that CMS revise the definition of "manufacturer" in the Proposed Rule to clarify that any manufacturer that has the NDC would have to report and pay rebates on the drug, while a manufacturer that does not have an NDC, but rather

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[8] 71 *Fed. Reg.* 77196.

[9] In other words, if Manufacturer A produces a drug for Manufacturer B, and B owns the NDC, then B has the rebate obligation.

[10] For purposes of the rebate statute, the relevant language is the following: "(5) MANUFACTURER.—The term "manufacturer" means any entity which is engaged in— . . . (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products." Social Security Act § 1927(k)(5). By using the term "engaged in," this definition could encompass both the entity that owns the NDC and the entity that is under contract to produce the drug.

[11] "Rebate Agreement between the Secretary of Health and Human Services and the Manufacturer Identified in Section XI of this Agreement," *available at* http://www.cms.hhs.gov/MedicaidDrugRebateProgram/downloads/rebateagreement.pdf.

[12] Using the example from footnote 9, it would be unfair to require Manufacturer A to pay rebates on Manufacturer B's product.

produces a drug directly on behalf of an NDC-holder for retail sales, will not be obligated to report and pay rebates on the drug (as the NDC-holder is already reporting on and paying these rebates).

Determination of Average Manufacturer Price – Section 447.504

In response to the Proposed Rule's discussion of AMP calculation, we have several requests for clarification and recommendations to ensure that manufacturers can actually implement the requirements CMS imposes. Many of these requests and recommendations are general concerns, applicable to every aspect of the proposed calculation of AMP. For this reason, we have organized the comments below such that we present our overarching concerns first. We make other suggestions item-by-item in this section after we present the broad areas of concern.

A. *Broad Concerns*

1. *Calculation of AMP*

a. Need for Operational Feasibility

Our first broad concern is that the requirements for calculating AMP be operationally feasible for manufacturers. An understanding of what is operationally feasible requires familiarity with the typical distribution chain for generic drugs. This pathway works as follows: generic pharmaceutical manufacturers distribute their products directly to warehousing chain pharmacies, mail order pharmacies, various managed care entities, wholesalers and distributors (who themselves resell to non-warehousing chain pharmacies, independent pharmacies, hospitals, clinics, etc.). While manufacturers are aware of the location of their drug product after the first sale, they frequently have no way of knowing where their products end up after that first purchaser resells or redistributes the product.

One example of the many situations in which manufacturers lack access to information arises with manufacturer sales to hospitals. The Proposed Rule requires manufacturers to include sales to hospitals when the drugs are used in the outpatient setting but to exclude these sales when the drugs are used in the inpatient setting.[13] However, when a manufacturer sells to a hospital, the manufacturer will not know whether the hospital ultimately uses the drugs in the outpatient context or in the inpatient context, since purchases for all hospital needs are consolidated to obtain the best possible discount. Manufacturers, therefore, are unable to ensure that their AMP calculations include only those sales in which the drugs are ultimately used in the hospital's outpatient department.

Manufacturers also experience a lack of information on downstream sales when selling to entities including, but not limited to, wholesalers, mail order pharmacies, and

[13] 71 *Fed. Reg.* 77197.

pharmacy benefit managers ("PBMs"). The AMP data reported will be much more complete and consistent if CMS imposes requirements that are clear and operationally feasible. The agency must be careful to formulate these requirements in consideration of which information is in fact available to manufacturers. If manufacturers are required to discriminate among particular types of sales but do not have access to the information that would enable them to do so, then manufacturers will be unable to comply with the requirements through no fault of their own.

b. Need for Clarity

In addition to operational feasibility, we are also concerned about the problems related to ambiguous definitions of key concepts related to the AMP calculation. Imprecise definitions could lead to inconsistent treatment of various transactions, so we recommend that CMS clearly indicate what is meant by certain terms. In particular, we request that CMS unambiguously define the following:

- "Repackagers/relabelers";
- "Nursing home pharmacies";
- "PBMs"/"Managed care organizations" ("MCOs").

Manufacturer compliance with the new mandates for AMP calculation necessitates clear and meaningful guidance from CMS.

2. *Need for Consistency with Medicaid and 340B Programs*

Another issue of particular importance to GPhA is the need for consistency between the Medicaid and 340B Drug Pricing Programs. In order to have drugs be Medicaid-covered, manufacturers must also participate in the Section 340B Drug Pricing Program. Under the 340B program, manufacturers must offer drugs to certain nonfederal entities at prices that do not exceed AMP decreased by the Medicaid rebate percentage (the "340B ceiling price") as specified in the statute.[14] Participation in Medicaid, thus, requires that manufacturers submit AMPs for the Medicaid Drug Rebate Program and for the 340B Drug Pricing Program.

While AMP is used in both programs, the Proposed Rule's definition of AMP will cause AMP for Medicaid purposes to differ from AMP for 340B purposes. In its January 30, 2007 letter to pharmaceutical manufacturers, the Office of Pharmacy Affairs ("OPA") clarified the definition of AMP in 340B ceiling price calculations ("OPA letter"):

> Although the Deficit Reduction Act amended the statutory definition of Average Manufacturers Price for purposes of Medicaid by removing the deduction for customary prompt payment discounts, Section 340B(c) of the Public Health

[14] SSA § 1927(k).

> Service Act states, "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section." Accordingly, manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts.[15]

Thus, while AMP is used in both the 340B and the Medicaid program, the calculation for each program will differ at least in relation to the treatment of customary prompt pay discounts.

While this difference is required by statute, other differences between the two calculations that are not statutorily mandated could be eliminated, thereby reducing manufacturers' administrative burdens. In recognition of the magnitude of these burdens, OPA stated in the letter: "We welcome comments from all parties about how to best implement the 340B Program requirements in the wake of changes in related areas impacted by the DRA. Our goal would be to minimize the burden on pharmaceutical manufacturers in submitting the required data."[16]

Operationally, the differences between the 340B and Medicaid programs will require manufacturers to move from 16 to 20 calculations annually. This move does not simply add four basic calculations to manufacturers' annual compliance requirement but, rather, requires a near-complete reprogramming of the data maintenance system for each reporting period. Because the same server cannot support hundreds of calculations per month or per quarter – as would be required to comply with both programs – manufacturers' submissions to at least one program could necessarily be delayed. Thus, the issue is not simply one of an onerous burden on manufacturers but is instead one of operational impracticability.

In accordance with the sentiment of the OPA letter, we recommend that the methodology for calculating AMP be as consistent as is statutorily possible across the Medicaid and PHS/340B programs. Calculation, maintenance, and reporting of differing AMPs for the two programs would create an undue burden for manufacturers as well as unnecessary confusion for organizations involved in the delivery of health care services. Moreover, duplicative reporting would waste time and energy within the federal programs. We ask that CMS coordinate its approach with OPA to prevent these problems.

The subsections above in this comment on AMP calculation address broad concerns that underlie all our AMP comments. Thus, while the remainder of this section addresses several specific elements of the AMP calculation, our general concerns still apply.

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[15] Jimmy Mitchell, Director of OPA, "Dear Pharmaceutical Manufacturer Letter Clarifying the Definition of Average Manufacturer Price" (January 30, 2007), *available at* http://www.hrsa.gov/opa/pharm-mfg-ltr013007.htm.

[16] *Id.*

B. *Specific Concerns on Particular Sections*

1. *Customary Prompt Pay Discounts*

The Proposed Rule states that a "customary prompt pay discount" will be defined as "any discount off the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified time."[17] There are significant uncertainties, however, in this definition. Therefore, GPhA respectfully suggests that CMS clarify what is meant by "routinely offered" and specify the criteria that manufacturers should use to determine what is "routine."

In addition, we request that CMS address whether a customary prompt pay discount could be considered a manufacturer's "routinely offered" prompt pay discount if:

- It differs across customers?
- It changes over the life cycle of a product? (e.g., the prompt pay discount offered at the introduction of the product differs from the prompt pay discount offered for the remainder of the product's life cycle.)
- It is different across products?

We ask that CMS provide guidance that would address these scenarios.

2. *State Pharmaceutical Assistance Program ("SPAP") Sales and Rebates*

CMS proposes to include all SPAP sales and rebates in AMP to the extent that these sales are made to the retail pharmacy class of trade. This proposal conflicts with the treatment required under previous CMS Manufacturer Release #68, which instructs manufacturers to distinguish between "qualified" and "unqualified" SPAPs, based on criteria listed in such release.[18] Pursuant to the release, only sales to qualified SPAPs are excluded from AMP, whereas sales to unqualified SPAPs are included in AMP. We request that CMS revisit this program release to address this inconsistency.

As an additional matter, if CMS ultimately decides to include all SPAP sales and rebates, then the agency should provide guidance regarding the method of inclusion. Specifically, CMS should specify over what ratio of sales manufacturers are to apply SPAP rebates, since the data available to manufacturers do not indicate the particular sales to which the rebates apply.

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[17] 71 *Fed. Reg.* 77196.

[18] Medicaid Drug Rebate Program Release No. 68 (April 1, 2005).

Determination of Best Price – Section 447.505

Manufacturers bear substantial administrative burdens in complying with Medicaid Drug Rebate Program requirements for data submission and retention. As mentioned above, these burdens are increased in light of the DRA's change to the definition of AMP for Medicaid purposes, since this definition now differs from the definition of AMP used in the 340B program. These burdens are also increased by new reporting and retention requirements imposed on manufacturers by the Proposed Rule. In order to reduce manufacturers' already significant administrative burdens, we recommend that CMS maintain as much consistency as possible between the treatment of underlying transactions in best price and in AMP calculations.

Authorized Generic Drugs – Section 447.506

In the Proposed Rule, CMS proposes to "require the NDA holder to include sales of the authorized generic product marketed by the secondary manufacturer or the brand manufacturer's subsidiary in its calculation of AMP and best price."[19] CMS has thus indicated that brand manufacturers' rebates must be calculated based on the sales of both the branded product and the authorized generic product. We understand that this requirement entails that generic manufacturers must provide their authorized generic drug information to the branded company holding the NDA. To avoid any potential antitrust implications that this exchange of information could raise, we request that CMS make the Federal Trade Commission ("FTC") aware of this requirement before implementing it.

Requirements for Manufacturers – Section 447.510

As noted at the beginning of these comments, the most important issue raised by the Proposed Rule for manufacturers is the public disclosure of AMP, and so we discussed this requirement at the outset rather than here with our other comments relating to this section of the Proposed Rule. Below we present the rest of our comments concerning the proposed requirements for manufacturers.

1. *Time to Implement Operational Changes*

Complex administrative system changes and additions will be needed to implement the new definitions and reporting requirements in the Final Rule. However, the proposed effective dates do not create adequate time to design and operationalize these changes. The certification required by the Proposed Rule, and the consequences of inaccurate certification, necessitate the utmost accuracy and reliability in the reporting of manufacturers' data. The revised definition of AMP requires new data fields to be created and substantial reprogramming of sales reporting systems that must be tested and validated. Manufacturers must also ensure that their government-pricing calculation is

[19] 71 *Fed. Reg.* 77184.

established accurately and that the system is compliant with Sarbanes-Oxley requirements. In light of these major changes, we request that CMS allow at least 180 days after issuance of the Final Rule for manufacturers to implement all reporting changes created by the Proposed Rule.

2. *Use of 12-Month Rolling Average Smoothing Mechanism*

In the Proposed Rule, CMS discussed two possible methodologies for "smoothing" monthly data: (1) 12-month rolling average estimates of all lagged discounts and (2) three-month rolling average estimates of all lagged discounts. CMS has invited comments on the appropriate methodology for calculating monthly AMP.[20] In response to the invitation for comments, we recommend that CMS allow manufacturers the choice of whether or not to use a smoothing mechanism but specify that smoothing must be done, if at all, using an annual period.

We support smoothing with an annual period rather than with a three-month period because the longer time period allows the AMPs to be less volatile. Smoothing has produced positive results in ASP pricing for Medicare Part B drugs, particularly in Healthcare Common Procedure Coding System ("HCPCS") codes that apply to multiple source products. Generic products are particularly well-suited for smoothing, due to the need to account for, in AMP, discontinued products, backordered products, and the large dollar value of chargebacks customarily processed for wholesaler sales for generic products. As a result, generic manufacturers should be encouraged (but not required) to use annual smoothing in the AMP calculation, in order to accommodate transaction timing and minimize fluctuations.

3. *Timeline for Use of Monthly AMPs*

When CMS implemented ASP pricing for Medicare Part B drugs, the agency provided manufacturers with a six- to nine- month "test" period. During this period, manufacturers could gain an understanding of the new requirements and make the necessary system-level adjustments to implement these requirements to ensure accurate reporting. Moreover, CMS guaranteed that it would not use ASP for reimbursement during this "test" period.

Similarly, when CMS began the implementation of the new Medicaid drug pricing requirements of the DRA, the agency recognized the need to allow extra time for manufacturers to come into compliance with the new requirements. While the DRA required publication of AMPs as of July 2006, CMS used its discretion to make these data available at that date only to the States and not to the public. According to then-Administrator Mark McClellan, the agency delayed public disclosure for the following reasons:

> We know that an imprecise definition of AMP, especially if publicly posted, will be misleading to state Medicaid directors and others who will use this as a

[20] 71 *Fed. Reg.* 77186.

> reference point for setting pharmacy reimbursement. . . Consequently, I am announcing today that CMS will not publicly release the current AMP figures. They just aren't the right numbers to use.[21]

In the press release accompanying the publication of the Proposed Rule, CMS indicated its intention to begin making AMP data available to States and to the public in late spring.[22] However, the same concerns expressed by Dr. McClellan in May 2006 still apply, since manufacturers have not been afforded sufficiently clear guidance and sufficient time to operationalize the new requirements to guarantee that AMP submissions will be accurate and consistent by late spring.

For these reasons, we recommend that CMS follow the ASP model when implementing AMP pricing for Medicaid drugs. To this end, as mentioned above, CMS should provide a 180 day period after the Final Rule is published for manufacturers to come into compliance with the new requirements. Further, CMS should indicate that the first reporting period will commence 90 days after the end of this implementation period. Only at the end of this reporting period could State Medicaid agencies rely on AMPs for reimbursement purposes. Finally, in addition, we request that manufacturers be permitted to refile monthly AMPs for up to three years after initially submitted, as is currently allowed with respect to quarterly AMP data.

Such allowances by the agency would not only treat manufacturers fairly in light of the burdensome changes required by the rule, but would also help ensure that data were not used for reimbursement until they were likely to be accurate and consistent across manufacturers. We suggest that CMS make these timing issues clear by publishing a timeline indicating how new monthly AMPs will be used over time.

4. *Net Unit Reporting*

The government needs a program in place to determine products per manufacturer that are not widely available to the retail class of trade. For ASPs, manufacturers are currently required to submit net units shipped (excluding returns) for each product so CMS will have some assistance in determining if a product is widely available. We recommend that the same method be adopted for AMPs. However, because the net unit number alone does not indicate whether a product is widely available, the government will also need to consider additional factors, such as whether the product is available from several wholesalers. Nonetheless, net unit reporting is a good tool to be used as part of this process of determining widely available products, and it should be required of manufacturers in their AMP submissions. Moreover, the net unit information could also be used for weighting, as required for the rebate calculation process. Importantly, CMS

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[21] Remarks of Mark B. McClellan, MD, PhD, as delivered to the NCPA 38th Legislation and Governance Conference (May 22, 2006).

[22] CMS, "Medicaid Drug Pricing Regulation Proposed" (December 15, 2006), *available at* http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=2062&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date.

must keep in mind that this information is confidential and, therefore, cannot be posted on the agency's website or otherwise released to the public.

5. *Record-Keeping Requirements*

In the Proposed Rule, CMS proposes the requirement that manufacturers retain "records used in calculating the customary prompt pay discounts and nominal price discounts reported to CMS."[23] To provide adequate guidance to manufacturers concerning implementation of the new record retention requirements, CMS should specify what prompt pay information is needed for retention.

6. *Reporting Requirements*

In the Proposed Rule, CMS stipulates that customary prompt pay discounts are to be reported as an aggregate dollar amount for each reported NDC-9, so as to include discounts extended to all purchasers in the rebate period.[24] However, the new file formats that have been provided to manufacturers from CMS for quarterly reporting do not include specifications for reporting customary prompt pay aggregate dollars. We ask that CMS include a field for aggregate prompt pay dollar amount in the file used for quarterly price submissions, or that CMS expressly allow manufacturers to submit aggregate prompt pay dollar amounts for each NDC-9 in a separate file with format determined by each manufacturer.

CMS also proposes to require manufacturers to report revisions to customary prompt pay discounts and nominal prices reported to CMS.[25] From this statement alone, it is unclear whether manufacturers need to do this reporting on an accrued basis or on a cash basis (i.e. whether manufacturers must report what they offered to customers or what their customers actually paid). CMS should specify that manufacturers report what they offered to customers, as this is the only information manufacturers are able to report.

7. *Certification Requirement*

In the Proposed Rule, CMS proposes to add a requirement that manufacturers must certify the pricing reports they submit to CMS. CMS proposes that this certification must be made by "the manufacturer's Chief Executive Officer (CEO), Chief Financial Officer (CFO), or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO."[26] We recommend that this requirement be altered slightly to allow an individual who reports directly or ***indirectly*** to the CEO or CFO to provide the certification. This flexibility is needed because a company's CEO or CFO (or their direct report) is not always available to review and certify data reports on a monthly basis.

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[23] 71 *Fed. Reg.* 77185.
[24] 71 *Fed. Reg.* 77198.
[25] 71 *Fed. Reg.* 77185.
[26] 71 *Fed. Reg.* 77186.

8. *Negative AMPs*

The Proposed Rule requires manufacturers to report AMPs on a monthly basis, whereas these data were formerly submitted only quarterly. One consequence of the new monthly AMP reporting requirements is a potential increase in the number of negative AMPs. CMS should clarify that negative AMPs should be reported.

Upper Limits for Multiple Source Drugs – Section 447.514

1. *Definition of "Formulation"*

Pursuant to the DRA, the Proposed Rule stipulates that upper limits are to be placed on multiple source drugs when there are two or more therapeutically and pharmaceutically equivalent formulations, regardless of whether all additional formulations are rated as such.[27] For purposes of determining which multiple source drugs require upper limits, the term "formulation" should be clarified to mean products of the same form and route of administration (i.e., tablet to tablet, controlled release tablet to controlled release tablet, liquid to liquid, etc.). It would not be appropriate for a liquid or controlled release tablet to be set at the same level of reimbursement as a standard tablet formulation. Such a comparison is unreasonable as the products will have different prices and be sold separately. We believe this is the intent of the Proposed Rule.

2. *Availability of Generics at the FUL Price*

CMS proposes "additional criteria to ensure that a drug is nationally available at the FUL price and that a very low AMP is not used by us to set a FUL that is lower than the AMP for other therapeutically and pharmaceutically equivalent multiple source drugs."[28] Specifically, CMS proposes to set the FUL based on the lowest AMP that is not less than 30 percent of the next highest AMP for that drug. CMS solicited comments regarding whether 30 percent is an appropriate measure to use.

While we support the intent of the proposed methodology, the 30 percent rule alone does not accomplish the stated objective of preventing outliers from determining the FUL. We are unaware of any evidence or experience, and CMS has offered no data, supporting the theory that products with AMPs that are 29 percent of the next highest AMP should qualify as outliers, but that those with AMPs that are 30 percent of the next highest AMP are routinely and nationally available. However, we believe the 30 percent rule, when used in conjunction with an aggregate, industry-wide weighted average AMP (as discussed below), is a good place to start. Over time, we request that CMS revisit the 30 percent rule to assess whether the accumulated AMP data support setting the threshold at a different percentage. Nonetheless, because there is nothing special about 30 percent, the use of this number alone as a threshold would not guarantee that outliers were removed from the FUL calculation.

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[27] *Id.*

[28] 71 *Fed. Reg.* 77188.

To accomplish this intent of "ensur[ing] that the FUL will be set at an adequate price to ensure that a drug is available for sale nationally," we would recommend using the 30 percent rule in conjunction with an aggregate, industry-wide weighted average AMP.[29] When calculating FULs, CMS should first remove any AMPs less than 30 percent (or whatever threshold is later adopted) of the next highest AMP, and then from this set of AMPs, calculate the aggregate, industry-wide weighted average AMP. This two-step process would ensure that the resulting FUL represents a nationally available price, not an arbitrary number.

3. *Reporting of AMPs at the NDC Nine-Digit Level*

The currently reported AMP is based on the nine-digit NDC, combining all package sizes of the drug into the same computation. CMS proposed to continue this policy and solicited comments on the alternative approach of using 11-digit NDC to calculate AMP as well as comments on the merits of using both approaches in calculating AMP for the FUL calculation.[30] We do not find a compelling reason to move away from the nine-digit NDC calculation, and we are concerned that significant system changes would be required to support 11-digit reporting. Therefore, we favor the proposed AMP reporting at the nine-digit level for FUL computation as well as rebate purposes.

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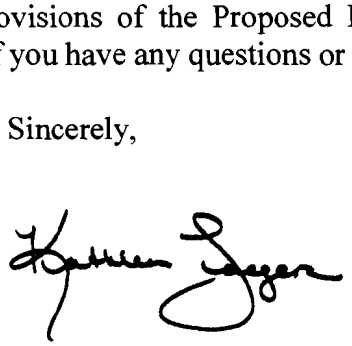
Thank you for the opportunity to submit these comments. GPhA looks forward to working with CMS while these provisions of the Proposed Rule are being finalized. Please do not hesitate to contact us if you have any questions or concerns.

Sincerely,



Kathleen D. Jaeger

[29] 71 *Fed. Reg.* 77187.
[30] *Id.*